RULES AND REGULATIONS RELATING TO

QUALITY ASSURANCE STANDARDS

FOR MAGNETIC RESONANCE IMAGING (R-23-17-MRI)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS DEPARTMENT OF HEALTH

January 2000

As Amended:

January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

INTRODUCTION

These Rules and Regulations Pertaining to Quality Assurance Standards for Magnetic Resonance Imaging (R23-1-MRI) are promulgated pursuant to the authority conferred under Chapters 23-17; 27-18; 27-19; 27-20, 27-20.1, 27-41 and 23-15 of the General Laws of Rhode Island, as amended and are established for the purpose of adopting quality standards for taking, processing and interpreting magnetic resonance imaging examinations in this state.

In accordance with the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, in the development of regulations, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) any significant economic impact on small business as defined in Chapter 42-35 of the General Laws. Based on available information, it has been determined that there will be a fiscal impact upon those providers receiving reimbursement from any health insurer, health maintenance organization, or health plan or health care facilities that are not presently accredited by the American College of Radiology to perform magnetic resonance imaging examinations. The cost for such accreditation is estimated to be \$2,100 for the first magnetic resonance imaging unit and \$1,400 for each additional unit. A full accreditation cycle lasts three (3) years. The health, safety and welfare of the public overrides any economic impact which may be incurred from these regulations.

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PART I DEFINITIONS AND GENERAL REQUIREMENTS

Section 1.0 **Definitions**

Wherever used in these rules and regulations, these terms shall be construed as follows:

- 1.1 "Director" means the Director of the Rhode Island Department of Health.
- 1.2 "Department" means the Rhode Island Department of Health.
- 1.3 "Health care facility" means those facilities subject to licensure by the Department of Health in accordance with the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, entitled "Licensing of Health Care Facilities", and as defined by regulations adopted thereunder.
- 1.4 "Health maintenance organization" hereinafter referred to as "HMO" means a single public or private organization seeking or maintaining certification as a health plan, that:
 - a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, x-ray, emergency and preventive services, and out-of-area coverage;
 - b) is compensated, except for co-payments, for the provision of the basic health care services listed in section 1.4 (a) {above} to enrolled participants on a predetermined periodic rate basis; and
 - c) provides physicians' services primarily:
 - (i) directly through physicians who are either employees or partners of such organization; or
 - (ii) through arrangements with individual physicians or one or more groups of physicians (organized on a group practice or individual basis).
- 1.5 **"Health plan"** means a plan operated by a health care entity as described in section 1.11 of the *Rules* and *Regulations for the Certification of Health Plans (R23-17.13-CHP)*, that provides for the delivery of health care services to individuals enrolled in such a plan through:
 - a) agreements with providers who have been selected by the health plan to furnish health care services; and/or
 - b) financial incentives for persons enrolled in the plan to use the participating providers and procedures provided for by the plan.
- 1.6 "Magnetic Resonance Imaging" (MRI) is the multiplanar imaging method based on an interaction between radiofrequency (RF) electromagnetic fields and certain nuclei in the body (usually hydrogen nuclei) after the body has been placed in a strong magnetic field. MRI demonstrates normal tissues, providing a sensitive examination to detect disease. This sensitivity is based on the high degree of inherent contrast due to variations in the magnetic relaxation properties of different tissues, both normal and diseased, and the dependence of the MR signal on these tissue properties.

- 1.7 *"Physician"* means an individual licensed to practice medicine or osteopathy pursuant to the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended.
- 1.8 "*Provider*" means any person licensed or otherwise authorized in this state to furnish magnetic resonance imaging examinations who is not a health care facility.
- 1.9 "Quality assurance program" means a program to consistently ensure state of the art performance by physicians, and other personnel, for taking, processing and interpreting magnetic resonance imaging examinations.
- 1.10 "Person" means an individual, trust or estate, partnership, corporation (including, but not limited to associations, joint stock companies, limited liability companies and insurance companies) state, or political subdivision or instrumentation of a state.

Section 2.0 General Requirements

- 2.1 Set forth herein are quality assurance standards issued by the Director of Health for taking, processing and interpreting magnetic resonance imaging examinations in the state of Rhode Island.
- 2.2 No health care facility shall provide magnetic resonance imaging examinations in Rhode Island unless such health care facility demonstrates continuing compliance with Part II, section 3 of these regulations.
- 2.3 No provider shall receive reimbursement from any health insurer, health maintenance organization, or health plan for provision of magnetic resonance imaging examinations unless said provider demonstrates continuing compliance with Part II, section 3 of these regulations.

