COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review:
Colorado Professional Review Act

October 15, 2018

COLORADO
Department of Regulatory Agencies
Executive Director's Office

October 15, 2018

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 Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Since that time, Colorado's sunset process has gained national recognition and is routinely highlighted as a best practice as governments seek to streamline regulation and increase efficiencies.

Section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), directs the Department of Regulatory Agencies to:

- Conduct an analysis of the performance of each division, board or agency or each function scheduled for termination; and

- Submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination.

The Colorado Office of Policy, Research and Regulatory Reform (COPRRR), located within my office, is responsible for fulfilling these statutory mandates. Accordingly, COPRRR has completed the evaluation of the Colorado Professional Review Act. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2019 legislative committee of reference.

The report discusses the question of whether there is a need for the activities authorized under Article 36.5 of Title 12, C.R.S. The report also discusses the effectiveness of the staff in the Division of Professions and Occupations in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Marguerite Salazar
Executive Director

COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2018 Sunset Review
Colorado Professional Review Act

SUMMARY

What is professional review?
Professional review is the process by which hospitals and other entities evaluate the quality of care provided by medical and nursing staff. Professional review is essentially an evaluation by one's peers, such as a group of oncologists evaluating the work of an oncologist. The primary purpose of professional review is to improve the quality of patient care.

Why is it necessary?
The Colorado Professional Review Act (Act) is necessary to protect patient safety. Typically, professional review is performed by health-care facilities, but other organizations, such as professional associations or insurance companies, may also engage in professional review. In order to achieve this, facility staff must be able to openly report, share and analyze information about patient care provided by colleagues. The protections provided by the Act enable facility staff to share information without fear of retribution from colleagues who are under review. Otherwise, important information would likely not be provided and patients would be at increased risk of incompetent or inappropriate care.

Who is regulated?
In calendar year 2017, the Colorado Division of Professions and Occupations (Division) registered 227 governing boards that engage in professional review activities.

How is it regulated?
Any governing board that engages in professional review activities must register with the Division within 30 days of approving written bylaws, policies or procedures. Otherwise, a governing board is not entitled to the immunity provided for under the Act.

What does it cost?
The Division has not assessed any registration fees. The expenditures and staffing related to professional review registration and reporting requirements are nominal and are absorbed by the Colorado Medical Board and the Colorado Board of Nursing.

What disciplinary activity is there?
The Division does not have any enforcement authority over governing boards.

Key Recommendations

Continue the Act for 11 years, until 2030.
The Act provides health-care facilities the ability to review the conduct of practitioners. Without its protections, colleagues would be less likely to report substandard or inappropriate conduct and unwilling to share information during a review. In order to ensure the open and honest discussions necessary to improve patient care in health-care facilities, the General Assembly should continue the Act.

Require governing boards to annually update the registry information and verify whether they are currently engaging in professional review activities and whether they will engage in professional review activities in the future.
The registry of governing boards provides the public with an understanding of professional review activity in Colorado. However, once a governing board is registered, its registration continues in perpetuity. Within a few years, the registry will likely be unreliable. The General Assembly should require governing boards to annually update the registry information.

Require the Division to establish, by rule, a process to remove governing boards from the registry.
The Division does not currently have any mechanism for removing a governing board from the registry even if the governing board no longer exists. In order to ensure that the registry continues to be a reliable source of information about professional review activity in Colorado, the General Assembly should require the Division to establish, by rule, a process to remove governing boards from the registry.

Methodology

As part of this review, staff in the Colorado Office of Policy, Research and Regulatory Reform interviewed Division staff, interviewed officials from professional associations, interviewed other stakeholders, conducted a literature review, reviewed Colorado statutes and rules, and reviewed federal laws and the laws of other states.

Major Contacts Made During This Review

American College of Emergency Physicians
Caplan & Earnest, LLC
Colorado Division of Professions and Occupations
Colorado Hospital Association
Colorado Medical Society
Colorado Obstetrical and Gynecological Society
Colorado Office of the Attorney General
Colorado Nurses Association
Colorado Society of Osteopathic Medicine
Colorado Trial Lawyers Association
COPIC
Denver Health and Hospital Authority
Doctors Company, The
Kaiser Permanente
Poudre Valley Hospital

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are prepared by:
Colorado Department of Regulatory Agencies
Colorado Office of Policy, Research and Regulatory Reform
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

[1] Criteria may be found at § 24-34-104, C.R.S.

- Whether the agency through its licensing or certification process imposes any disqualifications on applicants based on past criminal history and, if so, whether the disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subparagraph (i) of paragraph (a) of subsection (8) of this section shall include data on the number of licenses or certifications that were denied, revoked, or suspended based on a disqualification and the basis for the disqualification; and
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Types of Regulation

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.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR's website at: www.dora.colorado.gov/opr.

The Colorado Professional Review Act (Act) and the functions of the Division of Professions and Occupations (Division) as enumerated in Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2019, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the Act pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed activities should be continued and to evaluate the performance of the Division. During this review, the Division must demonstrate that the program serves the public interest. COPRRR's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff interviewed Division staff, interviewed officials from professional associations, interviewed other stakeholders, conducted a literature review, reviewed Colorado statutes and rules, and reviewed federal laws and the laws of other states.

