



**Dora**  
Department of Regulatory Agencies

**Office of Policy, Research and Regulatory Reform**

**2011 Sunset Review:  
Professional Review Committees  
and the Committee on  
Anticompetitive Conduct**

October 14, 2011





**Dora**  
Department of Regulatory Agencies

**Executive Director's Office**

Barbara J. Kelley  
Executive Director

John W. Hickenlooper  
Governor

October 14, 2011

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 sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of Colorado's laws relating to professional review committees and the Committee on Anticompetitive Conduct. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2012 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...

The department of regulatory agencies shall 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 report discusses the question of whether there is a need for the provisions of Article 36.5 of Title 12, C.R.S. The report also makes recommendations for statutory changes in the event this statute is continued by the General Assembly.

Sincerely,

Barbara J. Kelley  
Executive Director



John W. Hickenlooper  
Governor

Barbara J. Kelley  
Executive Director

## **2011 Sunset Review: Professional Review Committees and the Committee on Anticompetitive Conduct**

### **Summary**

#### ***What Is Regulated?***

The Colorado professional review act (CPRA) provides legal privilege and immunity to those entities that conduct professional review of physicians, so long as they comply with the due process provisions of CPRA. CPRA also creates the Committee on Anticompetitive Conduct (CAC).

#### ***Why Is It Regulated?***

It is generally recognized that in order for professional review to be meaningful, the process must be confidential, so as to encourage open and honest discussion. Those who participate in the process must have some degree of legal immunity to help safeguard the integrity and effectiveness of the review process.

The CAC was created to provide a quasi-appellate body with respect to those professional review actions that are allegedly taken based on unreasonable anticompetitive conduct.

#### ***Who Is Regulated?***

Most professional review occurs in hospitals, but it can also occur in ambulatory surgical centers and other settings. While there are currently no registration requirements for those entities that conduct professional review, the medical staff bylaws of those entities must afford physicians undergoing review certain due process protections, such as the opportunity to examine witnesses and to offer evidence in a hearing.

#### ***How Does the CAC Work?***

If a physician asserts that an adverse professional review action (i.e., suspension, limitation or revocation of privileges) was taken against him or her due to unreasonable anticompetitive conduct, the physician must file a complaint with the CAC before adjudicating any antitrust claims in court.

#### ***What Does It Cost?***

There are no State expenditures associated with professional review activities. The parties to cases before the CAC are required to reimburse the State for any direct and indirect costs associated with the proceeding.

#### ***What Activity Is There?***

There is no regulatory oversight of the professional review process. Accordingly, DORA is unable to determine how many entities conduct professional review, the number of physicians that are professionally reviewed or the outcomes of those reviews.

Since it was created in 1989, 11 cases have been brought to the CAC.

#### ***Where Do I Get the Full Report?***

The full sunset review can be found on the internet at: [www.dora.state.co.us/opr/oprpublications.htm](http://www.dora.state.co.us/opr/oprpublications.htm).

## Key Recommendations

### **Continue CPRA for seven years, until 2019.**

Professional review is required by The Joint Commission, in its standards of accreditation, and by the Centers for Medicare and Medicaid Services' Medicare Conditions of Participation. Thus, any health care entity that is accredited by The Joint Commission or that serves Medicare patients must conduct professional review. For those health care entities that conduct professional review and comply with enumerated due process provisions, CPRA ensures the professional review process remains confidential and it provides immunity to those who participate. CPRA embodies the best known mechanisms for promoting patient safety, and affording reviewed physicians a process to challenge adverse, and possibly unwarranted, professional review actions.

### **Sunset the CAC.**

The jurisdiction of the CAC is relatively limited. Only those final adverse actions of a professional review entity that a reviewed physician asserts were the result of anticompetitive conduct can be raised before the CAC. Any claims based on grounds other than antitrust can be taken directly to district court. In the 22 years since it was created, only 11 cases have been filed with the CAC. The continued necessity and utility of the CAC is, therefore, questionable.

## Major Contacts Made During This Review

American College of Nurse Midwives, Region 5, Chapter 3  
Center for Personalized Education for Physicians  
Colorado Academy of Physician Assistants  
Colorado Ambulatory Surgical Centers Association  
Colorado Association of Nurse Anesthetists  
Colorado Citizens for Accountability  
Colorado Consumer Health Initiative  
Colorado Defense Lawyers Association  
Colorado Department of Health Care Policy and Financing  
Colorado Department of Public Health and Environment  
Colorado Foundation for Medical Care  
Colorado Health Care Association  
Colorado Hospital Association  
Colorado Medical Society  
Colorado Nurses Association  
Colorado Patient Safety Coalition  
Colorado Physician Health Program  
Colorado Podiatric Medical Association  
Colorado Rural Health Center  
Colorado Trial Lawyers Association  
Emergency Medical Services Association

## What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not 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:  
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## Background

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### 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 Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria<sup>1</sup> 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;
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

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<sup>1</sup> Criteria may be found at § 24-34-104, C.R.S.

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## **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.

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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.



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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 via DORA's website at: [www.dora.state.co.us/pls/real/OPR\\_Review\\_Comments.Main](http://www.dora.state.co.us/pls/real/OPR_Review_Comments.Main).

The statutes governing professional review committees and the Committee on Anticompetitive Conduct (CAC) enumerated in Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.) (CPRA), shall terminate on July 1, 2012, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of these statutes pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether CPRA should be continued for the protection of the public. During this review, DORA must determine whether CPRA serves to protect the public health, safety or welfare, and whether CPRA is the least restrictive government intervention consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

### **Methodology**

As part of this review, DORA staff conducted a literature review; interviewed CAC members, Colorado Medical Board (CMB) staff, officials with state and national professional and trade associations, health care providers, representatives of hospitals and ambulatory surgical centers, and patient advocates; and reviewed CAC records and files, Colorado statutes, CMB and CAC rules, and the laws of other states.

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## **Overview of Professional Review Committees and the Committee on Anticompetitive Conduct**

Professional review, also known as peer review, is conducted in many contexts by many different types of professionals. However, for the purposes of this sunset report, unless otherwise indicated, the terms refer to the review of physicians. Given this limitation, professional review, at its most basic level, is intended to review the conduct of a particular physician to determine whether that physician is competent and safe to practice.

Although any organization can, technically, conduct professional review, only those enumerated in CPRA can claim legal privilege for such activities, and even then, only when they comply with the various provisions of CPRA.

In practice, most professional review is conducted by the organized medical staffs of hospitals and ambulatory surgical centers. The process is typically dictated by the medical staff bylaws, which are specific to each facility and to which all members of the medical staff agree to adhere when they join the staff.

How professional review is conducted can vary considerably from one facility to another. As a result, the following discussion provides generalized information.

A particular incident, data collection and “trending,” and the credentialing process can all trigger the professional review process.

Incident-based professional review can be triggered by a complaint or an outcome. A complaint may be lodged against a physician with the facility by any number of people, including other physicians, hospital staff, a patient or a patient’s family.

Many facilities maintain lists of events, or incidents, the occurrence of which will trigger automatic professional review. Some examples of these types of events include, but are not limited to:

- Unexpected death;
- Wrong-site surgery;
- Two admissions to the emergency room within 24 hours; and
- Readmission within 24 hours of discharge for the same or similar condition/symptoms.

Additionally, facilities collect and maintain copious amounts of data regarding patient outcomes, physicians, procedures, and many other topics. These data are tracked, or “trended,” to identify irregularities before they become actual problems or incidents.

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These data can be used to identify trends in the practice of a physician, which, in turn, can lead to professional review. For example, a particular physician may have an unusually high number of patients who develop post-operative infections. This type of professional review may begin as little more than a chart review to determine what the physician may be doing differently than his or her peers.

Regardless of the mechanism by which professional review is triggered, most facilities employ some kind of professional review coordinator to receive complaints or to initiate the professional review process.

Depending on the size of the facility, and thus the medical staff, the first level of professional review may be conducted by a single reviewer, or by a subcommittee of the facility's professional review committee, which itself may be a subcommittee of the facility's medical executive committee (MEC).

Two general models of professional review committees exist: departmental and multidisciplinary. In the departmental model, the first few phases of professional review are conducted by the physician's colleagues (which may include non-physicians, such as nurses or physician assistants) in the same department, and often of the same specialty. In the multidisciplinary model, the first few phases of professional review may be conducted by staff members from different departments and specialties.

The materials reviewed may include the patient's medical chart, as well as any incident reports or complaints that may be associated with the case. Depending on the facility, the information may or may not be de-identified, or "scrubbed," such that any reviewers cannot determine the identity of the physician involved from the documents reviewed.<sup>2</sup> The goal of the first level of review is to determine whether anything unusual stands out that merits further review.

If the first level of review finds nothing of concern, the case may still be logged for trending purposes. However, if the first level of review concludes that additional review is merited, the case is forwarded to the facility's professional review committee.

The composition of the professional review committee varies by facility. Membership may include non-physicians, as well as physicians of the same or different specialties. Regardless, the members are typically well-respected members of the staff and often serve as such without additional compensation.

