

May 8, 2001

VIA HAND DELIVERY

Board of Radiologic Technologists
301 South Park Avenue
P.O. Box 200513
Helena, MT 596220-0513

**RE: Public Hearing for ARM 8.56.602, 8.56.409, 8.56.602, 8.56.602A, 8.56.602C
and 8.56.607**

Dear Sir/Madam:

On behalf of the Society of Vascular Technology (“SVT”) and the Society of Diagnostic Medical Sonographers (“SDMS”), we are writing to comment on the Notice of Public Hearing on Proposed Amendment released by Board of Radiologic Technologists (the “Board”) regarding the regulations cited above. The Montana Department of Commerce will hold a public hearing on May 9, 2001. We submit our comments for consideration at the May 9 hearing.

I. INTRODUCTION

By way of background, SVT is a professional society comprising over 5,000 members who consist of registered vascular technologists, nurses as well as 1,000 physicians. SVT members provide high-quality vascular ultrasound services. SDMS, in turn, represents general and cardiac sonographers and vascular technologists and has 12,000 members. SDMS members are involved in the delivery of high-quality echocardiography, obstetrical and abdominal ultrasound, and vascular ultrasound services.

Ultrasound imaging provides a means of looking into the body of a patient and examining structures, such as organs, vessels and the fetus. By using sound waves to obtain images of the interior of the body, ultrasound offers a critical, low-cost diagnostic service to physicians and other clinicians that can, in many circumstances, eliminate the need for more costly, invasive and dangerous diagnostic studies. Unlike x-rays, which involve the emission of ionizing radiation, ultrasound consists of nonionizing radiation. As a result, ultrasound is an imaging modality for which accumulation of radiation need not be monitored and is, therefore, safer than conventional x-rays for patients and health care personnel alike.

II. COMMENTS

The Proposed Amendment was clearly written to allow the Board to exercise jurisdiction over ultrasound. Section 8.56.602(3), to which our comments are exclusively directed, expressly broadens the definition of “radiologic technology” to include medical disciplines and specialties that employ nonionizing radiation. In addition, where it introduces the list modalities for which specialty permits will be required, Section 8.56.602(3) reads “Specialty permits in radiologic technology include” Use of the word “include” indicates that the specialty permit

requirement will not necessarily be limited to the modalities listed in the Proposed Amendment, and could, therefore, be interpreted by the Board to apply to ultrasound. For the reasons set forth below, the Board should not adopt the Proposed Amendment as currently drafted.

A. The Board of Radiologic Technologists Exceeded its Grant of Statutory Authority by Broadening its Jurisdiction to Include Medical Disciplines that Employ Nonionizing Radiation.

We are concerned that in broadening the scope of radiologic technology to include disciplines that employ nonionizing radiation, such as ultrasound, the Board exceeded its grant of statutory authority. As explained below, under Montana law, an administrative body, such as the Board, has only those powers expressly conferred upon it by the state legislature. Courts will strike down as unconstitutional any administrative regulation that extends the scope of an agency's jurisdiction beyond that contemplated in the enabling legislation. We believe that Section 8.56.602(3) of the Proposed Amendment is unconstitutional under Montana law.

It is a fundamental precept of administrative law that an administrative body must exercise its rule-making authority within the grant of legislative power as expressed in the enabling statute. Bell v. Department of Licensing, 594 P.2d 331, 332 (Mont. 1979) (striking down as unconstitutional regulations promulgated by the Montana Board of Barbers and the Department of Professional and Occupational Licensing that engrafted additional licensing requirements not authorized by the Legislature) (See Attachment 1). Courts will treat an excursion by an administrative body beyond its enabling legislative guidelines as a usurpation of constitutional power. Id. at 333. Under Montana law, courts have uniformly held that administrative regulations are “out of harmony” with the enabling legislation, and, therefore, unconstitutional, if the regulations “engraft additional, noncontradictory requirements on the statute which were not envisioned by the legislature.” Id. (quoting Arizona State Board of Funeral Directors v. Perlman, 492 P.2d 694).