Profile of Professional Review

Professional review is the process by which hospitals and other entities evaluate the quality of care provided by medical and nursing staff. Professional review is essentially an evaluation by one's peers, such as a group of oncologists evaluating the work of an oncologist. The primary purpose of professional review is to improve the quality of patient care.

Professional review is often referred to as peer review. It may also be referred to as medical or clinical peer review. While peer review may also relate to a review of an article or performance evaluation, peer review in this context is primarily concerned with the evaluation of patient care.

Professional review committees review and evaluate the competence, professional conduct, and the quality and appropriateness of patient care by:[2]

- Physicians,
- Physician assistants, or
- Advanced practice nurses.

Professional review committees are created to protect patients by conducting investigations and taking disciplinary action, such as terminating hospital privileges or employment, when appropriate. If a professional review committee takes any action or makes a recommendation for action to be taken against anyone licensed by the Colorado Medical Board (Medical Board) or the Colorado Board of Nursing, it must inform the respective regulatory board.[3]

A professional review committee may be any of the following:[4]

- A governing board of a health-care facility or another entity,
- A hearing panel appointed by a governing board, or
- An independent third party designated by a governing board.

A governing board is ultimately responsible for the quality of care provided by a health-care facility.

In Colorado, a governing board must be registered with the Colorado Division of Professions and Occupations in order to retain the immunity from liability that is granted under state law for professional review activities.[5]

[2] Colorado Department of Regulatory Agencies. *Professional Review of Health Care Providers: Program Information.* Retrieved on November 2, 2017, from https://www.colorado.gov/pacific/dora/Prof_Review_Program_Info
[3] Colorado Department of Regulatory Agencies. *Professional Review of Health Care Providers: Program Information.* Retrieved on November 2, 2017, from https://www.colorado.gov/pacific/dora/Prof_Review_Program_Info
[4] Colorado Department of Regulatory Agencies. *Professional Review of Health Care Providers: Program Information.* Retrieved on November 2, 2017, from https://www.colorado.gov/pacific/dora/Prof_Review_Program_Info
[5] Colorado Department of Regulatory Agencies. *Professional Review of Health Care Providers: Program Information.* Retrieved on November 2, 2017, from https://www.colorado.gov/pacific/dora/Prof_Review_Program_Info

In all states and the District of Columbia, professional review proceedings are not subject to discovery in a lawsuit. However, if a violation of federal law, such as antitrust or discrimination, is alleged, all professional review proceedings are discoverable in federal courts.[6]

[6] The National Law Review. *Peer Review Is Not Always Privileged.* Retrieved on November 15, 2017, from https://www.natlawreview.com/article/peer-review-not-always-privileged

Legal Framework

History of Regulation

The General Assembly formally addressed professional review for the first time in 1975, when it enacted the Colorado Professional Review Act (Act).

Before the Act, hospitals, professional associations, and public and private insurance companies were already conducting professional review as a means of assuring that health-care services were of acceptable quality and cost. However, the medical community had two concerns about the professional review process.

First, the medical community was concerned that if a professional review committee made an unfavorable recommendation regarding a physician, the members of that committee would be vulnerable to legal action.

Second, the medical community feared that the lack of clarity and consistency regarding the discoverability of professional review proceedings could have a chilling effect on the process: committee members might be less likely to perform an honest assessment of a physician's practice if the professional review proceedings could potentially be used against that physician in civil court.

The Act defined which entities could form professional review committees, established standards for those who could serve on the committees and provided a level of legal immunity for those who did serve.

In 1988, the U.S. Supreme Court issued its opinion in *Patrick v. Burget*,[7] wherein it found that physicians could sue members of professional review committees under certain circumstances.

In response to this ruling, the General Assembly made substantial additions to the Act in 1989. It established that properly constituted and conducted professional review committees were effectively extensions of the Colorado Medical Board (Medical Board), and, as a result, entitled to immunity with respect to, among other things, antitrust laws. It also expanded the list of entities authorized to form professional review committees.

In 1994, the General Assembly added a new section to the statute regarding the conduct of other health-care professionals that might be discovered during hospital-based professional review. If a professional review committee were to identify a potential problem with the quality of care delivered by a health-care professional, the committee would have the authority to either refer the matter to the hospital quality management program or to consult with another member of that person's profession. The bill established that such referrals and consultations would remain confidential.

[7] *Patrick v. Burget*, 486 U.S. 94 (1988).

In 1994, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) conducted a sunset review of the Medical Board, and subsequently, the General Assembly required that any disciplinary action taken by a professional review committee against a physician be forwarded to the Medical Board.

In 2008, the General Assembly passed legislation authorizing the medical staff in ambulatory surgical centers to form professional review committees.

In 2011, COPRRR conducted a sunset review of professional review committees and the Committee on Anticompetitive Conduct, and subsequently, the General Assembly made several changes to the law:

- Authorized professional review of physician assistants and advanced practice nurses;
- Specified that the privilege afforded under the Act is not waived by the sharing of professional review information with regulators or with other professional review entities known to have also granted privileges to the same practitioner when the professional review process results in an adverse action; and
- Required entities that conduct professional review to register with the Division of Professions and Occupations (Division), required them to report various professional review activities and required the information to be public.