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<sup>2</sup> Depending on the size of the medical staff and the particulars of the case(s) being reviewed, the identity of the physician at issue may, nevertheless, be obvious.

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The professional review committee may conduct an initial review of the case to determine what additional information may be necessary to determine whether any type of action is warranted. At this time, the professional review committee typically informs the physician of the case and asks the physician to present his or her side of the story, and asks the physician to respond to any specific questions the professional review committee may have. Oftentimes, this is the first time the physician learns that he or she is being reviewed.

Additionally, the professional review committee may interview witnesses and obtain an independent evaluation of the physician's health or competency to practice. The professional review committee then reviews all of the available materials, and may interview witnesses as well. The members of the professional review committee then discuss the case to determine whether the physician's practice met the standard of care and whether there were any systems or other issues involved.<sup>3</sup>

If systems or other issues are identified, the case may be referred to the facility's quality management team for further review.

Importantly, a case may involve both systems issues and physician competency issues.

If the professional review committee finds that the physician's practice met the standard of care, the case is typically closed. However, if the professional review committee finds that the physician's practice failed to meet the standard of care, the professional review committee forwards the case to the MEC.

The composition of the MEC varies by facility. Membership typically includes senior members of the medical staff, such as department chairs (past, present or in-coming) and officers of the medical staff (past, present or in-coming).

The MEC reviews the case, and depending on the facility, may review the physician's entire practice. Importantly, the MEC may have at its disposal information not available to the professional review committee, such as the physician's credentials file (which would include applications for privileges and other related information).

If the MEC finds that the physician's practice met the standard of care, the case is dropped. However, if the MEC finds that the physician failed to meet the standard of care, the MEC forwards the case to the facility's governing board. The MEC will typically recommend a particular course of action, which could include practice monitoring, continuing education or some other type of remediation in a particular area, or it could include restricting or revoking the physician's privileges to practice in that facility.

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<sup>3</sup> A systems issue could include, for example, the facility's standard processes for setting-up an operating room, or for setting up a particular piece of equipment prior to use.

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The composition of the governing board varies by facility, but typically includes senior members of the medical staff, hospital administrators, and others.

Importantly, at any point during this process, the facility and the physician may enter into a remediation agreement,<sup>4</sup> thus bringing an end to the professional review process.

A governing board may decide to require the physician to obtain additional training, education, proctoring, practice monitoring or some other type of remediation, as well as limit, suspend or revoke the physician's privileges.

A governing board's decision to, or any agreement to, in any way restrict or revoke the physician's privileges to practice at the facility triggers several events.

First, the physician is entitled to a fair hearing. The fair hearing must afford the physician the opportunity to be represented by counsel, examine and cross-examine witnesses and offer evidence.

If, after the hearing, the physician's privileges are restricted, revoked or otherwise adversely affected, the facility must report the action to the National Practitioner Data Bank, maintained by the U.S. Department of Health and Human Services, and the Colorado Medical Board (CMB).

If the physician alleges that the actions of the professional review process were based on unreasonable anticompetitive conduct, and the physician desires to pursue any type of civil remedy based on such an allegation, the physician must file a complaint with the CAC.

Importantly, if the physician opts to file suit on other grounds, the physician can proceed directly to district court on those grounds only.

The CAC is a subcommittee of the CMB. Its jurisdiction, as well as the remedies it can award, are limited by statute. The CAC is limited to accepting cases that allege unreasonable anticompetitive conduct and it is limited to upholding, setting aside or modifying the actions of the facility's governing board. The CAC cannot award monetary damages.

Once adjudicated by the CAC, however, and regardless of the CAC's findings, the physician can proceed to district court with his or her antitrust claims. However, appeals of the CAC's decisions must be made to the Colorado Court of Appeals.

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<sup>4</sup> Under a remediation agreement, the physician typically agrees to obtain additional training, education, proctoring or some other type of practice remediation.

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Recall that a third type of professional review is based on credentialing. In order to join a facility's medical staff, physicians (and typically advanced practice nurses and physician assistants) must apply for privileges. This application process is referred to as credentialing, and involves a considerable amount of documentation. The physician is typically required to provide evidence of graduation from medical school, licensure to practice medicine, any board or other specialty certifications, and specialized training that may be necessary to perform the procedures he or she is seeking privileges to perform, and many other types of evidence of qualification.

Additionally, the credentialing process requires the physician to report any adverse professional review actions, as well as any malpractice judgments or settlements and any state disciplinary actions.

Credentialing is an extensive process performed by, like the other types of professional review, members of the medical staff. As a result, credentialing is generally considered to be professional review, though not all think this should be so.

Anecdotal estimates as to the number or percentage of physicians who undergo professional review at some point in their careers are difficult to come by. If credentialing is factored into the estimates, then most physicians, and certainly all who are privileged at a facility, undergo professional review at some point.

However, the estimates range from approximately 50 percent to less than 5 percent, when credentialing is factored out. Obviously, the more robust a particular facility's data gathering practices, the more likely a physician is to be subject to professional review.

Regardless, the estimates confirm that professional review is a relatively common phenomenon.

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## Legal Framework

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### ***History of Regulation***

The General Assembly formally addressed physician professional review for the first time in 1975, when it passed Senate Bill 75-252 (SB 252), the Colorado professional review act (CPRA).

Before the passage of SB 252, professional associations, hospitals, and public and private health insurers were already conducting professional review as a means of assuring 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.

Senate Bill 252 created a framework for the practice of professional review by defining which entities could form professional review committees, establishing standards for those who could serve on the committees, and providing a level of legal immunity for those who did serve.

In 1988, the U.S. Supreme Court issued its opinion in *Patrick v. Burget*,<sup>5</sup> 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 CPRA in 1989 via Senate Bill 89-261 (SB 261). The bill established that properly constituted and conducted professional review committees were effectively extensions of the Colorado Medical Board (CMB, formerly known as the Colorado Board of Medical Examiners), and thereby entitled to immunity with respect to, among other things, antitrust laws. SB 261 also expanded the list of entities authorized to form professional review committees, and created the Committee on Anticompetitive Conduct (CAC). The CAC was to serve as a body to which a physician who was sanctioned as a result of a professional review action based on anticompetitive grounds could appeal.

Finally, the bill contained provisions to bring Colorado into compliance with the federal Health Care Quality Improvement Act of 1986, which established standards for professional review committees and established the National Practitioner Data Bank.

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<sup>5</sup> *Patrick v. Burget*, 486 U.S. 94 (1988).

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In 1994, the General Assembly added a new section to the statute regarding the conduct of other (non-physician) licensed health care professionals that might be discovered during hospital professional review. If a professional review committee were to identify a potential problem with the quality of care delivered by a licensed health care professional, House Bill 94-1219 authorized the committee either to 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.

House Bill 95-1002, which contained the recommendations from the 1994 sunset review of the CMB, established that whenever a professional review committee makes recommendations to its governing board that would limit, suspend, or revoke the privileges of a physician, and thereby requiring a hearing to be held, it must forward copies of such recommendations to the CMB.

In 2005, House Bill 05-1240 sought to expand the list of entities authorized to form professional review committees, strengthen the committees' reporting requirements to the CMB, and authorize the CMB to levy civil penalties for failure to comply with the reporting requirement. Ultimately, the House Committee on Health and Human Services voted to postpone the bill indefinitely.

There was another attempt to revise CPRA the following year. Senate Bill 06-050, which was developed with input from a broad coalition of stakeholders, proposed numerous changes to the statute, including allowing professional review committees to share with one another confidential information regarding health care providers, and expanding the list of committee actions that were reportable to the CMB. Ultimately, the Senate Committee on Business, Labor and Technology voted to postpone the bill indefinitely.

House Bill 08-1075 authorized the medical staff of ambulatory surgical centers to form professional review committees.

In 2010, following a recommendation from the 2009 sunset report of the CMB, the General Assembly included a provision in House Bill 10-1260 establishing a sunset date of July 1, 2012 for CPRA.

### **Summary of Statutes**

There are two significant 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).



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## The Health Care Quality Improvement Act of 1986

In HCQIA, the U.S. Congress recognizes professional review as an effective way of identifying incompetent practitioners; establishes due process requirements for physicians undergoing professional review; grants immunity to professional review committees; authorizes creation of a federal database of adverse actions taken against physicians, including those taken by professional review committees; and creates a mechanism for states to share information on incompetent practitioners.

