COLORADO

Department of Regulatory Agencies

2014 Sunrise Review:

Radiologist Assistants

Office of Policy, Research and Regulatory Reform

October 15, 2014

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2014

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunrise reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed its evaluation of the sunrise application for regulation of radiologist assistants and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, which provides that DORA shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, whether the public can be adequately protected by other means in a more cost-effective manner and whether the imposition of any disqualifications for regulation based on criminal history serves public safety or consumer protection interests.

Sincerely,

Barbara J. Kelley
Executive Director

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Background

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:[1]

> (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
>
> (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence;
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner; and
>
> (IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

[1] § 24-34-104.1(4)(b), C.R.S.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation.

Methodology

DORA has completed its evaluation of the proposal for regulation of radiologist assistants (RAs). During the sunrise review process, DORA performed a literature search; contacted and interviewed the applicant; reviewed licensure laws in other states and conducted interviews of administrators of those programs; and contacted the Colorado Medical Society, the Colorado Hospital Association and the Colorado Radiological Society. In order to determine the number and types of complaints filed against RAs in Colorado, DORA contacted Colorado Medical Board staff. To better understand the practice of RAs, DORA staff observed RAs working with patients at Presbyterian/St. Luke's Hospital in Denver.

Profile of the Profession

Radiologist assistants (RAs) are health care professionals who perform a variety of duties under the supervision of licensed radiologists. More specifically, RAs are advanced-level radiographers who work to promote high standards of patient care by assisting radiologists in the diagnostic imaging environment (e.g., fluoroscopy).[2]

RAs have three main areas of responsibility:[3]

- Manage and assess the needs of patients;
- Perform selected radiology examinations and procedures; and
- Evaluate image quality.

Duties for RAs in the management and assessment area include: determining whether a patient has been appropriately prepared for a procedure, obtaining patient consent prior to an examination and answering questions from the patient or family members.[4]

RAs perform a variety of mid-level procedures on patients in hospital and outpatient settings. For example, RAs perform a voiding cystourethrogram (VCUG) procedure, which is a study of the bladder. The VCUG procedure is done by inserting a catheter through the patient's urethra into the bladder. Once inserted, a contrast (dye) called cystografin is used to fill the patient's bladder to capacity until the patient begins to urinate. Then, images are taken of the bladder using a fluoroscopy machine.

Fluoroscopy is an x-ray procedure in which x-rays are transmitted through the body onto a fluorescent screen or monitor.[5] An x-ray image, or radiograph, is produced when a small amount of radiation passes through a body part and is recorded on film, screen, video or computer to produce a black and white anatomical image.[6] Fluoroscopy procedures are particularly beneficial in evaluating (observing) the function of organ systems (e.g., the movement of material through the esophagus, stomach and intestines) or joints.[7]

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[2] The American Registry of Radiologic Technologists. *Registered Radiologist Assistant Entry-Level Clinical Activities.* Retrieved June 7, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Task-Inventory.pdf
[3] American Society of Radiologic Technologists. *The RA Advantage. Retrieved July, 29, 2014, from http://www.asrt.org/docs/default-source/careers/rafactsheet.pdf?sfvrsn=2*
[4] American Society of Radiologic Technologists. *The RA Advantage. Retrieved July 29, 2014, from http://www.asrt.org/docs/default-source/careers/rafactsheet.pdf?sfvrsn=2*
[5] Wentworth-Douglass Hospital. *X-rays and Fluoroscopic Procedures.* Retrieved July 29, 2014, from http://www.wdhospital.com/body.cfm?id=395
[6] Wentworth-Douglass Hospital. *X-rays and Fluoroscopic Procedures.* Retrieved July 29, 2014, from http://www.wdhospital.com/body.cfm?id=395
[7] Wentworth-Douglass Hospital. *X-rays and Fluoroscopic Procedures.* Retrieved July 29, 2014, from http://www.wdhospital.com/body.cfm?id=395

Additionally, RAs perform hysterosalpingogram (HSG) procedures on patients. The purpose of an HSG procedure is to look at the uterus and fallopian tubes.

RAs are also responsible for evaluating image quality, making initial image observations and forwarding those observations to the supervising radiologist.[8]

Importantly, RAs do not prescribe medication or therapies, diagnose or interpret medical images;[9] instead, licensed radiologists are responsible for those duties.

The American Registry of Radiologic Technologists (ARRT) and the Certification Board for Radiology Practitioner Assistants (CBRPA) offer certifications. The ARRT offers an RA certification, while the CBRPA offers certification to radiology practitioner assistants (RPA). Both RAs and RPAs are essentially the same profession, including performing the same duties, but they are certified by different certifying entities, thus creating different titles.

In order to apply to take the ARRT RA certification examination, a candidate must meet/or agree to the following requirements:[10]

- Complete an ARRT certification and registration in radiography;
- Complete one year of acceptable clinical experience;
- Complete an RA education program;
- Complete the didactic competence requirement;
- Complete the clinical education requirements;
- Complete a baccalaureate degree from an accredited institution;
- Adhere to the ARRT ethics requirements; and
- Complete an application for certification.