Although the Committee on Anticompetitive Conduct was repealed by operation of law in 2013, there are still several references to it in the Act.

Legal Summary

Federal Law

There are two federal laws that apply to professional review:

- The Health Care Quality Improvement Act of 1986 (HCQIA), and
- The Patient Safety and Quality Improvement Act of 2005 (PSQIA).

Health Care Quality Improvement Act of 1986

In 1986, the U.S. Congress enacted HCQIA in order to address an increasing number of medical malpractice lawsuits and a need to improve the quality of health care in the nation. The law sought to improve patient safety in health-care facilities by encouraging physician participation in professional review and by restricting physicians with a history of malpractice so that they could not simply move to another state or facility when they may no longer be safe to practice.[8]

[8] 42 U.S.C. § 11101.

The law addressed these two goals by creating:

- A peer review process that guaranteed due process and immunity for anyone participating in good faith, and
- The National Practitioner Data Bank (NPDB), a system of tracking physicians with a history of medical malpractice payments or adverse actions.

Due Process

HCQIA requires professional review committees to provide certain due process procedures to physicians undergoing professional review. After a health-care entity advises a physician of a proposed professional review action and the reasons for the proposed action, the physician must be provided at least 30 days to request a hearing.[9]

If the physician requests a hearing, the health-care entity must notify the physician at least 30 days in advance of the date, time and location of the hearing, as well as a list of witnesses expected to testify.[10]

The hearing must be conducted before:[11]

- An arbitrator acceptable to both the physician and the health-care entity, or
- A hearing officer or panel appointed by the entity that is not in direct economic competition with the physician involved.

During the hearing, the physician has the right to:[12]

- Employ legal representation;
- Call, examine and cross-examine witnesses;
- Present evidence; and
- Request—at his or her own expense—a copy of the record of the proceedings.

The law does not prohibit entities from initiating an immediate suspension or restriction of a physician's clinical privileges, subject to subsequent notice and hearing and other adequate procedures, when the failure to take such action poses an imminent danger to the health of any individual.[13]

[9] 42 U.S.C. § 11112(b)(1).
[10] 42 U.S.C. § 11112(b)(2).
[11] 42 U.S.C. § 11112(b)(3)(A).
[12] 42 U.S.C. § 11112(b)(3)(C).
[13] 42 U.S.C. § 11112(c)(2).

Immunity

HCQIA grants immunity from damages, with respect to actions taken by professional review committees, to the committee, the committee members, staff and contract employees,[14] provided they:[15]

- Made a reasonable effort to obtain the facts of the matter,
- Took the action warranted by the facts,
- Took the action to further the quality of health care, and
- Followed appropriate due process procedures.

Any person who provides information to professional review committees is also immune from damages, as long as that person does not knowingly provide false information.[16]

National Practitioner Data Bank

HCQIA also authorizes the creation of the NPDB, a federal database under the authority of the Secretary of the U.S. Department of Health and Human Services (Secretary), and it also establishes a list of adverse actions that must be reported to NPDB:

- Medical malpractice payments,
- Actions taken by state medical boards, and
- Actions taken by professional review committees.

Any entity, such as an insurance company, making medical malpractice payments or in settlement of a medical malpractice action or claim, is responsible for reporting this information, both to the NPDB and to the medical board of the state in which the malpractice claim occurred.[17] Entities that fail to report malpractice payments are subject to a civil penalty of up to $10,000 for each unreported payment.[18]

State medical boards are responsible for reporting disciplinary actions, which include:[19]

- Suspensions, revocations, censures and reprimands;
- Actions that restrict or place conditions on a physician's license, for reasons relating to the physician's professional competence or conduct; and
- Actions wherein a physician surrenders his or her license.

[14] 42 U.S.C. § 11111(a).
[15] 42 U.S.C. § 11112(a).
[16] 42 U.S.C. § 11111(a)(2).
[17] 42 U.S.C. §§ 11131(a) and 11134(c)(1).
[18] 42 U.S.C. § 11131(c).
[19] 42 U.S.C. § 11132(a)(1).

Health-care entities are responsible for reporting, to the NPDB and state medical boards, actions taken by professional review committees that relate to a physician's professional conduct or competence and:[20]

- Adversely affect the clinical privileges for a period longer than 30 days,
- Accept the surrender of clinical privileges while the physician is under an investigation relating to possible incompetence or improper professional conduct, or
- Adversely affect membership in a professional society.

Certain professional review actions are excluded from the reporting requirement, for example:[21]

- Actions relating to a physician's involvement with a professional society or association,
- Actions relating to a physician's fees, advertising or other competitive acts intended to solicit or retain business, or
- Any other matter that that does not stem from professional conduct or competence.