HCQIA requires that professional review committees 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 has a right to request a hearing. The physician must have at least 30 days to request a hearing.<sup>6</sup>

If the physician requests a hearing, the health care entity must give the physician at least 30 days' notice of the date, time, and location of the hearing, as well as a list of witnesses expected to testify.<sup>7</sup>

The hearing must be conducted before an arbitrator acceptable to both the physician and the health care entity, or before an individual or panel appointed by the entity that is not in direct economic competition with the physician involved.<sup>8</sup> During the hearing, the physician has the right to legal representation, and may call, examine, and cross-examine witnesses, present evidence, and request—at his or her own expense—a copy of the record of the proceedings.<sup>9</sup> The right to hearing may be forfeited if the physician fails to appear without a good reason.<sup>10</sup>

After the hearing, the physician has the right to receive the written recommendation of the hearing officer or panel and the basis for the recommendation. The health care entity must provide the physician with a copy of its final written decision, including the basis for the decision.<sup>11</sup>

These hearing procedures do not apply when the health care entity has:<sup>12</sup>

- Not taken an adverse professional action; or
- Suspended or restricted a physician's clinical privileges for 14 days or less, while it determines whether a professional review action is needed.

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<sup>6</sup> 42 U.S.C. § 11112(b)(1).

<sup>7</sup> 42 U.S.C. § 11112(b)(2).

<sup>8</sup> 42 U.S.C. § 11112(b)(3)(A).

<sup>9</sup> 42 U.S.C. § 11112(b)(3)(C).

<sup>10</sup> 42 U.S.C. § 11112(b)(3)(B).

<sup>11</sup> 42 U.S.C. § 11112(b)(3)(D).

<sup>12</sup> 42 U.S.C. § 11112(c)(1).

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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.<sup>13</sup>

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

- Made a reasonable effort to obtain the facts of the matter;
- Took the action with the reasonable belief that doing so was warranted by the facts and would further the goal of quality health care; and
- Followed all appropriate due process procedures for the physician involved.

Any person who provides information to professional review committees is also immune, as long as that person does not knowingly provide false information.<sup>16</sup>

Under HCQIA, professional review actions are presumed to have met the above standards unless a preponderance of the evidence proves otherwise.<sup>17</sup>

HCQIA also authorizes the creation of a federal database under the authority of the Secretary of the Department of Health and Human Services (Secretary), and establishes an extensive list of adverse actions that must be reported to the database, called the National Practitioner Data Bank (NPDB).

**Medical malpractice payments.** Any entity making medical malpractice payments pursuant to an insurance policy, 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.<sup>18</sup> Entities that fail to report malpractice payments are subject to a civil penalty of up to \$10,000 for each unreported payment.<sup>19</sup>

**Actions taken by state medical boards.** The state medical boards are responsible for reporting this information, which includes 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.<sup>20</sup> If the Secretary determines that a medical board has failed to report these data properly, the Secretary must designate another entity to report the data.<sup>21</sup>

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<sup>13</sup> 42 U.S.C. § 11112(c)(2).

<sup>14</sup> 42 U.S.C. § 11111(a).

<sup>15</sup> 42 U.S.C. § 11112(a).

<sup>16</sup> 42 U.S.C. § 11111(a)(2).

<sup>17</sup> 42 U.S.C. § 11112(a).

<sup>18</sup> 42 U.S.C. §§ 11131(a) and 11134(c)(1).

<sup>19</sup> 42 U.S.C. § 11131(c).

<sup>20</sup> 42 U.S.C. § 11132(a)(1).

<sup>21</sup> 42 U.S.C. § 11132(b).

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**Actions taken by professional review committees.** Health care entities are responsible for reporting to the state medical boards and the NPDB such actions, which must relate to a physician's professional conduct or competence and:<sup>22</sup>

- Adversely affect the clinical privileges of a physician for a period longer than 30 days; or
- Accept the surrender of clinical privileges of a physician while the physician is under an investigation relating to possible incompetence or improper professional conduct, or in return for not conducting such an investigation; or
- Adversely affect the membership of a physician in a professional society.

State medical boards are responsible for reporting the data to the NPDB. Certain actions are excluded from the reporting requirement, for example, actions relating to a physician's involvement—or lack of 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 does not stem from professional conduct or competence.<sup>23</sup>

State medical boards must report to the Secretary, health care entities that fail to report professional review actions as described above.<sup>24</sup> If the health care entity is located in another state, the medical board must also report the data to that other state's medical board.<sup>25</sup> If, after an investigation, the Secretary finds that a health care entity failed to report information as required, the Secretary publishes the name of the health care entity in the Federal Register and the entity is stripped of the immunity provided under HCQIA.<sup>26</sup> If the Secretary determines that a medical board failed to report data on non-compliant health care entities, the Secretary must designate another entity to report the data.<sup>27</sup>

Under HCQIA, hospitals must query the NPDB data for each physician or licensed health care practitioner who applies for a position on the medical staff or for clinical privileges at the hospital. Every two years, hospitals must query the NPDB for all practitioners on staff who have clinical privileges.<sup>28</sup>

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<sup>22</sup> 42 U.S.C. §11133(a)(1). Although HCQIA imposes the reporting requirement on state medical boards, the *NPDB Guidebook* clarifies that health care entities must report to both the NPDB and the state medical board. See *NPDB Guidebook*, U.S. Department of Health and Human Services (September 2001), pp. 6-17 and comments to 45 C.F.R. § 60.5 at 75 Fed. Reg. 4,668 (January 28, 2010).

<sup>23</sup> 45 C.F.R. § 60.3.

<sup>24</sup> 42 U.S.C. § 11133(b).

<sup>25</sup> 42 U.S.C. § 11134(c)(2).

<sup>26</sup> 42 U.S.C. §§ 11111 (b) and 11133(c)(1).

<sup>27</sup> 42 U.S.C. § 11133(c)(2).

<sup>28</sup> 42 U.S.C. § 11135(a).

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## The Patient Safety and Quality Improvement Act of 2005

PSQIA authorizes the creation of patient safety organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers.<sup>29</sup> PSQIA grants legal privilege and confidentiality protections to this information, and limits its use in criminal, civil, and administrative proceedings.<sup>30</sup>

If the Secretary finds an entity meets enumerated criteria, the Secretary certifies the entity as a PSO. This certification may be revoked if the Secretary finds that an entity no longer meets the criteria.<sup>31</sup>

Health insurers may not become PSOs.<sup>32</sup>

PSQIA contains extensive provisions regarding the privilege and confidentiality<sup>33</sup> of patient safety work product, which is defined as any data, reports, analyses, and the like, which are assembled or developed by a provider or PSO which could result in improved patient safety, health care quality, or health care outcomes; or which constitute a patient safety evaluation system.<sup>34</sup> Patient safety work product does *not* include:<sup>35</sup>

- 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:<sup>36</sup>

- Federal, state, or local civil, criminal, or administrative subpoenas or orders, including in 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;

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<sup>29</sup> 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.

<sup>30</sup> U.S. Department of Health and Human Services, Agency for Health Care Research and Quality. *The Patient Safety and Quality Improvement Act of 2005*. Retrieved on February 22, 2011, from <http://www.arhq.gov/qual/psoact.htm>

<sup>31</sup> 42 U.S.C. § 299b-24(c) and (e).

<sup>32</sup> 42 U.S.C. § 299b-24(b)(1)(D).

<sup>33</sup> Privilege applies to the discoverability and admissibility of evidence as part of a judicial proceeding.

Confidentiality, on the other hand, generally restricts the release of information to third parties outside of the judicial context.

<sup>34</sup> 42 U.S.C. § 299b-21(7)(A).

<sup>35</sup> 42 U.S.C. § 299b-21(7)(B).

<sup>36</sup> 42 U.S.C. § 299b-22(a).

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- Admission as evidence in any federal, state, or local governmental civil, criminal, or administrative proceeding, including any such proceeding against a provider; or
  - Admission 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.<sup>37</sup>

PSQIA defines numerous exceptions to the rule of privilege and confidentiality. Notable exceptions include:<sup>38</sup>

- Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court determines that the work product contains evidence of a criminal act that is not reasonably available from any other source;
- Disclosure of patient safety work product to carry out patient safety activities; and
- Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime, if the person making the disclosure believes that the disclosed information is necessary for criminal law enforcement purposes.

A person who knowingly discloses identifiable patient safety work product is subject to a civil monetary penalty of up to \$10,000 for each violation.<sup>39</sup>

### State Laws

Colorado's laws relating to professional review are located within Article 36.5 of Title 12, Colorado Revised Statutes (C.R.S.). Section 12-36.5-101, C.R.S., underscores that because most patients lack the knowledge, experience, or education to evaluate the quality of a physician's professional competence or conduct, the CMB must exercise its regulatory authority to protect the health, safety, and welfare of Coloradans. Professional review is one way for the CMB to identify physicians whose professional competence or conduct may be substandard.

The General Assembly, in drafting these provisions, recognized that the CMB does not have the resources to investigate each and every allegation of substandard practice or improper professional conduct in a timely manner. Therefore, section 12-36.5-103, C.R.S., establishes that professional review committees may serve as extensions of the CMB to assist it in fulfilling its statutory mandate.

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<sup>37</sup> 42 U.S.C. § 299b-22(b).

<sup>38</sup> 42 U.S.C. § 299b-22(c)(1).

<sup>39</sup> 42 U.S.C. § 299b-22(f)(1).