In order to be eligible for a certification as a registered RA, a candidate must be certified and registered in radiography by ARRT.[11] This is an entry-level certification and registration, and persons who possess this certification and registration work as radiologist technicians. They essentially run x-ray machines at hospitals and clinics.

A candidate must also complete the equivalent of at least one year of full-time clinical experience following radiography certification.[12] The clinical experience must be patient care related at the professional level.[13]

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[8] American Society of Radiologic Technologists. *The RA Advantage. Retrieved July 29, 2014, from http://www.asrt.org/docs/default-source/careers/rafactsheet.pdf?sfvrsn=2*

[9] American Registry of Radiologic Technologists. *ARRT – Radiologist Assistant Bill Introduced in the House.* Retrieved July 10, 2014, from https://www.arrt.org/news/articles/2011-09-22-RA-Bill-Introduced-in-House.aspx

[10] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf

[11] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf

[12] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf

[13] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf

A candidate must successfully complete an RA educational program that is recognized by ARRT, and completion must occur prior to sitting for the examination.[14]

Candidates must complete the didactic competence requirement that requires successful completion of coursework from a nationally recognized RA curriculum.[15]

The clinical education requirements are an essential part of the RA's education. This RA-supervised clinical preceptorship is where students learn to perform radiologic procedures.[16] During the clinical education portion of an RA's training, there are a variety of components he/she is required to complete. Some components are:[17]

- The documentation of the performance of radiologic procedures as well as passing a competence assessment for each procedure;
- The submission of case studies to their program director for review and discussion; and
- The completion of an overall evaluation by the chief preceptor of a candidate's cognitive, psychomotor and affective skills.

Once all of the aforementioned requirements are completed, a candidate must complete an application for certification to obtain approval to take the certification examination.

The ARRT certifying examination for registered RAs is administered by Pearson VUE at its test centers. There are three Pearson VUE test centers in Colorado: Greenwood Village, Pueblo and Westminster.[18]

The current fee to take the examination is $200. If a candidate does not pass the examination, he/she can apply to re-take the examination, and the current fee is $175.[19]

[14] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[15] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[16] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[17] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[18] Pearson VUE. *Test Center Search.* Retrieved August 1, 2014, from https://www7.pearsonvue.com/testtaker/registration/SelectTestCenterProximity/AMERICANREGISTR/73702
[19] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf

The examination consists of two parts: a multiple-choice section and a case study section. The multiple-choice section of the examination consists of 200 multiple-choice questions that must be completed in 3.5 hours.[20] The content categories (as well as the number of questions) on the multiple-choice portion of the examination are as follows:[21]

- Patient communication, assessment and management (45);
- Drugs and contrast materials (30);
- Anatomy, physiology and pathophysiology (55);
- Radiologist procedures (40);
- Radiation safety, radiation biology and fluoroscopic operation (15); and
- Medical-legal, professional and government standards (15).

The case study portion of the examination contains two studies and each case study is followed by four to six essay questions.[22] Candidates have 2.5 hours to complete the case study portion of the examination.[23]

In order to be eligible to take the CBRPA RPA certification examination, a candidate is required to meet/or agree to the following, including but not limited to:[24]

- Be an ARRT registered radiographer with an active status with ARRT;
- Have three years of experience as a radiographer; and
- Be a graduate from a CBRPA-recognized educational program, and meet all didactic requirements and evaluation of clinical competency by a radiologist.

Candidates who have met the eligibility requirements may apply to the take the examination. The CBRPA certifying examination is administered by Chi Tester, which is a web-based system for administering academic tests.[25] Chi Tester is developed and maintained at Weber State University.[26]

Candidates for certification utilize a proctor to take the examination. Suitable proctors include college or university testing centers and in some instances military education centers.[27]

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[20] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[21] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[22] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[23] The American Registry of Radiologic Technologists. *2014 Registered Radiologist Assistant (R.R.A.).* Retrieved July 29, 2014, from https://www.arrt.org/pdfs/RRA/RRA-Handbook.pdf
[24] Certification Board for Radiology Practitioner Assistants. *Candidate Handbook 2013.* Retrieved July 31, 2014, from http://cbrpa.org/wp-content/uploads/2013/01/2013-Candidate-Handbook.pdf
[25] Chi Tester User's Manual. *Introduction to Chi Tester.* Retrieved September 5, 2014, from http://chitester.wordpress.com/tableofcontents/section-1-introduction-to-chi-tester/
[26] Chi Tester User's Manual. *Introduction to Chi Tester.* Retrieved September 5, 2014, from http://chitester.wordpress.com/tableofcontents/section-1-introduction-to-chi-tester/
[27] Chi tester User's Manual. *Remote Proctors.* Retrieved August 1, 2014 from http://chitester.wordpress.com/section-6-student-guide/remote-proctors/

The current fee to take the examination is $200.

The examination consists of 200 multiple-choice questions.[28] The major content areas and the number of questions in each area are as follows:[29]

- Patient education (6);
- Patient assessment and management (25);
- Professional communication (10);
- Pharmacology and contrast (20);
- Anatomy, physiology, pathophysiology and image evaluation (75);
- Medical imaging procedures (40);
- Radiation biology and health physics (8);
- Fluoroscopic equipment and operation (8);
- Medical documentation and records (4); and
- Medical-legal circumstances (4).