Under HCQIA, hospitals are required to query the NPDB data for each licensed health-care provider who applies for a position on the medical staff or for clinical privileges at the hospital, and every two years, hospitals must also query the NPDB for any providers who are on staff or have clinical privileges. Hospitals may query the NPDB at other times as well.[22]

Patient Safety and Quality Improvement Act of 2005

The U.S. Congress created the PSQIA in 2005 in an effort to increase patient safety and reduce the incidence of adverse events by creating a voluntary program for health-care providers to share information related to medical errors.

Patient Safety Organizations (PSO's) are authorized to collect, aggregate and analyze the information reported by health-care providers.[23] To encourage providers to participate, the patient safety information is protected as confidential and privileged.[24]

The Secretary is authorized to certify PSO's if they meet the criteria outlined in statute, and the Secretary may revoke the certification if the entity ceases to meet the required criteria.[25]

[20] 42 U.S.C. §11133(a)(1).
[21] 42 U.S.C. § 11151(9)
[22] 42 U.S.C. § 11135(a).
[23] Pursuant to 42 U.S.C. § 299b-21(8), PSQIA defines a "provider" as an individual or an entity licensed under state law to provide health-care services.
[24] U.S. Department of Health and Human Services. *Understanding Patient Safety Confidentiality*. Retrieved on December 15, 2017, from www.hhs.gov/hipaa/for-professionals/patient-safety/index.html
[25] 42 U.S.C. § 299b-24(c) and (e).

PSQIA contains extensive provisions regarding the privilege and confidentiality[26] of patient safety work product, which includes any data, reports, analyses and the like, that are:[27]

- Assembled or developed by a provider and reported to a PSO,
- Developed by a PSO for the conduct of patient safety activities, or
- Connected with a patient safety evaluation system.

Patient safety work product does not include:[28]

- A patient's medical records, billing or discharge information, or any original patient or provider record; or
- Any information that is collected or maintained separately from the patient safety evaluation system.

Under PSQIA, patient safety work product is not subject to:[29]

- Subpoenas or orders in a federal, state or local civil, criminal or administrative proceeding, including a disciplinary proceeding against a provider;
- Discovery in connection with a federal, state or local civil, criminal or administrative proceeding, including in a disciplinary proceeding against a provider;
- Disclosure pursuant to the Freedom of Information Act or any other similar law;
- Evidence in any federal, state or local governmental civil, criminal or administrative proceeding, including any such proceeding against a provider; or
- Evidence in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law.

PSQIA deems patient safety work product confidential. This provision supersedes all state or local laws.[30]

PSQIA defines numerous exceptions to the rule of privilege and confidentiality.[31]

A person who knowingly discloses identifiable patient safety work product is subject to a civil penalty of up to $10,000 for each violation.[32]

[26] Privilege applies to the discoverability and admissibility of evidence as part of a judicial proceeding; whereas, confidentiality generally restricts the release of information to third parties outside of a judicial context.
[27] 42 U.S.C. § 299b-21(7)(A).
[28] 42 U.S.C. § 299b-21(7)(B).
[29] 42 U.S.C. § 299b-22(a).
[30] 42 U.S.C. § 299b-22(b).
[31] 42 U.S.C. § 299b-22(c)(1).
[32] 42 U.S.C. § 299b-22(f)(1).

State Law

Colorado's laws relating to professional review are located within Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.) (Act).

Professional review committees are deemed extensions of the Medical Board and the Colorado Board of Nursing (Board of Nursing) under the Act,[33] and all governing boards that establish professional review committees in Colorado are required to register with the Division.[34]

A professional review committee may be created to review and evaluate the professional conduct or patient care of a physician, physician assistant or advanced practice nurse.[35] Specifically, a professional review committee may investigate an individual regarding his or her:[36]

- Qualifications and competence,
- Quality or appropriateness of patient care, and
- Professional conduct.

A professional review committee may be any of the following:[37]

- A governing board of a peer review entity,
- A hearing panel appointed by a governing board, or
- An independent third party designated by a governing board.

A professional review committee may be established by many different types of entities, known as authorized entities, such as:[38]

- The medical staff of a hospital,
- The medical staff of a hospital-related corporation,
- An association of physicians whose membership is at least one third licensed physicians,
- An association of advanced practice nurses,
- An individual practice association,
- A health maintenance organization,
- A company providing professional liability insurance to practitioners subject to professional review under the Act,
- A statewide hospital association that meets certain conditions,
- The medical or nursing staff of an ambulatory surgical center,
- A professional services corporation, and
- A provider network.

[33] § 12-36.5-103(3)(a), C.R.S.
[34] § 12-36.5-104(4), C.R.S.
[35] § 12-36.5-104(1), C.R.S.
[36] § 12-36.5-104(6)(a), C.R.S.
[37] § 12-36.5-102(6), C.R.S.
[38] § 12-36.5-104(4), C.R.S.