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A professional review committee is defined as any committee authorized to review and evaluate physicians' professional conduct and the quality and appropriateness of the patient care they provide.<sup>40</sup>

Entities authorized to form professional review committees include:<sup>41</sup>

- The medical staff of a hospital, hospital-related corporation, or ambulatory surgical center;
- A society or association of physicians;
- A preferred provider organization comprised of at least 25 physicians or a medical group which predominantly serves members of a health maintenance organization; and
- A corporation that insures physicians.

A non-profit association comprised of representatives from the statewide medical society and hospital association may also establish, or contract for, professional review committees to review the care by hospital staff physicians. Physicians must form the majority of the association. The association must offer professional review services to hospitals across the state on a fee-for-service basis, giving priority to small medical staffs in rural areas. If a physician being reviewed specializes in a generally recognized specialty of medicine, at least one of the physicians on the professional review committee must be a physician practicing such specialty.<sup>42</sup>

A professional review committee may investigate the qualifications, professional conduct, or professional competence of physicians subject to its authority.<sup>43</sup> For example, a professional review committee at a hospital can investigate physicians who are on the medical staff, as well as those who have applied for a medical staff position or clinical privileges at that hospital.

The statute outlines numerous due process provisions that professional review committees must follow.

If an investigation indicates that a physician lacks qualifications, has provided substandard patient care, or has exhibited inappropriate professional conduct, the professional review committee must hold a hearing to consider the findings. The committee must give the physician reasonable notice of the hearing. The physician has a right to be present at the hearing, to have legal representation, and to offer evidence on his or her own behalf.<sup>44</sup>

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<sup>40</sup> § 12-36.5-102(3), C.R.S.

<sup>41</sup> § 12-36.5-104(4), C.R.S.

<sup>42</sup> § 12-36.5-104(4)(i), C.R.S.

<sup>43</sup> § 12-36.5-104(6), C.R.S.

<sup>44</sup> § 12-36.5-104(7), C.R.S.

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After the hearing, the professional review committee must forward any recommendations it finds necessary to the governing board,<sup>45</sup> the physician who was the subject of the investigation,<sup>46</sup> and to the CMB.<sup>47</sup>

The physician has the right to appeal the committee's findings and recommendations to the governing board.<sup>48</sup> The governing board may allow a committee comprised of at least three members of the board or a board-designated, independent third party to hear the appeal.<sup>49</sup>

Governing boards must adopt written bylaws that provide that the physician be given reasonable notice of the right to appeal, to appear before the governing board, to be represented by legal counsel, and to offer argument on his or her behalf.<sup>50</sup>

Section 12-36.5-104.4, C.R.S., specifically addresses hospital professional review committees. Recognizing that reviewing the patient care provided in a hospital inevitably involves evaluating the care provided by other licensed health care professionals (not just physicians), the section allows committees that identify potentially substandard care delivered by such professionals to refer the matter to a hospital quality management program, or to consult with another representative of that profession.

By law, all proceedings, recommendations, records, and reports involving professional review committees or governing boards are confidential,<sup>51</sup> and exempt from any law requiring that proceedings be conducted publicly or that records be open to public inspection.<sup>52</sup>

The records of a professional review committee or governing board are not subject to subpoena or discovery and are not admissible in any civil suit brought by a physician who is the subject of such records. However, the records are subject to subpoena and must be available for use by the CAC and by either party appealing or seeking judicial review of a decision.<sup>53</sup>

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<sup>45</sup> § 12-36.5-104(7)(d), C.R.S. Section 12-36.5-102(2), C.R.S., defines "governing board" as any body that has the authority to take final action regarding the recommendations of any authorized professional review committee.

<sup>46</sup> § 12-36.5-104(7)(e), C.R.S.

<sup>47</sup> § 12-36.5-104(7)(f), C.R.S.

<sup>48</sup> § 12-36.5-104(7)(e), C.R.S.

<sup>49</sup> § 12-36.5-104(8)(b), C.R.S.

<sup>50</sup> § 12-36.5-104(8)(a), C.R.S.

<sup>51</sup> § 12-36.5-104(13), C.R.S.

<sup>52</sup> § 12-36.5-104(12), C.R.S.

<sup>53</sup> § 12-36.5-104(10), C.R.S.

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Professional review committees and their members, witnesses before such committees, complainants, or anyone who otherwise participates in the professional review process, are immune from suit in any civil or criminal action brought by a physician who is the subject of the review, as long as they:<sup>54</sup>

- Made a reasonable effort to obtain the facts of the matter;
- Acted in the reasonable belief that the action taken was warranted by the facts, and
- Otherwise acted in good faith within the scope of the professional review committee process.

Further, the governing board, its members and staff, and anyone acting as a witness or consultants to the board, as well as the entity that established the professional review committee, are immune from liability in any civil action, as long as the individual or entity:<sup>55</sup>

- Acted in good faith within the scope of his or her respective capacity;
- Made a reasonable effort to obtain the facts of the matter in which he or she acted; and
- Acted in the reasonable belief that the action taken was warranted by the facts.

Section 12-36.5-106(1), C.R.S., establishes the CAC as a permanent, independent committee of the CMB. The purpose of the CAC is to serve as the sole and exclusive remedy for physicians who believe that a governing board's final action denying, terminating, or restricting their employment or privileges, resulted from unreasonable anticompetitive conduct. Such physicians must file a complaint with the CAC, which reviews the governing board's final action. This review is limited to the single issue of whether the action resulted from unreasonable anticompetitive conduct. Until a physician has exhausted this administrative remedy,<sup>56</sup> he or she cannot seek judicial review of the case on the issue of unreasonable anticompetitive conduct.<sup>57</sup>

The CAC has five members. The CMB appoints four physician members, who must be in active practice, represent different subspecialties, work in different counties, and may not be members of the CMB. The Governor appoints one member, who must be a Colorado-licensed attorney possessing expertise and experience in antitrust law.<sup>58</sup>

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<sup>54</sup> § 12-36.5-105(1), C.R.S.

<sup>55</sup> § 12-36.5-105(2), C.R.S.

<sup>56</sup> Importantly, only allegations of anticompetitive conduct that arise out of the peer review process must be brought to the CAC before suit can be filed in court. *Ryals v. St. Mary-Corwin Regional Medical Center*, 10 P.3d 654, 656 (Colo. 2000).

<sup>57</sup> § 12-36.5-106(7), C.R.S.

<sup>58</sup> § 12-36.5-106(2), C.R.S.



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Members serve three-year terms, and may be reappointed once.<sup>59</sup> Members can be removed for neglect of duty, incapacity, or misconduct.<sup>60</sup> The CAC elects a chairman from among its members. Any three members constitute a quorum.<sup>61</sup>

CAC members receive a per diem allowance of \$50 for each day spent attending meetings or hearings, and are reimbursed for actual and necessary expenses incurred.<sup>62</sup>

To initiate the CAC review process, physicians must file a verified complaint with the CAC no later than 30 days after receiving notice of the governing board's final action. The complaint should contain all known facts supporting the allegation that the final action resulted from unreasonable anticompetitive conduct.<sup>63</sup> When submitting the complaint, the complainant must post a \$3,000 cash bond or equivalent liquid security to cover anticipated costs of the CAC review process.<sup>64</sup>

Within five days of receiving the verified complaint, the CAC mails a copy of the complaint to the governing board and the professional review committee and advises them of their right to file a verified answer to the allegations in the complaint.<sup>65</sup> The governing board and professional review committee have 30 days to file their answer.<sup>66</sup> Within 30 days of receiving the complaint, or when filing its answer with the CAC, whichever is earlier, the governing board must also post a \$3,000 cash bond or equivalent liquid security to cover anticipated costs.<sup>67</sup>

In the meantime, within 30 days of receiving the complaint, the CAC must determine whether the allegations in the complaint would, if true, substantiate a finding of probable cause that the final action resulted from unreasonable anticompetitive conduct. The CAC can extend this timeframe for one additional 30-day period.<sup>68</sup>

If the CAC finds no such probable cause exists, it dismisses the complaint, which constitutes the final administrative action.<sup>69</sup>

If the CAC finds such probable cause does exist, it schedules a hearing within a reasonable timeframe. The CAC must limit its review to the sole issue of whether the final action of the governing board resulted from unreasonable anticompetitive conduct and can take evidence only with regard to this end, except when the interests of a fair hearing demand otherwise.<sup>70</sup>

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<sup>59</sup> § 12-36.5-106(3), C.R.S.

<sup>60</sup> § 12-36.5-106(4), C.R.S.

<sup>61</sup> § 12-36.5-106(5), C.R.S.

<sup>62</sup> § 24-34-102(13), C.R.S.

<sup>63</sup> § 12-36.5-106(9)(a), C.R.S.

<sup>64</sup> § 12-36.5-106(10)(c), C.R.S.

<sup>65</sup> § 12-36.5-106(9)(b), C.R.S.

<sup>66</sup> § 12-36.5-106(9)(c), C.R.S.

<sup>67</sup> § 12-36.5-106(10)(c), C.R.S.

<sup>68</sup> § 12-36.5-106(9)(d), C.R.S.