[28] Certification Board for Radiology Practitioner Assistants. *Content Specifications for the Radiology Practitioner Assistant Examination.* Retrieved August 1, 2014, from http://cbrpa.org/wp-content/uploads/2013/02/2013-CBRPAContentSpecs.pdf

[29] Certification Board for Radiology Practitioner Assistants. *Content Specifications for the Radiology Practitioner Assistant Examination.* Retrieved August 1, 2014, from http://cbrpa.org/wp-content/uploads/2013/02/2013-CBRPAContentSpecs.pdf

Proposal for Regulation

The Executive Board of the Colorado Society of Radiology Physician Extenders (Applicant) has submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies state licensure of radiologist assistants as the appropriate level of regulation to protect the public.

The sunrise application states that state licensure of radiologist assistants (RAs) would ensure compliance with pending federal legislation (HR 1148) and safety for patients undergoing advanced radiology procedures.

The Applicant also submitted proposed statutory language for the regulation of RAs. The Applicant, however, is not required to use this as a basis for actual legislation. It merely provides a starting point for discussion. A copy of the proposed statutory language is included in Appendix A on page 18.

The proposed statutory language requires RAs to become registered with the Division of Registrations (now known as the Division of Professions and Occupations) within DORA. Requirements for registration are:

- Completion of an accredited radiologist assistant education program;
- Certification and registration by the American Registry of Radiologic Technologists or certification by the Certification Board of Radiology Practitioner Assistants;
- Submission of an application for registration to DORA; and
- Submission of the applicable registration fee.

Additionally, the proposed statutory language authorizes the Director of the Division of Professions and Occupations to revoke, deny, suspend, refuse to renew a registration or issue a cease and desist order. Registered RAs would be subject to discipline for any of the following violations, including but not limited to:

- Engaging in a sexual act with a person receiving services while a clinical relationship existed or within six months immediately following termination of the clinical relationship;
- Falsifying information in the application or attempting to obtain or obtaining a registration by fraud, deception or misrepresentation; and
- Being an excessive or habitual user or abuser of alcohol or habit-forming drugs or being a habitual user of a controlled substance.

The proposed statutory language also provides title protection to registered RAs. Only a person who is registered as an RA is authorized to use the title "radiologist assistant," the letters "R.A," or any other generally accepted terms, letters or figures that indicate that the person is an RA.

Summary of Current Regulation

The Colorado Regulatory Environment

Currently, radiologist assistants (RAs) are an unregulated profession in Colorado, and as such, there are no laws that specifically provide regulatory oversight. However, the Colorado Department of Public Health and Environment (CDPHE) provides oversight of, among other things, radiation machines (x-ray, computed tomography, bone densitometry, mammography and fluoroscopy), facilities and the operators of the machines. The CDPHE, in its Rules and Regulations Pertaining to Radiation Control, outlines the requirements for inspectors of radiation machines in Colorado. Specifically, inspectors, who essentially ensure that radiation machines are in good working order, are required to register with the CDPHE.

The facilities that house radiation machines, such as hospitals and outpatient clinics are required to secure a registration from the CDPHE. In order to register a facility, the facility must, among other things, designate a radiation safety officer who is responsible for overall radiation protection for the facility.[30]

The CDPHE also requires operators of radiation machines to become registered prior to providing services to consumers. However, the CDPHE, through its rules related to radiation control, offers an exemption to the registration requirement for operators who are certified by the American Registry of Radiologic Technologists (ARRT). Importantly, RAs are required to be certified through ARRT prior to becoming an RA, so this requirement essentially exempts all RAs from the current CDPHE registration requirement.

The Federal Regulatory Environment

Currently, there are no federal laws regulating RAs. However, there is a congressional bill (HR 1148) that was referred to the House of Representatives Subcommittee on Health on March 14, 2013. The bill would provide a change in the billing requirements for services rendered by RAs to Medicare patients. The bill, which is cited as the "Medicare Access to Radiology Care Act of 2013 (MARCA)," would amend the Social Security Act to provide payment for services of qualified RAs under the Medicare program.

[30] Department of Public Health and Environment. Rules and Regulations Pertaining to Radiation Control. Rule 2.4.1.1(3)(a).

Specifically, MARCA would,

> recognize RAs as non-physician providers of health care services to Medicare beneficiaries and would authorize physician reimbursement through the Centers for Medicare and Medicaid Services for procedures performed by RAs in states that have laws establishing RA practice guidelines.[31]

Since the bill was referred to the Subcommittee on Health, it has not received a hearing, and it does not appear to be moving forward in Congress at this time.

Regulation in Other States

According to the sunrise application, there are 29 states that regulate RAs. In order to determine the number of RAs regulated in other states, the Department of Regulatory Agencies (DORA) staff surveyed a random sample of 14 states. The states that responded to DORA's request for information include: Arkansas, Arizona, Iowa and Montana.

The total number of licensed RAs was fairly consistent for each state. Arkansas has five licensed RAs, Arizona and Iowa each have eight and Montana has five.