A hearing panel that is established to review physicians or physician assistants must include a majority of physicians among its voting members.[39]

A professional review committee that is established to review an advanced practice nurse must include at least one voting member who is an advanced practice nurse with a similar scope of practice, or engage an advanced practice nurse with a similar scope of practice to conduct an independent review.[40]

Investigations of professional review committees must be conducted according to the written bylaws, policies and procedures adopted by its governing board,[41] which must include at a minimum:[42]

- An individual subject to adverse action must be provided a hearing at which the findings and recommended action is to be considered;
- Anyone involved in the investigation may appear as a witness but may not participate as a member of a professional review committee that is conducting the hearing;
- The entity must provide reasonable notice of a hearing and allow the subject to be present, represented by legal counsel and provide evidence on his or her own behalf;
- Any recommendations made by the professional review committee must be provided to the governing board, unless otherwise authorized by federal law or regulation;
- A copy of the recommendations must be provided to the subject of the investigation;
- The subject of an investigation must be allowed to appeal any adverse findings or recommendations to the governing board; and
- The professional review committee must promptly forward a copy of any recommendations to the Medical Board or Board of Nursing, as appropriate.

The bylaws may authorize a committee of three or more members to hear an appeal on behalf of the governing board.[43]

The records of a professional review committee are not subject to subpoena or discovery and are not admissible in any civil suit, except:[44]

- By either party in an appeal or de novo proceeding brought pursuant to the Act;
- By the subject of peer review, governing board or authorized entity seeking judicial review;
- By the Colorado Department of Public Health and Environment (CDPHE) related to health facility licensing or certification;

[39] § 12-36.5-104(2), C.R.S.
[40] § 12-36.5-104(2.5), C.R.S.
[41] § 12-36.5-104(6)(b), C.R.S.
[42] § 12-36.5-104(7), C.R.S.
[43] § 12-36.5-104(8)(b), C.R.S.
[44] § 12-36.5-104(10), C.R.S.

- By the Centers for Medicare and Medicaid Services in accordance with its authority over federal health-care program participation by an authorized entity;
- By the Medical Board related to regulating its licensees; and
- By the Board of Nursing related to regulating its licensees.

The records of a peer review committee provided to CDPHE, the Medical Board or the Board of Nursing related to their regulatory activities are confidential and may not be disclosed to any other parties.[45]

The records of an authorized entity or its professional review committee or governing board may be shared by and among authorized entities and their professional review committees and governing boards concerning the competence, professional conduct of, or the quality and appropriateness of patient care provided by, a health care provider who seeks to subject himself or herself to, or is currently subject to, the authority of the authorized entity.[46] Otherwise, peer review investigations and hearings are confidential and not subject to open meetings or open records laws.[47]

If a professional review committee determines that the quality or appropriateness of care provided by health-care professionals, other than those covered by the Act, adversely affected the outcome of patient care, it must:[48]

- Refer the matter to a hospital committee created to perform quality management functions, or
- Consult with a representative of the profession.

The confidentiality, immunities and privileges of the Act also extend to these proceedings and communications.[49]

A professional review committee may collaborate with a hospital committee established to conduct quality management functions.[50]

Any governing board in Colorado that creates a professional review committee must register with the Division.[51] The Division must publish a list of registered governing boards that are in compliance with the Act.[52]

[45] § 12-36.5-104(11)(b), C.R.S.
[46] § 12-36.5-104(12), C.R.S.
[47] §§ 12-36.5-104(14) and (15), C.R.S.
[48] § 12-36.5-104.4(2)(a), C.R.S.
[49] § 12-36.5-104.4(2)(b), C.R.S.
[50] § 12-36.5-104.4(2)(a)(II), C.R.S.
[51] § 12-36.5-104.6(2)(a), C.R.S.
[52] § 12-36.5-104.6(3)(b), C.R.S.

Each governing board must annually report, to the respective regulatory board, the number of professional review actions taken against anyone licensed as an advanced practice nurse, a physician or a physician assistant, in which the:[53]

- Action adversely affected the licensee;
- Licensee surrendered his or her clinical privileges, membership or affiliation while under investigation;
- Licensee surrendered his or her clinical privileges, membership or affiliation in lieu of an investigation; and
- Professional review committee made recommendations to the governing board.

The Medical Board and the Board of Nursing must forward these reports to the Division with all identifying information redacted.[54]

Additionally, each governing board must also report to the Division, in a de-identified manner, aggregate data including the:[55]

- Number of investigations completed during the year,
- Number of investigations that resulted in no action,
- Number of investigations that resulted in written involuntary requirements for improvement sent to the subject of the investigation by the authorized entity, and
- Number of investigations that resulted in written agreements for improvement between the subject of the investigation and the authorized entity.

The Division is required to publish the aggregate data provided by governing boards. The data may not identify the governing board, the authorized entity or any of the licensees,[56] and the reports made by the governing boards to the Division are otherwise not public records.[57]

The Division is required to adopt rules in order to implement the registration and reporting requirements of governing boards, and it may collect a reasonable registration fee to cover the registration and publication costs associated with these requirements.[58]

The Medical Board and the Board of Nursing may not initiate an investigation or issue a subpoena solely based on any of the data provided by the governing board to the Division.[59]

Professional review committees and their members are granted immunity from lawsuits and liability for damages in a civil or criminal lawsuit, including antitrust actions, arising

[53] §§ 12-36.5-104.6(2)(b)(I) and (II), C.R.S.
[54] § 12-36.5-104.6(2)(c)(II)(A), C.R.S.
[55] § 12-36.5-104.6(2)(c), C.R.S.
[56] § 12-36.5-104.6(3)(a), C.R.S.
[57] § 12-36.5-104.6(2)(c)(II)(B), C.R.S.
[58] § 12-36.5-104.6(4), C.R.S.
[59] § 12-36.5-104.6(6), C.R.S.

from activities that are taken within the scope of peer review, unless a person knowingly provides false information in professional review.[60]

Additionally, the following people are also granted immunity:[61]

- Committee staff,
- Witnesses,
- Consultants, and
- Complainants.