<sup>69</sup> § 12-36.5-106(9)(e), C.R.S.

<sup>70</sup> §§ 12-36.5-106(9)(f) and (i) C.R.S.

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The CAC may subpoena witnesses, patient records, and other pertinent documents.<sup>71</sup> The hearing cannot last more than eight hours, unless the CAC determines that additional time is necessary in the interests of a fair hearing. The hearing must be conducted in accordance with the State Administrative Procedure Act, as provided in sections 24-4-105(4) and (7), C.R.S.<sup>72</sup>

Within a reasonable time after the hearing, the CAC must issue its written findings and final order.<sup>73</sup>

- If it finds that the final action of the governing board resulted from unreasonable anticompetitive conduct, the CAC issues a final order either setting aside or modifying the action taken by the governing board. This final order is binding on the parties.<sup>74</sup>
- If the CAC fails to find that the final action of the governing board resulted from unreasonable anticompetitive conduct, it issues an order dismissing the complaint, and the final action stands.<sup>75</sup>
- If the CAC finds that the record of the governing board is insufficient to allow it to make a finding on the issue of unreasonable anticompetitive conduct, it may remand the case for further review by the governing board.<sup>76</sup>

In any case presented to the CAC where the complaining physician's practice constitutes a clear and present danger to patients, the committee must refer the case to the CMB.<sup>77</sup>

After the CAC has issued its final order, either party wanting to appeal the order must do so in the Court of Appeals.<sup>78</sup>

Regardless of whether the CAC determines to uphold, strike down, or modify a governing board's final action, the administrative remedy is now exhausted, and a physician can proceed with filing suit in Colorado District Court. The CMB or the CAC cannot be made parties to such an action.<sup>79</sup>

At the conclusion of its review, the CAC determines the total cost of the review, including CAC attorney fees and committee member expenses. The CAC then collects payment from the losing party or however it deems appropriate.<sup>80</sup>

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<sup>71</sup> § 12-36.5-106(9)(g), C.R.S.

<sup>72</sup> § 12-36.5-106(9)(h), C.R.S.

<sup>73</sup> § 12-36.5-106(9)(j), C.R.S.

<sup>74</sup> § 12-36.5-106(9)(k), C.R.S.

<sup>75</sup> § 12-36.5-106(9)(l), C.R.S.

<sup>76</sup> § 12-36.5-106(9)(m) C.R.S.

<sup>77</sup> § 12-36.5-106(9)(n), C.R.S.

<sup>78</sup> § 12-36.5-106(10)(a), C.R.S.

<sup>79</sup> § 12-36.5-106(10)(b), C.R.S.

<sup>80</sup> § 12-36.5-106(11), C.R.S.

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The CAC members and staff, anyone acting as a witness or consultant to the CAC, and physicians filing complaints with the CAC, are immune from liability in any civil action, as long as the individual or entity:<sup>81</sup>

- Acted in good faith within the scope of his or her respective capacity;
- Made a reasonable effort to obtain the facts of the matter in which he or she acted; and
- Acted in the reasonable belief that the action taken was warranted by the facts.

Under section 12-36.5-104(10)(a), C.R.S., the records of the CAC are not subject to subpoena or discovery, and are not admissible in any civil suit brought by a physician.

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<sup>81</sup> § 12-36.5-106(13), C.R.S.

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## **Program Description and Administration**

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Although Colorado law treats professional review committees as extensions of the Colorado Medical Board (CMB),<sup>82</sup> the CMB's involvement with them is minimal.

The CMB's larger role in the professional review process comes through its involvement with the Committee on Anticompetitive Conduct (CAC).

### ***The Colorado Medical Board***

Along with the legal privileges associated with conducting professional review activities, come several reporting requirements.

Any health care facility licensed by the Colorado Department of Public Health and Environment (CDPHE) is required to report to the CMB, for physicians, and to the Colorado Podiatry Board, for podiatrists, any disciplinary action to suspend, revoke, or otherwise limit the privileges of the designated health care practitioner.<sup>83</sup>

Although the Colorado Podiatry Board does not track complaints based on whether they are received pursuant to this requirement, staff reports that, based on memory, no complaint has ever been received under this provision.

Additionally, the Colorado professional review act (CPRA) requires those facilities that engage in professional review to report to the CMB those professional review actions that result from the "fair hearing" required by CPRA.<sup>84</sup>

Although the CMB does not track complaints based on whether they are received pursuant to either of these requirements, CMB staff surveys, on an annual basis, Colorado-licensed hospitals. Table 1 illustrates, for the calendar years indicated, the results of these surveys.

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<sup>82</sup> § 12-36.5-103(3)(a), C.R.S.

<sup>83</sup> § 25-3-107(1), C.R.S.

<sup>84</sup> § 12-36.5-104(7)(f), C.R.S.

**Table 1  
Hospital Professional Review Actions Reported to the CMB**

<b>Calendar Year</b>	<b>Number of Surveys Sent</b>	<b>Number of Surveys Returned</b>	<b>Number of Facilities Reporting Action Taken</b>	<b>Number of Actions Previously Reported to the CMB</b>
1999	69	67	7	5
2000	Not Available	66	4*	3
2001	Not Available	71	17*	14
2002	Not Available	68	16*	13
2003	Not Available	85	6*	2
2004	90	89	11	7
2005	90	76	10	8
2006	87	81	11	10
2007	94	92	8	7
2008	93	82	4	3
2009	93	82	10	10
<b>Total</b>	<b>616</b>	<b>859</b>	<b>104</b>	<b>82</b>

\* Reported numbers pertain to the number of physicians against whom facilities reported having taken action, not the number of facilities reporting having taken an action.

Though the numbers are difficult to compare, it appears as though hospitals report to the CMB most of the physicians the hospitals think they are required to report, though certainly not all.

Since the CMB does not track the sources of the complaints it receives,<sup>85</sup> it is not possible to determine the extent to which these reported cases resulted in discipline by the CMB.<sup>86</sup>

### ***The Committee on Anticompetitive Conduct***

At the outset, it is important to note that CAC files have not been well maintained. This is, in all likelihood, attributable to the fact that many are old and individual staff members deal with CAC issues so sporadically that recordkeeping has been inconsistent.

The CAC comprises five members: four physicians appointed by the CMB and one attorney with antitrust experience appointed by the Governor. Although it is technically a standing body, it does not meet regularly. Rather, it meets only when it has a case to adjudicate.

<sup>85</sup> The CMB received 1,137 complaints in fiscal year 10-11.

<sup>86</sup> The CMB took 161 disciplinary actions in fiscal year 10-11.

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The jurisdiction of the CAC is limited to allegations pertaining to professional review actions that are the result of unreasonable anticompetitive conduct. In other words, only those cases in which the physician alleges that the professional review process was used to eliminate or reduce competition, as opposed to legitimate concerns regarding the physician's practice of medicine, may be heard by the CAC.

Since its creation in 1989, only 11 cases have been filed with the CAC. Table 2 indicates the years in which cases were filed and the number filed in those years.

**Table 2**  
**Number of Cases Filed with CAC**

<b>Year</b>	<b>Number of Cases Filed</b>
1990	2
1992	1
1994	1
1995	1
1998	3
2001	1
2007	1
2011	1
<b>Total</b>	<b>11</b>

The case in 2001 was the only case to reach the CAC that involved a credentialing matter (the physician was denied privileges at the particular hospital).

In two cases, the one in 1994 and one of the three in 1998, the CAC did not actually adjudicate the cases. In the 1994 case, the activities complained of were not the result of the professional review process, so the CAC did not have jurisdiction. In the 1998 case, the Colorado Court of Appeals forced the plaintiff to file with the CAC, even though the plaintiff and the CAC argued that the CAC did not have jurisdiction. The Colorado Supreme Court ultimately agreed that the case need not have been filed with the CAC, but only after it actually was filed.

The remedies available before the CAC are also quite limited. Essentially, the CAC can uphold the professional review actions of the facility, or it can modify or set the actions aside. In the eight cases in which the CAC has rendered a decision,<sup>87</sup> the CAC upheld the facility's professional review actions in all but two instances (the cases in 1992 and 2001).

The CAC has no dedicated staff of its own and it receives no appropriations from the General Assembly. Rather, CMB staff serves as staff to the CAC when a case is filed. Additionally, legal services are provided by the Attorney General's Office (AGO) and cases may be referred by the CAC to the Office of Administrative Courts (OAC) for hearing by an administrative law judge (ALJ).

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<sup>87</sup> As of this writing, the 2011 case had not yet been heard.

In any CAC proceeding, each party is required to post a \$3,000-bond, and at the conclusion of the proceedings, the parties pay the CAC's expenses, as determined by the CAC. Table 3 illustrates, how much each case has cost and how those costs were apportioned among the parties. For years in which there were multiple cases, the cases are delineated separately.