The statutes from which the Board derives its rule-making authority are Sections 37-14-101 and 37-14-102 in the Montana Code. MONT. CODE ANN. §§ 37-14-101, 37-14-102. (See Attachments 2 and 3). Section 37-14-101 provides the general grant of authority: “[t]he legislature declares that the practice of radiologic technology affects the public health, safety, and welfare and that it is necessary therefore to regulate and control such practice in the public interest.” MONT. CODE ANN. 37-14-101. Section 37-14-102, in turn, provides the relevant definitions. Significantly, Section 37-14-102 makes no mention of disciplines, such as ultrasound, that employ nonionizing radiation. Section 37-14-102 makes clear, however, that the discipline of radiologic technology pertains strictly to “x-ray procedures,” i.e., those radiologic procedures that involve ionizing radiation. Id. § 37-14-102. The terms “license,” “limited permit technician,” “permit,” and “radiologic technologist” are all defined in Section 37-14-102 to involve the “performance of x-ray procedures.” Id. Moreover, although the term “x-ray procedures” is not defined, Section 37-14-102 defines “performance of x-ray procedures” to mean “the involvement or completion of any portion of an x-ray procedure that may have an effect on the patient’s accumulated x-ray radiation exposure” Id.

Thus, it is clear from the enabling legislation that the Board's jurisdiction is confined to the performance of x-ray procedures, i.e., procedures that involve ionizing radiation. By including mention of nonionizing procedures in the Proposed Amendment, and thereby attempting to broaden the scope of its jurisdiction beyond that which was contemplated by the legislature, we fear that the Board could be seen by a reviewing court as unconstitutionally usurping the legislature's authority. Bell, 594 P.2d 331.

B. Ultrasound is Distinct from Traditional X-ray and Should Not Therefore Be Regulated by the Board of Radiologic Technology.

Ultrasound is a unique imaging modality that is distinct from traditional x-ray. This is evidenced by (1) the fact that federal legislation recognizes ultrasound as distinct from radiologic technology, (2) Medicare data pertaining to the technical component of ultrasound services, (3) the United States Department of Labor's Occupational Outlook Handbook, which recognizes vascular technology as a separate classification than radiologic technology, and (4) the education and training requirements for sonographers, vascular technicians and cardiovascular technicians. Accordingly, we believe that ultrasound should not be subjected to the jurisdiction of a Board of a clearly distinct discipline.

1. Federal Legislation Recognizes that Ultrasound and Radiologic Technology are Distinct Disciplines.

Federal legislation recognizes that ultrasound and radiologic technology are inherently different disciplines and preserves the integrity of each. For example, the Consumer-Patient Radiation Health and Safety Act (also known as the Randolph Bill or Public Law 9735), which was signed into law in 1981, required that the Secretary of the Department of Health and Human Services ("Department") develop minimum standards for state certification and licensure of persons who administer radiation. The Department's proposed minimum standards, published in the Federal Register in 1983, included standards for both ionizing and nonionizing radiation. Significantly, however, when the final standards were published in 1985, they included only standards for ionizing radiation. It is clear from this rulemaking, that the Department recognized ultrasound as distinct from radiologic technology.

A second, more recent example of federal legislation that recognizes the fundamental difference between ultrasound and radiologic technology is the Consumer Assurance of Radiologic Excellence Act (also known as the CARE Act or H.R. 1011). H.R. 1011, 107th Leg., 1st Sess. (2001). (See Attachment 4). The CARE Act amends the Social Security Act to prohibit certain payments to states for expenditures for medical imaging procedures or radiation therapy procedures, unless the state meets certain requirements for state medical radiation licenses. Under the CARE Act, a state must have in place a policy that requires individuals who "administer medical imaging procedures or radiation therapy procedures" to obtain a "medical radiation license." Significantly, the CARE Act expressly exempts "individual[s who] exclusively perform medical ultrasound or echocardiography" from the license requirement. Although the CARE Act has not yet been signed into law, it clearly reveals that federal legislators understand the uniqueness of ultrasound.

2. Few Radiologists, and by Extension Their Radiologic Technologists, Account for the Technical Component of Ultrasound Services.

The Medicare data base indicates that relatively few radiologic technologists perform the technical component of ultrasound procedures, when compared with sonographers and specialized ultrasound technicians. We are concerned that allowing the Board to bring ultrasound into its purview, as Section 8.56.603(3) allows, makes little clinical sense and could possibly threaten the quality of ultrasound services provided to Montana citizens.

One of the most common ultrasound procedures provided to Medicare patients is Common Procedure Coding System (also known as “HCPCS”) code 93880, the descriptor for which reads “duplex scan of the extracranial arteries; complete bilateral study.” According to the Medicare data base, radiologists provide only 18% of the technical component services for this procedure. The vast majority of these services are provided by non-radiologists, such as cardiologists, general surgeons, vascular surgeons, neurologists, neurosurgeons, and primary care physicians. Because radiologic technologists generally perform the technical component of services accounted for by radiologists (and sonographers or specialized ultrasound technicians generally perform the technical component of services accounted for by non-radiologists), this data demonstrates that radiologic technicians perform relatively few ultrasound procedures.