Immunity for professional review committees is conditional, and any actions taken by the professional review committee must be:[62]

- Warranted by the facts of the case,
- Conducted in accordance with procedures that are fair to the individual under review,
- Taken to improve the quality of health care, and
- Taken to obtain the facts of the case.

A governing board is only afforded immunity in professional review when it registers with the Division. However, a governing board's failure to register does not affect the immunity, confidentiality or privilege afforded to individuals participating in professional review.[63]

Additionally, a governing board's failure to report data as required by the Act does not affect its immunity.[64]

The Medical Board and the Board of Nursing are authorized to adopt rules in order to comply with HCQIA and may participate in the NPDB.[65]

[60] § 12-36.5-105(1), C.R.S.
[61] § 12-36.5-105(1), C.R.S.
[62] § 12-36.5-105(2), C.R.S.
[63] § 12-36.5-104.6(7)(a), C.R.S.
[64] § 12-36.5-104.6(7)(b), C.R.S.
[65] § 12-36.5-202, C.R.S.

Program Description and Administration

Professional review is the process by which hospitals, insurance companies and other entities evaluate the quality of care provided by medical and nursing practitioners. Professional review is governed by the Colorado Professional Review Act (Act), located within Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.).

Governing boards of entities that establish professional review committees are required to register with the Division of Professions and Occupations (Division),[66] and they are required to report certain actions and data to the appropriate licensing boards.

The expenditures and staffing related to professional review registration and reporting requirements are nominal and are absorbed by the Colorado Medical Board and the Colorado Board of Nursing.

Registration

Any governing board of an entity that engages in professional review activities must register with the Division within 30 days of approving written bylaws, policies or procedures. Otherwise, a governing board is not entitled to the immunity provided for under the Act.

In order to register, a governing board must submit the following information through the Division's online registration system:

- The name of the governing board;
- The address of the governing board;
- The mailing address;
- A point of contact, including a name, title, phone number and email address; and
- An alternate point of contact, including a name, title, phone number and email address.

Although the Division is authorized to assess a registration fee to cover the costs associated with registration, it has not.

The Division publishes a list of registered governing boards on its website.

[66] § 12-36.5-104(4), C.R.S.

Table 1 illustrates the total number of governing boards that registered with the Division over a five-year period.

Table 1
Registered Governing Boards

Calendar Year	Number
2013	164
2014	185
2015	202
2016	208
2017	227

The registration requirement began on July 1, 2013, so Table 1 represents the life of the registration program. Governing boards have an incentive to register.

The total number of governing boards registered with the Division increased steadily over the five-year period, slowing somewhat in 2016 but increasing again during the following year.

Governing boards are not required to renew. Once a governing board registers, its registration continues in perpetuity.

Professional Review Activities

The Act affords those involved in professional review activities certain protections. For instance, all proceedings, recommendations, records and reports are confidential, and records are not subject to subpoena or discovery. Anyone participating in professional review activities is immune from criminal or civil suits related to professional review activities unless the person knowingly provides false information.

In conjunction with the legal protections related to professional review activities are several reporting requirements. The Division requires governing boards to report the statutorily required data for the previous calendar year between January 1 and March 1.

The Division compiles and publishes the reported data on its website.

Table 2 shows the data that was reported to the Division regarding certain professional review activities connected with both medical and nursing staff over a five-year period.

Table 2
Professional Review Activities

Calendar Year	Number of Investigations	No Action Taken	Written Involuntary Requirements	Written Agreements
2013	743	661	13	51
2014	836	669	16	63
2015	982	763	17	149
2016	1,242	949	16	207
2017	1,708	1,064	56	323

It is not possible to verify the percentage of governing boards that reported and whether any of the data are duplicated because the data is de-identified. Therefore, the reliability of the data cannot be confirmed and any analysis of the data would be misleading.

Table 3 provides the data reported to the Division regarding professional review actions connected with physicians and physician assistants.

Table 3
Professional Review Actions
Physicians and Physician Assistants

Calendar Year	Adverse Actions	Surrendered Privileges/Affiliation During Investigation	Surrendered Privileges/Affiliation In Lieu of Investigation	Recommendations Made
2013	7	4	0	0
2014	9	4	1	3
2015	8	3	1	4
2016	10	6	2	1
2017	15	10	0	3

It is not possible to verify the percentage of governing boards that reported and whether any of the data are duplicated because the data is de-identified. Therefore, the reliability of the data cannot be confirmed and any analysis of the data would be misleading.

Table 4 provides the data reported to the Division regarding professional review actions connected to advanced practice nurses.