**Table 3  
CAC Expenses and Apportionment Among the Parties**

Year	Cost	Apportionment
1990 (1)	Unknown	
1990 (2)	\$0	
1992	\$13,143	Costs split equally by Petitioner and Respondent
1994	\$0	
1995	\$12,297	Unknown
1998 (1)	\$0	
1998 (2)	\$17,717	Unknown
1998 (3)	\$15,822	Respondent paid \$3,000 (the bond) and Petitioner paid the balance
2001	\$24,250	Respondent paid full amount
2007	\$19,545	Respondent paid \$3,000 (the bond) and Petitioner paid the balance
2011	Still Pending	

Importantly, Table 3 reflects the costs incurred by the CAC, not the parties themselves.

Except for the case in 1992, the CAC has historically required the losing party to pay most of the CAC's expenses.

How a proceeding before the CAC is conducted varies somewhat. In 1993, the CAC entered into a Memorandum of Understanding (MOU) with the OAC's predecessor organization, the Division of Administrative Hearings, whereby the CAC has three options in terms of how to conduct a proceeding:

**Option 1:** The CAC can rule on all preliminary matters<sup>88</sup> and conduct the actual hearing. This Option has been utilized in three cases, although one of these cases occurred prior to the MOU.

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<sup>88</sup> Preliminary matters can include resolution of discovery disputes and discovery-related rulings, as well as resolution of pretrial motions.

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**Option 2:** The CAC can refer the case to the OAC such that an ALJ rules on all preliminary matters and conducts the hearing. In such a case, the ALJ issues an initial decision, which is subject to review by the CAC. The CAC may elect to allow the parties limited oral arguments before rendering the final decision. This Option has been utilized twice, including the case pending as of this writing.

**Option 3:** The CAC can bi-furcate the process such that an ALJ rules on all preliminary matters, and the CAC conducts the actual hearing. This Option was utilized in three cases.

Two of the three cases in which none of these Options were utilized occurred prior to the MOU, so there really were no options, and it is difficult to determine from the CAC file how the cases were handled. Presumably, the CAC ruled on all preliminary matters and conducted the hearings.

In the third case, the case was filed and disposed of prior to any hearings or preliminary matters occurring.<sup>89</sup>

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<sup>89</sup> This was the case in which the Colorado Court of Appeals ruled that the physician first had to file a complaint with the CAC. This was subsequently overruled by the Colorado Supreme Court, but not before the physician had filed a complaint with the CAC.



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## Analysis and Recommendations

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### **Recommendation 1 – Continue the Colorado professional review act for seven years, until 2019.**

Professional review is required by The Joint Commission, in its standards of accreditation,<sup>90</sup> and by the Centers for Medicare and Medicaid Services' Medicare Conditions of Participation.<sup>91</sup> Thus, any health care entity that is accredited by The Joint Commission or that serves Medicare patients must conduct professional review.

The Colorado professional review act (CPRA) is a collection of statutory provisions that, in short, provides legal privileges to professional review records and proceedings and legal immunity to participants in professional review activities, provided professional review entities comply with enumerated procedural requirements. CPRA does not require professional review; it merely provides protections for the professional review process.

The first sunset criterion requires this sunset review to determine whether CPRA is necessary to protect the public health, safety and welfare.<sup>92</sup>

To answer this, it is necessary to explore the purpose of CPRA. While most agree that the purpose is to improve patient safety, not all agree that CPRA represents the most effective means to achieve this goal.

Arguably, CPRA serves to improve patient safety in several ways. First, its confidentiality and privilege provisions serve to encourage facility staff to report physicians suspected of incompetent practice. These same provisions further encourage other physicians, the reported physician's peers, to participate in the professional review process by protecting, in some cases, their identities, but, more importantly, their meetings, analyses and thought processes. Confidentiality and privilege, it is argued, enable reviewing physicians to engage in open, honest and frank discussions with one another in reviewing the care provided by one of their colleagues.<sup>93</sup>

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<sup>90</sup> Although The Joint Commission's Accreditation Standards do not use the terms "professional review" or "peer review," such processes are clearly envisioned in various Standards, including Standard MS.08.01.01 and MS.09.01.01 most specifically.

<sup>91</sup> Although the Conditions of Participation do not use the terms "professional review" or "peer review," such processes are clearly envisioned in 42 C.F.R. §§ 482.21 and 482.22.

<sup>92</sup> § 24-34-104(9)(b)(I), C.R.S.

<sup>93</sup> Bryan A. Liang, "The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems" *Journal of Law, Medicine & Ethics* (Fall-Winter 2001), p. 351.

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Next, CPRA's due process provisions require that a physician who is deemed by his or her peers to have provided incompetent care such that the physician's privileges to practice at that facility should somehow be restricted, be granted a fair hearing at which the physician may be represented by counsel, present evidence, and examine and cross examine witnesses.

Finally, a physician who believes that an adverse professional review action was taken against him or her, for anticompetitive reasons (i.e., the reviewing physicians sought to eliminate the competition posed by the reviewed physician), can file a complaint with the Committee on Anticompetitive Conduct (CAC).

In short, this line of reasoning justifies CPRA based on the premise that CPRA's confidentiality and privilege provisions ensure that open, honest and frank reviews of physician performance are conducted. CPRA's due process provisions ensure that the confidentiality and privilege provisions are not abused, by ensuring that a physician has the ability to challenge adverse professional review actions to ensure that such actions are taken to protect patients, and not the reviewing physicians' competitive positions relative to the reviewed physician's.

Given all of these considerations, it is reasonable to conclude that CPRA embodies the best known mechanisms for promoting patient safety, and affording reviewed physicians a process to challenge adverse, and possibly unwarranted, professional review actions.

However, the Patient Protection and Affordable Care Act (Affordable Care Act), passed by the U.S. Congress in 2010, will, even if only partially enacted, fundamentally alter the way health care in the U.S. is delivered. Thus, a seven-year continuation period for CPRA is justified, given the dynamic environment and the various implementation timelines of the Affordable Care Act.

Therefore, the General Assembly should continue CPRA for seven years, until 2019.

### ***Recommendation 2 – Sunset the Committee on Anticompetitive Conduct.***

The jurisdiction of the CAC is relatively limited. Only those final adverse actions of the professional review entity that the reviewed physician believes were the result of anticompetitive conduct can be raised before the CAC.<sup>94</sup> Any claims based on grounds other than antitrust can be taken directly to district court.

Additionally, antitrust allegations must be filed with the CAC before any district court can adjudicate such claims. The CAC process does not preclude the district court from adjudicating these claims; CPRA merely requires a physician-plaintiff to exhaust the administrative remedy afforded by the CAC prior to the district court adjudicating such claims.

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<sup>94</sup> § 12-36.5-106(7), C.R.S.

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The sole remedy that the CAC can award a successful physician-plaintiff is to disapprove and set aside, or modify the professional review entity's action, in whole or in part.<sup>95</sup> Any decision of the CAC may be appealed to the Colorado Court of Appeals.<sup>96</sup>

Each party to a proceeding before the CAC is required to post a cash bond or equivalent liquid security of \$3,000,<sup>97</sup> and at the conclusion of the proceedings, the CAC assess and collects all costs associated with its activities, from the losing party or as the CAC deems appropriate.<sup>98</sup>

Importantly, the State never becomes a party to a CAC proceeding, and the State recovers its costs associated with a CAC proceeding directly from the parties involved in the case. No State expenditures go unreimbursed.

To understand the purpose of the CAC, it is first important to know its history, which entails an extremely brief primer on U.S. antitrust law.

In *Parker v. Brown*, the U.S. Supreme Court established what has become known as the state action doctrine, essentially an exemption from the federal Sherman Antitrust Act (Sherman Act), in holding that the Sherman Act was not intended "to restrain state action or official action directed by a state."<sup>99</sup>

The U.S. Supreme Court later extended the state action doctrine exemption to private parties when their anticompetitive actions are the product of state regulation so long as: 1) the challenged action is one that is clearly articulated and affirmatively expressed as state policy; and 2) the anticompetitive conduct is actively supervised by the state itself.<sup>100</sup>

Sometime around 1981, a physician in Oregon sued the participants (the physicians) of a professional review committee alleging, among other things, that the professional review committee members had violated the Sherman Act by initiating and participating in professional review activities in order to reduce competition, rather than to improve patient care.<sup>101</sup>

After the roughly \$2 million verdict for the plaintiff-physician, appeals ensued, resulting in the landmark decision of *Patrick v. Burget*, in which the U.S. Supreme Court held that since no state actor was actively supervising hospital professional review decisions, the state action doctrine did not apply.<sup>102</sup>

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<sup>95</sup> § 12-36.5-106(9)(k), C.R.S.

<sup>96</sup> § 12-36.5-106(10)(a), C.R.S.

<sup>97</sup> § 12-36.5-106(10)(c), C.R.S.

<sup>98</sup> § 12-36.5-106(11), C.R.S.

<sup>99</sup> *Parker v. Brown*, 317 U.S. 341, 351 (1943).

<sup>100</sup> *California Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

<sup>101</sup> *Patrick v. Burget*, 486 U.S. 94, 97 (1988).