As explained in Section II.A. above, the legislature created the Board to “regulate and control” the practice of radiologic technology in such a manner that promotes the “public health, safety and welfare” of Montana residents. MONT. CODE ANN. § 37-14-101. We are troubled that Section 8.56.602(3) thwarts that legislative objective. Allowing the Board to exert jurisdiction over ultrasound, a distinct imaging modality with which Board-certified radiologic technologists have much less experience than other allied health professionals, makes little clinical sense and raises concerns about the public health and safety of Montana residents.

3. The United States Department of Labor Recognizes Vascular Technology as a Different Occupation than Radiologic Technology.

In addition to the Medicare data, the Occupational Outlook Handbook (the “Handbook”), published by the United States Department of Labor, supports the notion that ultrasound is a discipline that is distinct from radiologic technology. The Handbook maintains separate occupation classifications for radiologic technologists and cardiovascular technologists and technicians. (See Attachment 5). Significantly, the Handbook classifies vascular technologists, defined as technologists who “use ultrasound instrumentation, such as doppler ultrasound, to noninvasively record vascular information, such as blood pressure, limb volume changes, oxygen saturation, cerebral circulation, peripheral circulation, and abdominal circulation,” as cardiovascular technologists and technicians, rather than radiologic technologists.

Section 8.56.602(3) cannot be squared with the Department of Labor’s classification. In defining radiologic technology, Section 8.56.602(3) lumps together modalities that employ ionizing radiation with those that employ nonionizing radiation. Further, Section 8.56.602(3)

also lists “cardiovascular interventional technology” as one of the subsets of radiologic technology, for which a specialty permit is required. These aspects of Section 8.56.602(3) blur the well-recognized distinction -- a distinction supported by the United States Department of Labor -- between a sonography modality and traditional radiologic technology.

4. Ultrasound Is a Unique Discipline with its Own Education and Training Requirements and Credentialing Bodies.

Diagnostic ultrasound is a multi-specialty field comprised of diagnostic medical sonography, with subspecialties in abdominal, neurologic, obstetrical/gynecologic and ophthalmic ultrasound, diagnostic cardiac sonography, with subspecialties in adult and pediatric echocardiography, and vascular technology. All of these specialties and subspecialties share the common denominator of ultrasound as the imaging modality. Absent from these specialties is use of traditional x-ray technology.

A diagnostic ultrasound professional is a person qualified by professional credentialing and academic and clinical experience to provide diagnostic patient care services that employ ultrasound. Educational programs for ultrasound are geared to enable students to acquire the knowledge necessary to pass credential exams which are administered by credentialing bodies. Ultrasound credentialing bodies, such as the American Registry of Diagnostic Medical Sonographers (“ARDMS”), are accredited by the National Commission for Certifying Agencies (“NCCA”).

The above description of the ultrasound specialties and subspecialties and education and training requirements indicate that ultrasound is a unique discipline and that little, if any, overlap exists between ultrasound and radiologic technology. Significantly, education, training and credentialing in one of these disciplines does not readily substitute that of the other. Accordingly, we believe that the Board ought not to be permitted amend its regulations to acquire jurisdiction over ultrasound.

III. RECOMMENDED CHANGES

For the reasons set forth above, we recommend that Section 8.56.602(3) be revised as follows:

- (3) Pursuant to 37-14-301(1), MCA, a permit is required for specialty areas of radiologic technology. The education requirements for individuals practicing radiography limited to specific areas of the human body must be equivalent to the educational standards recognized by the national accreditation and certification agencies. Radiologic technology is the term that describes the medical disciplines and specialties that use ionizing ~~and non-ionizing~~ radiation for diagnostic medical imaging, interventional procedures and radiation therapy. Specialty permits in radiologic technology ~~include~~ **are the following:**

We believe that these revisions will cure the constitutional infirmities that currently plague Section 8.56.602(3) and preserve the widely accepted view that ultrasound is a unique imaging modality.

* * * * *

On a final note, we wish to thank the Montana Department of Commerce for the opportunity to comment on the Proposed Amendments. We are hopeful that the Board will undertake a careful review of the concerns expressed above.

Sincerely,

Donald Haydon
Executive Director
Society of Diagnostic Medical Sonographers

Laurinda Andrist
Government Relations Chair
Society of Diagnostic Medical Sonographers

Suzanne Stone
Executive Director
Society of Vascular Technology

Anne Jones
Government Relations Co-Chair
Society of Vascular Technology

Attachments

cc: William A. Sarraille
Arthur S. Di Dio, M.D.
Joseph Mazurek