[31] American Society of Radiologic Technologists. *MARCA Bill.* Retrieved July 29, 2014, from http://www.asrt.org/main/standards-regulations/federal-legislative-affairs/marca-bill

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

> Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

Before moving forward in the analysis of harm concerning radiologist assistants (RAs), it is important to identify what constitutes harm to the public. It is self-evident that the improper actions of RAs could result in physical and even emotional harm to patients and their families. For example, one of the functions of RAs is to conduct invasive procedures which entail inserting catheters and needles into patients.

In order to determine whether regulation of RAs is necessary, the Department of Regulatory Agencies (DORA) requested that the sunrise applicant provide specific examples of harm to the public. The application to regulate RAs, however, did not contain any specific examples of harm.

DORA staff also contacted the Colorado Medical Board (Board) and the Colorado Department of Public Health and Environment (CDPHE) staff to identify any complaints filed concerning RAs. Board and CDPHE staff stated that they have not received any complaints against RAs.

However, the potential for harm does exist. RAs perform a variety of mid-level procedures on patients, many of which are invasive. In order to highlight the types of procedures RAs perform on patients, two invasive procedures are detailed below.

RAs perform a voiding cystourethrogram (VCUG), which is a study of the bladder through a urinary catheter. A VCUG procedure requires an RA to insert a catheter through a patient's urethra into the bladder.

During a VCUG procedure, there are many circumstances where patients may be harmed due to the incorrect actions of RAs. For example, the incorrect insertion of the catheter could lead to a variety of problems, including perforating the urethra, bladder or the vagina.

RAs also perform a hysterosalpingogram (HSG) procedure. An HSG procedure is performed for two different reasons. First, the procedure is done to evaluate the uterus and fallopian tubes to make sure that they are normal and the tubes are open. This is done on women who are having difficulty getting pregnant.

The other reason for an HSG procedure is to ensure that the fallopian tubes are occluded after a sterilization procedure.

When performing an HSG, there is the potential that an RA could insert the catheter incorrectly, causing the perforation of the cervix and/or uterus. Doing so could cause a condition known as endometriosis. This condition occurs when the lining inside the uterus is flushed through the fallopian tubes into the abdominal cavity. Not only is the condition painful to the patient, but it may lead to the removal of the uterus.

Further, both of the procedures highlighted above, as well as a variety of other procedures, necessitate the use of fluoroscopy machines. Fluoroscopy is an x-ray procedure in which x-rays are transmitted through the body onto a fluorescent screen or monitor.[32] These machines are capable of giving some of the highest radiation doses in medical imaging. So, the potential of overexposing patients to radiation could pose danger and therefore harm to consumers.

Although harm to consumers was not identified during this sunrise review, RAs perform a variety of invasive, mid-level procedures that could, if done incorrectly, physically harm consumers.

Need for Regulation

The second sunrise criterion asks:

> Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

This criterion addresses the proposition of whether the state should require a certain level of education and/or impose a requirement that RAs pass an examination before being licensed in Colorado.

[32] Wentworth-Douglass Hospital. *X-rays and Fluoroscopic Procedures.* Retrieved July 29, 2014, from http://www.wdhospital.com/body.cfm?id=395

The nature of work that RAs perform, which is often complex and highly specialized, requires a high level of education, professional and clinical training and a minimum level of competency in order to practice safely. As a result, the implementation of minimum requirements, such as education and training may be necessary to ensure consumer safety.

The requirements for certification by the American registry of Radiologic Technologists (ARRT) and the Certification Board for Radiology Practitioner Assistants (CBRPA) are also indicative of the minimum competencies and training necessary to safely perform the services and duties expected of an RA.

Alternatives to Regulation

The third sunrise criterion asks:

> Whether the public can be adequately protected by other means in a more cost-effective manner.

Public protection for consumers who utilize the services of RAs could potentially be realized in a cost-effective manner by requiring certification from ARRT or CBRPA.

Generally, to obtain a certification in ARRT or CBRPA, candidates are required to pass an examination, meet minimum education requirements and possess a minimum level of clinical experience.

Obtaining a certification from ARRT or CBRPA ensures that RAs are uniquely qualified to practice as RAs in hospitals and outpatient clinics. As such, the certifications offered by ARRT and CBRPA appear to insulate consumers from incompetent practitioners.

The certifications offered by ARRT and CBRPA are utilized by many practitioners throughout the country, including Colorado. Consequently, certification by one of the aforementioned organizations may be a viable option and alternative to state regulation.

Collateral Consequences

The fourth sunrise criterion asks:

> Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Neither the sunrise application nor the proposed statutory language that was included in the sunrise application (Appendix A) proposes using an applicant's criminal history as a disqualifier for RA licensure. This sunrise review did not highlight instances where issues occurred to warrant the implementation of a criminal history requirement as a precursor to licensure.

Conclusion

The sunrise application requests licensure of RAs, which is the most restrictive type of regulatory program. Further, the sunrise application states that licensure would ensure compliance with pending federal legislation (HB 1148), which would,

> recognize RAs as non-physician providers of health care services to Medicare beneficiaries and would authorize physician reimbursement through the Centers for Medicare and Medicaid Services for procedures performed by RAs in states that have laws establishing RA practice guidelines.[33]

This legislation has been in Congress for several years and it is unclear if or when the legislation will pass. As a result, HB 1148 does not provide justification to regulate RAs in Colorado.