<sup>102</sup> *Patrick v. Burget*, 486 U.S. 94, 105 (1988).

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Timing is critical to the remaining history. *Burget* was handed down in 1988, but the events giving rise to the claims in *Burget* occurred in the early 1980s. The federal Health Care Quality Improvement Act of 1986 (HCQIA) was passed in 1986.

Importantly, the *Burget* court did not consider the qualified immunity afforded under HCQIA because HCQIA became law after the events giving rise to the claims in *Burget*.

Regardless, *Burget* created a mild panic in the professional review community because suddenly individual participants on professional review committees (physicians) could be sued under the Sherman Act's antitrust provisions.

As a result of this panic, most states, including Colorado, revisited their professional review statutes and amended them to account for *Burget*, notwithstanding the untested immunities afforded under HCQIA.

In Colorado, Senate Bill 89-261 (SB 261) amended CPRA, and in direct response to *Burget*, attempted to create a system of more active state oversight of professional review. In particular, SB 261:

- Recognized that the Board of Medical Examiners (now the Colorado Medical Board (CMB)) “cannot practically and economically assume responsibility over every single allegation or instance of purported deviation from the standards of quality for the practice of medicine.”<sup>103</sup>
- Declared the use of professional review committees “to be an extension of the authority of the [CMB].”<sup>104</sup>
- Created the CAC.<sup>105</sup>

Additionally, SB 261 specifically provided new statutory immunity for professional review participants.

According to interviews, conducted as part of this sunset review, with individuals involved in the crafting and passage of SB 261, the CAC was, at the time, considered to be groundbreaking. The CAC was expected to handle approximately 20 cases each year.

Regardless, no other state followed Colorado's lead, and the CAC remains unique in the nation.

Similarly, the anticipated caseload failed to materialize. In the 22 years since it was created, only 11 cases have been filed with the CAC.

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<sup>103</sup> § 12-36.5-103(1), C.R.S.

<sup>104</sup> § 12-36.5-103(3)(a), C.R.S.

<sup>105</sup> § 12-36.5-106, C.R.S.

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Additionally, stakeholders interviewed as part of this sunset review expressed considerable doubt as to whether the CAC and the other, more passive provisions of SB 261, would be found by a court to constitute sufficient state oversight so as to allow the invocation of the state action doctrine. And even if it did, it is no longer necessary given HCQIA's and CPRA's more direct immunity provisions.

Further, relatively few professional review-generated cases involve allegations of unreasonable anticompetitive behavior. There are several possible explanations for this. First, antitrust cases are complex and difficult to prove, and, typically, professional review-generated cases involve more traditional tort-based claims that are easier, and less costly, to prove.

Next, the remedies available at the CAC are limited to, in essence, reinstatement of privileges. Most physicians, by the time they reach the litigation stage, are more interested in monetary compensation than returning to work with colleagues with whom there is tremendous animosity. Although monetary damages are available in the courts under antitrust laws, the CAC process must still be exhausted before the physician-plaintiff can file such claims in district court.

As a result of all of this, antitrust claims are rarely pursued.

Regardless, professional review necessarily involves a physician's competitors (either direct or indirect competitors) evaluating the physician's performance and rendering a decision that will impact that physician's ability to continue to compete. Antitrust concerns are well founded.

Indeed, the literature is replete with echoes of these concerns:

- Rather than using peer review committees for analyzing and attempting to correct adverse events or to discipline health care providers who deserve to be disciplined, a current trend among hospitals is to use the committees as a way to weed out competition.<sup>106</sup>
- Although the goal of peer review to encourage the medical profession to weed out its incompetent members is laudable, it has proven difficult simultaneously to: 1) protect the peer-review participants from the threat of legal liability for their legitimate weeding-out actions, 2) avoid insulating them from liability if their actions were in fact purely self-interested, and 3) decide quickly and cheaply whether any given case involves legitimate review of professional competence or illegitimate economic self-protection.<sup>107</sup>

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<sup>106</sup> Leigh Ann Lauth, "The Patient Safety and Quality Improvement Act of 2005: An Invitation for Sham Peer Review in the Health Care Setting," *Indiana Health Law Review*, (2007), p. 167.

<sup>107</sup> Charity Scott, "Medical Peer Review, Antitrust, and the Effect of Statutory Reform," *Maryland Law Review* (1991), p. 320.

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Along similar lines, others have posited that the immunity granted by HCQIA, and presumably CPRA, “has been abused by hospitals and physicians to harm ‘disruptive physicians’ (i.e., whistleblowers) or financial competitors.”<sup>108</sup>

All of this would seem to argue in favor of continuing the CAC. However, sunseting the CAC does not prevent an aggrieved physician from raising antitrust claims at trial. On the contrary, sunseting the CAC likely makes it easier for such physicians to raise these claims because the administrative remedy of the CAC would not need to be exhausted.

The initial purpose in creating the CAC was laudable: create a body to protect physicians from unreasonable anticompetitive conduct perpetrated by their peers, to ensure that professional review is utilized to ensure patient safety, rather than to drive competitors from the market.

However, the fears that spawned the CAC did not come to pass, primarily due to the immunity provisions in both HCQIA and CPRA. The continued necessity and utility of the CAC is, therefore, questionable. As a result, the General Assembly should sunset the CAC.

***Recommendation 3 – Authorize professional review of physician assistants and advanced practice nurses.***

The professional review process outlined in CPRA is very clearly geared towards looking at physicians. In only one subsection does CPRA address professional review of non-physicians, and even then, only as it relates to the professional review of a physician.<sup>109</sup>

Recall that the purpose of professional review is to improve patient care. To this end, CPRA provides certain legal protections to the professional review process. However, CPRA was drafted at a time when physicians, almost exclusively, made decisions regarding care.

However, today, other health care professionals render front-line medical care and exercise a certain level of independent medical judgment. Most notable among these are physician assistants (PAs) and advanced practice nurses (APNs). Additionally, like physicians, PAs and APNs go through a credentialing process and are granted privileges to practice at facilities.

Given the projected shortages of primary care physicians, and the increasing use of PAs and APNs in the acute care setting, it is reasonable to conclude that these midlevel practitioners will be called upon to do more and more.

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<sup>108</sup> Roland Chalifoux, “So What is a Sham Peer Review?” MedGenMed (2005). Retrieved on December 30, 2010, from [www.ncbi.nlm.nih.gov/pmc/articles/PMC1681729/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681729/)

<sup>109</sup> § 12-36.5-104.4(2), C.R.S.

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Since the purpose of CPRA is to improve patient safety, it only makes sense to extend the legal protections of physician professional review to these non-physician practitioners.

Further, at least 39 states allow for the professional review of non-physicians. There is no consistency, however, among these states as to which professions are included.

Therefore, the General Assembly should extend CPRA's legal protections to professional review of PAs and APNs.

***Recommendation 4 – Specify that the sharing of professional review records and information with regulators and, when professional review results in an adverse action, with other professional review entities, does not constitute a waiver of the professional review privilege or constitute a violation of CPRA's confidentiality provisions.***

CPRA expressly protects the professional review process in three distinct ways, by:

- Declaring professional review records to be privileged;
- Declaring professional review activities to be confidential; and
- Providing immunity to professional review participants.

Only the first two of these protections -- confidentiality and privilege -- are relevant to this Recommendation 4. Privilege differs from confidentiality in that,

privilege protections apply to discoverability and admissibility of evidence as part of a judicial proceeding; confidentiality generally applies to the release of peer review information to third parties outside of the judicial context.<sup>110</sup>

CPRA addresses the privilege issue by declaring that,

The records of a professional review committee, governing board, or the [CAC] shall not be subject to subpoena or discovery and shall not be admissible in any civil suit brought against a physician who is the subject of such records.<sup>111</sup>

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<sup>110</sup> Susan O. Scheutzow, "State Medical Peer Review: High Cost But No Benefit – Is It Time for a Change?" *American Journal of Law and Medicine* (1999), p. 17.

<sup>111</sup> § 12-36.5-104(10)(a), C.R.S.

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CPRA provides confidentiality to the professional review process by declaring that,

All proceedings, recommendations, records and reports involving professional review committees or governing boards shall be confidential.<sup>112</sup>

In short, the confidentiality provision is generally considered to prohibit the sharing of professional review information with anyone outside of the entity that conducted the professional review activity. If this is done, the professional review entity risks losing the privilege and the information could be introduced in a civil suit. As a result, professional review entities do not share information with one another, or with regulators aside from the CMB.

While this “silo effect” may have made sense when CPRA was enacted – when each physician typically held medical staff privileges at a single hospital – it actually hinders patient safety efforts in the modern era, when many physicians hold privileges at multiple facilities.

From a consumer protection standpoint, this prohibition can be problematic in that it could allow a problem physician who has privileges at multiple facilities, to continue to practice.

For example, Hospital A may revoke the privileges of Dr. Problem to perform Procedure 1 at Hospital A. Dr. Problem is also privileged to perform Procedure 1 at Hospital B.