Table 4
Professional Review Actions
Advanced Practice Nurses

Calendar Year	Adverse Actions	Surrendered Privileges/Affiliation During Investigation	Surrendered Privileges/Affiliation In Lieu of Investigation	Recommendations Made
2013	4	1	0	1
2014	1	0	0	1
2015	3	0	0	2
2016	6	2	0	2
2017	8	2	1	0

It is not possible to verify the percentage of governing boards that reported and whether any of the data are duplicated because the data is de-identified. Therefore, the reliability of the data cannot be confirmed and any analysis of the data would be misleading.

Collateral Consequences – Criminal Convictions

Section 24-34-104(6)(b)(IX), C.R.S., requires the Colorado Office of Policy, Research and Regulatory Reform to determine whether the agency under review, through its licensing processes, imposes any disqualifications on applicants or registrants based on past criminal history, and if so, whether the disqualifications serve public safety or commercial or consumer protection interests.

This provision is not relevant to the Act since governing boards are not disqualified based on criminal history.

Analysis and Recommendations

Recommendation 1 – Continue the Colorado Professional Review Act for 11 years, until 2030.

Professional review is the process by which professional review committees in hospitals, insurance companies and other entities evaluate the quality of care provided by medical and nursing practitioners. Professional review is governed by the Colorado Professional Review Act (Act), located within Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.).

The Act affords those involved in professional review certain protections. For instance, any proceedings, recommendations, records and reports are confidential, and the records are not subject to subpoena or discovery. Anyone participating in professional review activities is immune from criminal or civil suits related to professional review activities unless the person knowingly provides false information.

Section 24-34-104, C.R.S., questions whether the Act is necessary to protect the public health, safety and welfare.

The purpose of professional review is to protect the quality of patient care. Typically, professional review is performed by health-care facilities, but other organizations, such as professional associations or insurance companies, may also engage in professional review. In order to achieve this, facility staff must be able to openly report, share and analyze information about patient care provided by colleagues. The protections provided by the Act enable facility staff to share information without fear of retribution from colleagues who are under review or through malpractice lawsuits. Otherwise, important information would likely not be provided and patients would be at increased risk of incompetent or inappropriate care.

When a health-care facility or another entity receives a complaint alleging that patient care is substandard or inappropriate, it may convene a professional review committee to establish the facts and to determine whether any actions should be taken. If a professional review committee determines that patient care was substandard or inappropriate, it may make a recommendation to the governing board to restrict or remove a practitioner's privileges at the facility. In this case, the practitioner is afforded due process, including the right to a hearing, in which he or she may be represented by counsel, present evidence and examine witnesses.

Not all recommendations made by peer review committees result in adverse actions, such as losing hospital privileges. A peer review committee may, for example, make a recommendation to change hospital processes.

The Act is necessary to protect the public because it provides health-care facilities and other entities the ability to review the conduct of practitioners. Without its protections, colleagues would be less likely to report substandard or inappropriate conduct, and they may also be unwilling to share information during a review in case the information they

provide is used in a lawsuit. In order to ensure the open and honest discussions necessary to improve patient care in health-care facilities and other professional review entities, the Act should be continued.

While not all stakeholders are satisfied with the Act, most find that it works well and few substantive issues were raised during the course of the review.

Therefore, the General Assembly should continue the Act for 11 years, until 2030.

Recommendation 2 – Clarify that the governing board and the data reported by the governing boards to the Colorado Medical Board and the Colorado Board of Nursing and to the staff of the Division of Professions and Occupations may be known to the Division staff.

Governing boards that establish professional review committees are required to register with the Division of Professions and Occupations (Division),[67] and they are also required to report certain actions to the Colorado Medical Board (Medical Board), the Colorado Board of Nursing (Board of Nursing) and to the Division.

The purpose of registering governing boards and requiring actions to be reported is to provide transparency in professional review so that regulators, policymakers and the public may have a better understanding of the professional review activity that is taking place in Colorado.

The Act provides significant protections to health-care facilities. For example, any proceedings, recommendations, records and reports are confidential, and professional review records are not subject to subpoena or discovery. Anyone participating in professional review is also immune from criminal or civil suits related to professional review activities. In exchange for these protections, it is, therefore, reasonable to expect facilities and other organizations that benefit from professional review to provide some limited information about their activities.

For instance, section 12-36.5-104.6(2)(c)(I), C.R.S., requires governing boards to:

> Report to the Division, *in a de-identified manner*, on its professional review activities during the immediately preceding calendar year in a form satisfactory to the Division. These reports must include aggregate data, which is limited to the following:
>
> - The number of investigations completed during the year,
> - The number of investigations that resulted in no action,
> - The number of investigations that resulted in written involuntary requirements for improvement sent to the subject of the investigation by the authorized entity, and

[67] § 12-36.5-104(4), C.R.S.

- The number of investigations that resulted in written agreements for improvement between the subject of the investigation and the authorized entity.

Also, sections 12-36.5-104.6(2)(b)(I) and (II), C.R.S., require the governing board to report the number of professional review activities to the Medical Board and the Board of Nursing in which:

- The subject of professional review was adversely affected,
- An authorized entity accepted the individual's surrender of clinical privileges, membership or affiliation while the individual was under investigation,
- An authorized entity accepted the subject's surrender of clinical privileges, membership or affiliation in return for not conducting an investigation, and
- The professional review committee made recommendations regarding the individual following a hearing.