The sunrise application also states that licensure would ensure safety of patients who undergo advanced radiology procedures.

As highlighted earlier in this sunrise review, RAs perform a variety of procedures on patients, many of which are invasive. Although the sunrise applicant did not provide specific examples of harm to patients resulting from the actions of RAs, there is clearly the potential for and risk of serious injury caused by RAs.

A related question is what might be the scope and probability of the occurrence of harm to patients in Colorado. According to the sunrise application, there are only 23 RAs practicing in Colorado. Such a small number could be an indication that the procedures they conduct on patients are specialized and require highly trained practitioners.

The fact that RAs generally operate under the direct supervision of a licensed radiologist may also contribute to the low probability of the occurrence of harm. However, as a practical matter, the actual procedures performed by RAs are rarely conducted in the presence of a licensed radiologist. A more common practice is that the radiologist is "in the building" or "on campus" in the event that the RAs need assistance or something goes wrong during the procedure.

[33] American Society of Radiologic Technologists. *MARCA Bill.* Retrieved July 29, 2014, from http://www.asrt.org/main/standards-regulations/federal-legislative-affairs/marca-bill

Additionally, employers (hospitals and outpatient clinics) are sophisticated in evaluating the qualifications and experience of practitioners. Generally, hospitals require RAs to participate in a credentialing process prior to being granted privileges to practice at a given location. Although certain hospitals "outsource" their credentialing process to a third-party business, the general premise behind this process is to ensure that qualified practitioners are practicing in hospitals and outpatient clinics.

However, the potential for and risk of serious bodily harm to patients by RAs during many of the procedures they perform provides a sufficient basis to warrant some level of state regulation. While the information and evidence set forth in the sunrise application does not support a full licensure program, a less intrusive and costly regulatory scheme seems appropriate.

The implementation of a registration program will create a more direct form of regulation concerning minimum levels of education, training and competency required of RAs.

The ARRT and CBRPA offer certifications, which require a minimum education, training and the passage of an examination. The two entities appear to provide adequate safeguards to ensure practitioners are competent. As such, the State of Colorado should create a registration or certification program that would require RAs to attain certification by either the ARRT or CBRPA. Doing so is consistent with the proposed statutory language provided by the applicant in its sunrise application, and it is the least restrictive form of regulation consistent with the public interest. Importantly, the state would determine that RAs meet minimum qualifications before providing patient services, enhancing consumer protection.

Recommendation – Create a regulatory program for radiologist assistants in Colorado.

Appendix A – Proposed Radiologist Assistant Practice Act

12-29.X-XXX. Short title.

This article shall be known and may be cited as the "Radiologist Assistant Practice Act".

12-29.X-XXX. Legislative declaration.
The general assembly hereby finds and declares that the practice of a radiologist assistant by a person who does not possess a valid registration issued pursuant to this article is not in the best interests of the people of the state of Colorado. It is not, however, the intent of this article to restrict the practice of a person duly registered pursuant to any article of this title or other laws of this state from practicing within the person's scope of practice and authority pursuant to those laws.

12-29.X-XXX. Definitions.
As used in this article, unless the context otherwise requires:
(1) "Accredited radiologist assistant program" means a program of instruction in radiologist assistant that is offered by an institution of higher education and accredited by a national, regional, or state agency recognized by the United States secretary of education, or another program accredited and approved by the director.
(3) "Radiologist Assistant" means a person registered to practice as a radiologist assistant under this article.
(4) "Radiologist Assistant practice" means the performance, under the supervision of a Colorado licensed or otherwise lawfully practicing radiologist of those services that require the education, training, and experience required by this article for registration as an radiologist assistant pursuant to section 12-29.X-XXX. "Radiologist assistant practice" includes radiology services provided under the direction and supervision of a radiologist, but does not include image interpretation, diagnosis or prescribing of medications or therapies.
(5) "Direction of a radiologist" means the planning of services with a radiologist; the development and approval by the radiologist of procedures and protocols to be followed in provision of radiology services; and the appropriate consultation and referral between radiologist and the radiologist assistant.
(6) "Director" means the director of the division of registrations or his or her designee.
(7) "Division" means the division of registrations in the department of regulatory agencies created in section 24-34-102, C.R.S.
(8) "Registrant" means a radiologist assistant registered pursuant to this article.

12-29.X-XXX. Use of titles restricted.
Only a person registered as a radiologist assistant may use the title "radiologist assistant", the letters "R.A.", or any other generally accepted terms, letters, or figures that indicate that the person is a radiologist assistant.

12-29.X-XXX. Limitations on authority.
(1) Nothing in this article shall be construed to authorize a radiologist assistant to perform the practice of medicine, as defined in article 36 of this title; or any other form of healing except as authorized by this article.