Pursuant to HCQIA, Hospital A reports to the U.S. Department of Health and Human Services’ National Practitioner Data Bank (NPDB) that it has taken an adverse professional review action against Dr. Problem, but provides few details. Pursuant to CPRA, Hospital A reports to the CMB that it initiated a professional review hearing against Dr. Problem. Further, Dr. Problem must disclose, under the Michael Skolnik Medical Transparency Act of 2010,<sup>113</sup> that his privileges to perform Procedure 1 at Hospital A were revoked, within 30 days.<sup>114</sup>

However, Hospital A is prohibited from directly informing Hospital B of any of this, even if the two hospitals are owned by the same organization. As a result, Dr. Problem is able to continue to perform Procedure 1 at Hospital B until Dr. Problem is due to reapply for privileges at Hospital B. At that point, he will have to disclose the professional review action taken by Hospital A and Hospital B will likely require Dr. Problem to sign a waiver authorizing Hospital A to release information to Hospital B.

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<sup>112</sup> § 12-36.5-104(13), C.R.S.

<sup>113</sup> § 24-34-110(4)(d), C.R.S.

<sup>114</sup> § 24-34-110(8), C.R.S.



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Additionally, Hospital B will check the NPDB for any actions reported against Dr. Problem.<sup>115</sup>

In short, the information regarding Dr. Problem will eventually make its way to Hospital B. The problem is one of timing. Dr. Problem's license is subject to renewal every two years. Similarly, hospitals operate on a two-year credentialing cycle. Finally, even if the CMB opts to investigate Dr. Problem based on the report filed by Hospital A, the CMB administrative process takes time to run its course. In the meantime, Dr. Problem is free to continue to perform Procedure 1 at Hospital B and Hospital B will not conduct its own professional review because it will be ignorant of the activities at Hospital A.

This is not in the best interests of consumer protection.

Consumers would be better served if professional review entities could share information related to adverse professional review actions, such as the suspension, revocation or limitation of privileges, with one another. The entity receiving the information should not be required to take any specific action, but hospitals should, at least, be able to share such information with one another in order to prevent negative patient outcomes without jeopardizing the privilege that CPRA affords.

Similarly, professional review entities should be able to share professional review information with regulators. They are required to share such information with the CMB and CAC, when requested, but risk waiving the privilege provided under CPRA if they share information with the Colorado Department of Public Health and Environment (CDPHE). This is problematic because CDPHE licenses and regulates hospitals, and CDPHE conducts surveys of those facilities it licenses.

Although CDPHE's focus is generally on systems issues, such issues can spur professional review activity. CDPHE may need to examine the professional review information to determine whether the facility adequately addressed the issue. The facility, however, will not share the information with CDPHE claiming that such information is privileged.

Therefore, the General Assembly should provide that the privilege afforded under CPRA 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.

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<sup>115</sup> 42 U.S.C. §§ 11135 (a and b) require health care entities to query the NPDB every two years.

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**Recommendation 5 – Require entities that conduct professional review to register with the Colorado Medical Board, require them to report various professional review activities and require the information to be public.**

There is a general sense among members of the CMB that professional review activities occur in Colorado that are not reported to the CMB.

This sentiment was echoed by a recent analysis of the National Practitioner Data Bank Public Use File (NPDB Public Use File) that found that, between 1990 and 2009, of the 10,672 physicians in the NPDB with one or more clinical privilege actions, 55 percent of them had no state licensing actions.<sup>116</sup>

There are at least two possible conclusions to draw from this: 1) that state medical boards are not taking disciplinary action when they receive such reports; or 2) that entities that engage in professional review are not reporting them to state medical boards.

Unfortunately, the CMB does not track whether the complaints it receives are filed due to a professional review action, so it is not possible to determine how many complaints were opened as a result of a report of an adverse professional review action, or what the results of those cases may have been.

However, according to the same study of the NPDB Public Use File, as of December 31, 2009, there were 45 Colorado-licensed physicians with one NPDB clinical privilege report and no CMB action, and one physician with six NPDB clinical privilege reports and no CMB action.<sup>117</sup>

As of 2009, according to the most recent data available as of this writing, Colorado had 87 hospitals registered with the NPDB, and 50 (57.5 percent) had never reported to the NPDB.<sup>118</sup>

It is impossible to draw any definitive conclusions from these data because the professional review process created by CPRA generally lacks transparency.

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<sup>116</sup> Alan Levine, Robert Oshel and Sidney Wolfe, *State Medical Boards Fail to Discipline Doctors with Hospital Actions Against Them*, Public Citizen, March 2011, p. 1.

<sup>117</sup> Alan Levine, Robert Oshel and Sidney Wolfe, *State Medical Boards Fail to Discipline Doctors with Hospital Actions Against Them*, Public Citizen, March 2011, Exhibit C.

<sup>118</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, Division of Practitioner Data Banks, *National Practitioner Data Bank Combined Annual Report: 2007, 2008 and 2009*, Table 12, p. 72 (September 2011). Retrieved on October 12, 2011, from [www.npdb-hipdb.hrsa.gov/resources/reports/2007-08-09NPDBAnnualRep.pdf](http://www.npdb-hipdb.hrsa.gov/resources/reports/2007-08-09NPDBAnnualRep.pdf)

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CPRA authorizes a whole laundry list of entities to form “approved” professional review committees:<sup>119</sup>

- The medical staff of a hospital;
- The medical staff of a hospital-related corporation;
- A society or association of physicians whose membership includes at least one-third of the licensed physicians in the state;
- A society or association of physicians specializing in a specific discipline of medicine;
- An individual practice association or preferred provider organization of at least 25 physicians or a medical group that predominantly serves members of a health maintenance organization;
- A corporation authorized to insure physicians;
- The governing board of any entity that has a professional review committee;
- Any professional review committee established or created by a combination or pooling of any of the organizations authorized by CPRA to have a professional review committee;
- A nonprofit corporation or association comprised of representatives from a statewide medical society and a statewide hospital association; and
- The medical staff of an ambulatory surgical center.

CPRA further provides certain legal protections to the proceedings of and participants in professional review activities.

However, CPRA provides no approval mechanism and no requirement that entities that avail themselves of the protections provided under CPRA to in any way notify the State that they are engaging in professional review activities.

This is problematic for at least three reasons. First, since there is no way to determine which entities are conducting professional review and the outcomes of those processes, there is no way to measure the efficacy of the professional review process.

Next, CPRA specifically declares professional review committees to be extensions of the CMB. However, the CMB has no data regarding the number or identity of such extensions or what those extensions are doing.

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<sup>119</sup> § 12-36.5-104(4), C.R.S.

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Finally, under HCQIA, the CMB has an affirmative obligation to report to the U.S. Department of Health and Human Services health care entities that fail to report the required professional review actions.<sup>120</sup> The CMB is unable to do this because the CMB does not even know what professional review activity is occurring in the state.

As a first step in rectifying this situation, entities that engage in professional review activities should be required to register with the CMB. This will serve to formalize the professional review process and clearly identify those entities that may legitimately claim the protections afforded by CPRA.

Registration will also, for the first time, provide information as to how many and which organizations conduct professional review activities. It will then be possible to evaluate the data discussed earlier in this discussion to determine whether, indeed, professional review entities are not reporting to the CMB and NPDB, or whether the CMB is not taking disciplinary action.<sup>121</sup>

Next, just as the CMB reports its complaint and disciplinary statistics to the General Assembly each year in its budget request, so too should registered professional review entities be required to report certain types of information to the CMB. This could include data such as the number and types of professional review activities undertaken and the results of those professional review activities. This information should be aggregated and de-identified.

To further the mission of consumer protection, the CMB should then summarize this data and make it available to the public.

All of this, taken together, will create a more transparent professional review environment without jeopardizing the confidentiality and privileges that make it all possible. Only then will the process have a level of transparency that allows for the painting of a more accurate depiction of the level, frequency and efficacy of professional review in Colorado.

Therefore, the General Assembly should require those entities that conduct professional review activities to register with the CMB and require them to report, on an annual basis, their professional review activities. Further, the CMB should be directed to promulgate rules on the types of aggregated and de-identified information to be reported under this system, and the form that these reports should take. This information should be available to the public.

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<sup>120</sup> 42 U.S.C. §§ 11133(a)(1) and 11133(b).

<sup>121</sup> It should be noted that the CMB's lack of disciplinary action in such cases does not necessarily indicate that the CMB is failing in its mission. A professional review entity may take an adverse professional review action based on grounds that do not constitute a violation of the Medical Practice Act.

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***Recommendation 6 – Clarify that CPRA applies to professional review, as opposed to peer review.***

In all but six instances, CPRA uses the term “professional review.” However, in those six instances, CPRA uses the term “peer review.” While these are generally considered to be synonymous, given Recommendation 3 and the expansion of professional review to non-physicians, CPRA should consistently use the term “professional review.”

This is also consistent with HCQIA, which uses the term “professional review” exclusively.

Therefore, the General Assembly should change all references in CPRA from “peer review” to “professional review.”