Then, the Medical Board and the Board of Nursing are required to report this data in a "de-identified manner" to the Division.[68]

Because these provisions require the professional review activities to be reported to the Division in a "de-identified manner," this has been interpreted as prohibiting Division staff from knowing which governing board reported which activities, resulting in a system that prevents Division staff from verifying the data. For this reason, the data are unreliable.

The Act also requires the Division to publish the data from these reports online. Since the reported data cannot be confirmed, the data published by the Division may be inaccurate. This could be improved by a simple clarification of the law. Doing so would provide the public with verifiable and meaningful data.

In order to provide the public with some basic information about the professional review activity that is taking place in Colorado, staff must be able to manage the data reported to it. Doing so will not compromise the confidentiality or privileges granted by the Act since these reports are not public record.

For this reason, the General Assembly should clarify that the governing board and the data reported by the governing board to the Medical Board, the Board of Nursing and to the Division pursuant to sections 12-36.5.104.6(2)(b)(I) and (II), and section 12-36.5-104.6(2)(c)(I), C.R.S., may be known to Division staff so that staff may manage and accurately report the data to the public.

[68] § 12-36.5-104.6(2)(c)(II), C.R.S.

Recommendation 3 – Require governing boards to update their information on the registry annually, including reporting whether they are currently, or will in the future, engage in peer review activities.

Any governing board that establishes a professional review committee must register with the Division within 30 days of approving written bylaws, policies or procedures.

In order to register, a governing board must submit the following information through the Division's online registration system:

- The name of the governing board;
- The address;
- The mailing address;
- A point of contact including a name, title, phone number and email address; and
- An alternate point of contact including a name, title, phone number and email address.

In exchange for registering with the Division, a governing board is afforded immunity from lawsuits related to professional review activity.

The registry of governing boards serves a purpose: it provides the state with an understanding of who is engaging in professional review and the level of professional review activity that is taking place in Colorado. However, once a governing board is registered, it is not required to renew and its registration continues in perpetuity.

This creates some problems with the registry at the outset. Governing boards may come and go, and addresses and contacts may change from time to time. Within a few years, the registry will likely be so unreliable that it will no longer serve its purpose.

There are a couple of solutions to this issue.

One solution would be to require governing boards to renew their registration. However, if a governing board failed to renew and it were removed from the registry, it would lose its immunity in conducting professional review. This is a fairly severe consequence considering the purpose of the registry.

It would be better to require governing boards to annually update their information on the registry, including reporting whether they are, or will in the future, engage in professional review activity. If governing boards do this, then the registry should continue to provide a fairly accurate picture of which entities are engaged in professional review in Colorado.

The benefit of annually updating this information is threefold. One, it is easier to remember to update information if it is required every year. If it were every other year or every few years, then governing boards may lose track of when they need to update. Moreover, the longer the time period between updates of information, the more likely the registry will be out of date. Two, since governing boards are already required to

annually report professional review activity, it should not be difficult to update the registration at the same time. Finally, the cost and resources required to make this change should be minimal.

Therefore, the General Assembly should require governing boards to annually update the registry information that is required for initial registration and, at the same time, verify whether they are currently engaging in professional review activities and whether they will engage in professional review activities in the future.

Recommendation 4 – Require the Division to establish, by rule, a process to remove governing boards from the registry.

Governing boards that form professional review committees are required to register with the Division. In exchange for registering, governing boards are afforded immunity from lawsuits. At this time, once a governing board registers with the Division, it remains on the registry in perpetuity.

There are obvious benefits for governing boards to be provided the convenience of remaining on the registry without the need to renew. Unfortunately, this creates a situation in which the registry may become meaningless after only of few years if governing boards change or cease to exist.

However, at this time, the Division does not have any mechanism for removing a governing board from the registry even if the governing board no longer exists.

Recommendation 3 of the sunset report proposes requiring governing boards to update their information annually and to report whether they are currently, or will in the future, engage in professional review activity. If a governing board reports that it is not engaging in professional review activity and will not engage in it in the future, the Division should have the ability to remove the governing board from the registry.

Additionally, if the Division determines that the governing board has not reported professional review activity for several years and, after taking reasonable steps, that the governing board no longer exists, it should also have the ability to remove the governing board from the registry.

Doing this would ensure that the registry continues to provide a reliable source of information about which entities are engaging in professional review activity in Colorado.

Therefore, the General Assembly should require the Division to establish, by rule, a process to remove governing boards from the registry.

Recommendation 5 – Make technical amendments to the Act.

The Act was adopted in 1975. As with any law, it contains instances of obsolete language. In order to modernize the law, it should be revised to eliminate outdated references. These changes are technical in nature, so they will have no substantive impact on professional review activities.

The General Assembly should make the following technical changes:

- Repeal references to the Committee on Anticompetitive Conduct since it no longer exists; and
- Change "Utilization and Quality Control Peer Review Organization" in section 12-36.5-104(3), C.R.S., to "Quality Improvement Organization" as it is currently referred to in federal law.