12-29.X-XXX. Registration required.
Except as otherwise provided in this article, a person shall not practice as a radiologist assistant or represent himself or herself as being able to practice as a radiologist

assistant in this state without possessing a valid registration issued by the director in accordance with this article and any rules adopted under this article.
12-29.X-XXX. Requirements for registration - denial - renewal - fees.
(1) Every applicant for a registration to practice as a radiologist assistant shall have:
(a) Successfully completed an accredited radiologist assistant education program;
(b) (I) Be certified and registered by the American Registry of Radiologic Technologists as a radiologist assistant; or
(II) Be certified by the Certification Board of Radiology Practitioner Assistants as a radiology practitioner assistant;
(c) Submitted an application in the form and manner designated by the director;
(d) Paid a fee in an amount determined by the director; and
(e) Submitted additional information as requested by the director to fully and fairly evaluate the applicant's qualifications for registration and to protect the public health and safety.
(2) When an applicant has fulfilled the requirements of subsection (1) of this section, the director shall issue a registration to the applicant. The director may deny registration if the applicant has committed an act that would be grounds for disciplinary action under section 12-29.X-XXX.
(3) (a) An applicant for registration by endorsement shall file an application and pay a fee as prescribed by the director and shall hold a current, valid license or registration in a jurisdiction that requires qualifications substantially equivalent to those required for registration by subsection (1) of this section.
(b) An applicant for registration shall submit with the application verification that the applicant has actively practiced for a period of time determined by rules of the director or has otherwise maintained continued competency as determined by the director.
(c) Upon receipt of all documents required by paragraphs (a) and (b) of this subsection (3), the director shall review the application and make a determination of the applicant's qualification to be registered by endorsement.
(d) The director may deny the registration if the applicant has committed an act that would be grounds for disciplinary action under section 12-29.7-109.
(4) (a) A registrant shall be required to renew the registration issued pursuant to this article according to a schedule of renewal dates established by the director. The registrant shall submit an application in the form and manner designated by the director and shall pay a renewal fee in an amount determined by the director.
(b) Registrations shall be renewed or reinstated in accordance with the schedule established by the director, and such renewal or reinstatement shall be granted pursuant to section 24-34-102 (8), C.R.S. The director may establish renewal fees and delinquency fees for reinstatement pursuant to section 24-34-105, C.R.S. If a registrant fails to renew his or her registration pursuant to the schedule established by the director, the registration shall expire. A person whose registration has expired shall be subject to the penalties provided in this article or section 24-34-102 (8), C.R.S., for reinstatement.
(c) The registrant shall submit additional information as may be requested by the director to fully and fairly evaluate the applicant's qualifications for registration and to protect the public health and safety.
(5) All fees collected pursuant to this article shall be determined, collected, and appropriated in the same manner as set forth in section 24-34-105, C.R.S., and periodically adjusted in accordance with section 24-75-402, C.R.S.

12-29.X-XXX. Scope of article - exclusions - authority for clinical setting.
(1) Nothing contained in this article shall prohibit:
(a) The practice of a radiologist assistant that is an integral part of a program of study by students enrolled in an accredited radiologist assistant education program. Students enrolled in an accredited radiologist assistant education program shall be identified as "student radiologist assistant" and shall only practice as a radiologist assistant under the direction and immediate supervision of a Colorado licensed or otherwise lawfully practicing radiologist. A student radiologist assistant shall not hold himself or herself out as a radiologist assistant.
(b) The practice as a radiologist assistant by a person who is certified by the American Registry of Radiologic Technologists as a radiologist assistant or by the Certification Board of Radiology Practitioner Assistants as a radiology practitioner assistant and who is employed by the United States government or any bureau, division, or agency of the federal government while acting in the course and scope of such employment.
(c) The ability of a radiologist assistant to direct the activities of a x-ray system operator defined in 6 CCR 1007-1 Part 02 Appendix 2D who is assisting the radiologist assistant in the performance of radiology services directed and supervised by a radiologist.
(c) The practice of any health care profession other than radiologist assistant by a person licensed or registered under any other article of this title in accordance with the lawful scope of practice of the other profession.

12-29.X-XXX. Grounds for discipline - disciplinary proceedings.
(1) The director may take disciplinary action against a person registered under this article if the director finds that the person registered has represented himself or herself as a registered radiologist assistant after the expiration, suspension, or revocation of his or her registration.
(2) The director may revoke, deny, suspend, or refuse to renew a registration, or issue a cease-and-desist order in accordance with this section upon reasonable grounds that the registrant:
(a) Has engaged in a sexual act with a person receiving services while a clinical relationship existed or within six months immediately following termination of the clinical relationship. For the purposes of this paragraph (a):
(I) "Sexual act" means sexual contact, sexual intrusion, or sexual penetration as defined in section 18-3-401, C.R.S.
(II) "Clinical relationship" means the period beginning with the initial evaluation and ending upon the written termination of treatment.
(b) Has falsified information in an application or has attempted to obtain or has obtained a registration by fraud, deception, or misrepresentation;
(c) Is an excessive or habitual user or abuser of alcohol or habit-forming drugs or is a habitual user of a controlled substance, as defined in section 18-18-102 (5), C.R.S., or other drugs having similar effects; except that the director has the discretion not to discipline the registrant if he or she is participating in good faith in a program approved by the director to end such use or abuse;
(d) Has a physical or mental condition or disability that renders the registrant unable to provide radiologist assistant services with reasonable skill and safety or that may endanger the health or safety of individuals receiving services;
(e) Has had a registration or license suspended or revoked for actions that are a violation of this article;