PART II QUALITY ASSURANCE STANDARDS

Section 3.0 Administrative Requirements

- 3.1 A provider receiving reimbursement from any health insurer, health maintenance organization, or health plan for performing magnetic resonance imaging examinations or health care facility performing magnetic resonance imaging examinations shall, at all times, meet all applicable requirements of the American College of Radiology's *Standard for the Performance of Magnetic Resonance Imaging*.
 - 3.1.1 When these regulations initially become effective, a provider receiving reimbursement from any health insurer, health maintenance organization, or health plan for performing magnetic resonance imaging examinations or a health care facility currently performing magnetic resonance imaging examinations shall file an application for accreditation with the American College of Radiology within six (6) months of the effective date of these regulations. Such accreditation shall be attained within eighteen (18) months of the effective date of these regulations. After such accreditation is attained, a provider receiving reimbursement from any health insurer, health maintenance organization, or health plan for performing magnetic resonance imaging examinations or a health care facility performing magnetic resonance imaging examinations shall, at all times, maintain accreditation with the American College of Radiology.
 - 3.1.2 A provider receiving reimbursement from any health insurer, health maintenance organization, or health plan or a health care facility who begins performing magnetic resonance imaging examinations after the effective date of these regulations shall file an application for accreditation with the American College of Radiology within six (6) months of the date of initiation of the magnetic resonance imaging examinations. Such accreditation shall be attained within eighteen (18) months of the date of initiation of the magnetic resonance imaging examinations. After such accreditation is attained, a provider receiving reimbursement from any health insurer, health maintenance organization, or health plan for performing magnetic resonance imaging examinations or a health care facility performing magnetic resonance imaging examinations shall, at all times, maintain accreditation with the American College of Radiology.
- 3.2 In each health care facility where magnetic resonance imaging examinations are performed, a designated physician, who meets the qualifications specified in the most current version of the American College of Radiology's *Standard for the Performance of Magnetic Resonance Imaging*, shall be responsible for all aspects of the magnetic resonance imaging study including but not limited to: reviewing all indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating written reports, and assuring the quality of both the images and interpretations. In each health care facility where magnetic resonance imaging examinations are performed, a designated staff person shall be responsible for the comprehensive over-all quality assurance program.

Other providers receiving reimbursement from any health insurer, health maintenance organization, or health plan for performing magnetic resonance imaging examinations shall have a designated physician, who meets the qualifications specified in the most current version of the American College of Radiology's *Standard for the Performance of Magnetic Resonance Imaging*, to be responsible for all aspects of the magnetic resonance imaging study including but not limited to:

reviewing all indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating written reports, and assuring the quality of both the images and interpretations. Said designated physician shall also be responsible for the comprehensive over-all quality assurance program.

Each quality assurance program shall include methods to ensure state-of-the art performance by personnel and maximal operation of equipment, with the ultimate objective of providing the highest quality medical care possible to the patient.

- 3.3 The quality assurance program shall ensure at a minimum:
 - 3.3.1 Credentialing of all personnel in accordance with all applicable laws and regulations and the American College of Radiology's *Standard for the Performance of Magnetic Resonance Imaging*; and
 - 3.3.2 Compliance with equipment specifications, safety guidelines, and quality control testing of the American College of Radiology's *Standard for the Performance of Magnetic Resonance Imaging*.

PART III: SANCTIONS AND SEVERABILITY

Section 4.0 Revocation or Suspension of Facility License

4.1 The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any health care facility which: (1) has failed to comply with these rules and regulations herein; and (2) has failed to comply with the provisions of reference 1.

Section 5.0 **Severability**

5.1 If any provision of these rules and regulations or the circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

PART IV REFERENCES

1.	American	College of Radiology:	ACR Standard for	the Performance	of Magnetic	Resonance
	Imaging,	1998 and subsequent am	endments thereto.			

2.	Rules and Regulations for the Certification of Health Plans (R23-17.13-CHP), Rhode Island
	Department of Health, September 1997 and subsequent amendments thereto.

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