(f) Has been convicted of or pled guilty or nolo contendere to a felony or any crime defined in title 18, C.R.S. A certified copy of the judgment of a court of competent jurisdiction of the conviction or plea shall be prima facie evidence of the conviction or plea. In considering the disciplinary action, the director shall be governed by section 24-5-101, C.R.S.
(g) Has practiced as a radiologist assistant without a registration;
(h) Has failed to notify the director of any disciplinary action in regard to the person's past or currently held license, certificate, or registration required to practice as a radiologist assistant in this state or any other jurisdiction;
(i) Has refused to submit to a physical or mental examination when so ordered by the board pursuant to section 12-29.7-110; or
(j) Has otherwise violated any provision of this article.
(3) Except as otherwise provided in subsection (2) of this section, the director need not find that the actions that are grounds for discipline were willful but may consider whether such actions were willful when determining the nature of disciplinary sanctions to be imposed.
(4) (a) The director may commence a proceeding to discipline a registrant when the director has reasonable grounds to believe that the registrant has committed an act enumerated in this section.
(b) In any proceeding held under this section, the director may accept as evidence of grounds for disciplinary action any disciplinary action taken against a registrant in another jurisdiction if the violation that prompted the disciplinary action in the other jurisdiction would be grounds for disciplinary action under this article.
(5) Disciplinary proceedings shall be conducted in accordance with article 4 of title 24, C.R.S., and the hearing and opportunity for review shall be conducted pursuant to that article by the director or by an administrative law judge, at the director's discretion. The director has the authority to exercise all powers and duties conferred by this article during the disciplinary proceedings.
(6) (a) The director may request the attorney general to seek an injunction, in any court of competent jurisdiction, to enjoin a person from committing an act prohibited by this article. When seeking an injunction under this paragraph (a), the attorney general shall not be required to allege or prove the inadequacy of any remedy at law or that substantial or irreparable damage is likely to result from a continued violation of this article.
(b) (I) The director is authorized to investigate, hold hearings, and gather evidence in all matters related to the exercise and performance of the powers and duties of the director.
(II) In order to aid the director in any hearing or investigation instituted pursuant to this section, the director or an administrative law judge appointed pursuant to paragraph (c) of this subsection (6) is authorized to administer oaths, take affirmations of witnesses, and issue subpoenas compelling the attendance of witnesses and the production of all relevant records, papers, books, documentary evidence, and materials in any hearing, investigation, accusation, or other matter before the director or an administrative law judge.
(III) Upon failure of any witness or registrant to comply with a subpoena or process, the district court of the county in which the subpoenaed person or registrant resides or conducts business, upon application by the director with notice to the subpoenaed person or registrant, may issue to the person or registrant an order requiring the person or registrant to appear before the director; to produce the relevant papers,

books, records, documentary evidence, or materials if so ordered; or to give evidence touching the matter under investigation or in question. If the person or registrant fails to obey the order of the court, the person or registrant may be held in contempt of court.
(c) The director may appoint an administrative law judge pursuant to part 10 of article 30 of title 24, C.R.S., to conduct hearings, take evidence, make findings, and report such findings to the director.
(7) (a) The director, the director's staff, any person acting as a witness or consultant to the director, any witness testifying in a proceeding authorized under this article, and any person who lodges a complaint pursuant to this article shall be immune from liability in any civil action brought against him or her for acts occurring while acting in his or her capacity as director, staff, consultant, or witness, respectively, if such individual was acting in good faith within the scope of his or her respective capacity, made a reasonable effort to obtain the facts of the matter as to which he or she acted, and acted in the reasonable belief that the action taken by him or her was warranted by the facts.
(b) A person participating in good faith in making a complaint or report or in an investigative or administrative proceeding pursuant to this section shall be immune from any civil or criminal liability that otherwise might result by reason of the participation.
(8) A final action of the director is subject to judicial review by the court of appeals pursuant to section 24-4-106 (11), C.R.S. A judicial proceeding to enforce an order of the director may be instituted in accordance with section 24-4-106, C.R.S.
(9) An employer or radiologist supervisor of a radiologist assistant shall report to the director any disciplinary action taken against the radiologist assistant or the resignation of the radiologist assistant in lieu of disciplinary action for conduct that violates this article.
(10) When a complaint or an investigation discloses an instance of misconduct that, in the opinion of the director, warrants formal action, the complaint shall not be resolved by a deferred settlement, action, judgment, or prosecution.
(11) (a) If it appears to the director, based upon credible evidence as presented in a written complaint by any person, that a registrant is acting in a manner that is an imminent threat to the health and safety of the public, or a person is acting or has acted without the required registration, the director may issue an order to cease and desist such activity. The order shall set forth the statutes and rules alleged to have been violated, the facts alleged to have constituted the violation, and the requirement that all unlawful acts or unregistered practices immediately cease.
(b) Within ten days after service of the order to cease and desist pursuant to paragraph (a) of this subsection (11), the respondent may request a hearing on the question of whether acts or practices in violation of this article have occurred. The hearing shall be conducted pursuant to sections 24-4-104 and 24-4-105, C.R.S.
(12) (a) If it appears to the director, based upon credible evidence as presented in a written complaint by any person, that a person has violated any other portion of this article, in addition to any specific powers granted pursuant to this article, the director may issue to the person an order to show cause as to why the director should not issue a final order directing the person to cease and desist from the unlawful act or unregistered practice.
(b) A person against whom an order to show cause has been issued pursuant to paragraph (a) of this subsection (12) shall be notified promptly by the director of the

issuance of the order, along with a copy of the order, the factual and legal basis for the order, and the date set by the director for a hearing on the order. The notice may be served on the person against whom the order has been issued by personal service, by first-class, postage-prepaid United States mail, or in another manner as may be practicable. Personal service or mailing of an order or document pursuant to this paragraph (b) shall constitute notice of the order to the person.
(c) (I) The hearing on an order to show cause shall be held no sooner than ten and no later than forty-five calendar days after the date of transmission or service of the notification by the director as provided in paragraph (b) of this subsection (12). The hearing may be continued by agreement of all parties based upon the complexity of the matter, number of parties to the matter, and legal issues presented in the matter, but in no event shall the hearing be held later than sixty calendar days after the date of transmission or service of the notification.
(II) If a person against whom an order to show cause has been issued pursuant to paragraph (a) of this subsection (12) does not appear at the hearing, the director may present evidence that notification was properly sent or served on the person pursuant to paragraph (b) of this subsection (12) and such other evidence related to the matter as the director deems appropriate. The director shall issue the order within ten days after the director's determination related to reasonable attempts to notify the respondent, and the order shall become final as to that person by operation of law. Such hearing shall be conducted pursuant to sections 24-4-104 and 24-4-105, C.R.S.
(III) If the director reasonably finds that the person against whom the order to show cause was issued is acting or has acted without the required registration, or has or is about to engage in acts or practices constituting violations of this article, a final cease-and-desist order may be issued, directing the person to cease and desist from further unlawful acts or unregistered practices.
(IV) The director shall provide notice, in the manner set forth in paragraph (b) of this subsection (12), of the final cease-and-desist order within ten calendar days after the hearing conducted pursuant to this paragraph (c) to each person against whom the final order has been issued. The final order issued pursuant to subparagraph (III) of this paragraph (c) shall be effective when issued and shall be a final order for purposes of judicial review.
(13) If it appears to the director, based upon credible evidence presented to the director, that a person has engaged or is about to engage in an unregistered act or practice; an act or practice constituting a violation of this article, a rule promulgated pursuant to this article, or an order issued pursuant to this article; or an act or practice constituting grounds for administrative sanction pursuant to this article, the director may enter into a stipulation with the person.
(14) If any person fails to comply with a final cease-and-desist order or a stipulation, the director may request the attorney general or the district attorney for the judicial district in which the alleged violation exists to bring, and if so requested such attorney shall bring, suit for a temporary restraining order and for injunctive relief to prevent any further or continued violation of the final order.
(15) A person aggrieved by the final cease-and-desist order may seek judicial review of the director's determination or of the director's final order as provided in subsection (8) of this section.

12-29.X-XXX. Mental or physical examination of registrants.

(1) If the director has reasonable cause to believe that a person registered under this article is unable to practice with reasonable skill and safety, the director may order the person to take a mental or physical examination administered by a physician or other licensed health care professional designated by the director. Unless due to circumstances beyond the registrant's control, if the registrant refuses to undergo a mental or physical examination, the director may suspend the person's registration until the results of the examination are known and the director has made a determination of the registrant's fitness to practice. The director shall proceed with an order for examination and shall make his or her determination in a timely manner.
(2) An order requiring a registrant to undergo a mental or physical examination shall contain the basis of the director's reasonable cause to believe that the registrant is unable to practice with reasonable skill and safety. For purposes of a disciplinary proceeding authorized under this article, the registrant shall be deemed to have waived all objections to the admissibility of the examining physician's or licensed health care professional's testimony or examination reports on the ground that they are privileged communications.
(3) The registrant may submit to the director testimony or examination reports from a physician chosen by the registrant and pertaining to any condition that the director has alleged may preclude the registrant from practicing with reasonable skill and safety. The testimony and reports submitted by the registrant may be considered by the director in conjunction with, but not in lieu of, testimony and examination reports of the physician designated by the director.
(4) The results of a mental or physical examination ordered by the director shall not be used as evidence in any proceeding other than one before the director and shall not be deemed a public record or made available to the public.

12-29.X-XXX. Unauthorized practice - penalties.
A person who practices or offers or attempts to practice as a radiologist assistant without an active registration issued under this article commits a class 2 misdemeanor and shall be punished as provided in section 18-1.3-501, C.R.S., for the first offense. For the second or any subsequent offense, the person commits a class 1 misdemeanor and shall be punished as provided in section 18-1.3-501, C.R.S.

12-29.X-XXX. Rule-making authority.
The director shall promulgate rules that may be necessary for the administration of this article.

12-29.X-XXX. Severability.
If any provision of this article is held to be invalid, such invalidity shall not affect other provisions of this article that can be given effect without the invalid provision.

12-29.X-XXX. Repeal of article - review of functions.
This article is repealed, effective July 1, 2020, and the powers, duties, and functions of the director specified in this article are repealed on said date. Prior to the repeal, such powers, duties, and functions shall be reviewed as provided in section 24-34-104, C.R.S.

END DRAFT STATUTE