Colorado Professional Review Act

2018 Recommendations

August 27, 2018

To: Board of Directors
From: Alfred Gilchrist, CEO
Re: CMS Recommendations: Professional Review Sunset

Background: At the July 13 meeting, the board of directors passed a motion to recruit and appoint a one-time work group on professional review composed of physicians currently involved in professional review to: (1) Review and comment on all recommendations and questions being posed to DORA under Sunset of Professional review; (2) Advise the COL and BOD on legislation on CMS policy; (3) Serve as experts during hearings on professional review sunset legislation in 2019; and (4) Serve as media spokespersons on 2019 professional review legislation; (5) Disband immediately following the 2019 General Assembly.

Immediately after the July board meeting, a highly experienced physician work group on professional review was recruited. The work group held its first meeting on August 7. Work group members were asked to read and consider a confidential backgrounder prior to the meeting that included:

1: A briefing document on Professional Review Sunset

2: Review of publicly available deidentified, aggregate data required to be reported to DORA from 2013 to 2017 that includes:

- Number of investigations completed during the year,
- Number of investigations resulting in no action,
- Number of investigations resulting in involuntary requirements for improvement sent to the person by the entity, and the
- Number of investigations resulting in written agreements for improvement between the person and the entity.

3: A list of questions about the publicly available data and others posed by DORA.

The meeting was professionally designed and facilitated. As a result, CMS submitted the following letter with recommendations and answers to questions posed by DORA on Professional Review Sunset. This letter positions CMS proactively on public reporting of professional review data (de-identified and aggregate) to ensure the public that professional review is making care safer and holding physicians accountable while maintaining legal protections so necessary for professional review to succeed.

The following letter was posted on the board of directors' Base Camp on August 21.

August 21, 2018

Ms. Vivienne Belmont, Policy Analyst
Colorado Department of Regulatory Agencies
1560 Broadway, Suite 1550
Denver, CO 80202

Dear Ms. Belmont,

During the course of the 2011 sunset review process for the Colorado Professional Review Act (CPRA), the Colorado Medical Society (CMS) and Colorado Hospital Association (CHA) made a series of joint recommendations, including the recommendation that this vital public safety process be reviewed under sunset in 2018. At the time we emphasized the importance of evolving this body of law since peer review entities vary in practice, and medicine is more than a check the box set of standards. The current sunset process therefore presents an excellent opportunity to improve the data gathered on peer review to give the public greater assurance that the peer review system is working to make care safer. Ultimately, our experts believe the data can be utilized for granular and broader population health analytics, the purpose of which would be to guide not just error prevention but to advance best practices at both system and clinical levels.

CMS convened a panel of physician experts who lead or participate on peer review teams to assure that our counsel and recommendations are grounded in the realities of how physicians and care delivery systems advance and improve. These experts worked with us and our partners to prepare the initial comments outlined below on current and prospective enhanced use of these reports and the questions posed by DORA Sunset.

It should almost go without comment, given our physicians' historical engagement on professional review since 1975 in the legislative and regulatory process, that we strongly support the continuation of CPRA, with the equally critical component that the work of these professional review entities continues to be protected and the participants be immune from civil liability. The impressive increase in reporting, as well as routine actions as a result of such reports, would collapse virtually overnight absent these legal assurances.

Our expert panel carefully reviewed the 2013-2017 professional review reports posted on the DORA website. During an extensive, facilitator-guided discussion the panel offered a number of professional observations to upgrade and strengthen these reports in order to give the public greater assurances that professional review is working and that patient care is safer as a result.

The following suggestions are conceptual at this point and require further discussion to develop actionable legislation. Please also note that these ideas rely entirely on the continued protections of the CPRA to accomplish their goals.

1. **Have professional review entities report on improvements resulting from professional review to give the public greater assurance that CPRA is working to make care safer and to hold providers accountable.**

The professional review reporting system was constructed to report adverse actions against individual providers. While such information is still useful to the public, this information alone is inadequate to reflect how care is delivered today. Current medical care is delivered in complex systems, not by individual solo practitioners. And medical error today is often the result of systems failures. The current data reporting system on the DORA website for professional review entities may cause consumers to mistakenly believe that "no action" on credentialing means a professional review entity conducted an investigation and analysis and took no action at all. The professional review investigatory process instead consistently results in identification of broader issues which are then addressed through other appropriate processes, resulting in safety modifications such as policy or workflow changes. We propose adding a category for "action taken not provider-specific" so that professional review entities can present data on the improvements that result from their work.

2. **Have professional review entities report when an investigation was the result of provider self-reporting to give the public greater assurance that CPRA promotes provider participation.**

Our expert panel reports that many professional review investigations originate from self-reporting. The public should be aware of the significant number of self-reported cases, which demonstrate physicians' voluntary, active participation in the professional review process. This data will be particularly useful given that self-reports will decrease to zero without the confidentiality provided by CPRA.

In addition, the panel of physician experts provided feedback on the specific questions posed by DORA.

3. **Should DORA sunset CPRA?**

Response: In a word, no.

Professional review is keeping patients safer and holding providers accountable. And, the increase in professional review investigations inevitably leads to tangible patient safety benefits in the form of identifying and resolving medical systems issues which go beyond individual providers. For example, the current CPRA permits a hospital to identify, evaluate and determine that a provider gave the wrong medication to a patient because medication bottles look alike and are being maintained in bins labeled with numbers instead of medication names. This problem can then be fixed to prevent another occurrence. Another example is found in the ongoing opioid crisis. With the intact CPRA, physician groups can monitor, analyze and discuss opioid prescribing habits among peers openly and candidly, without fear of exposure to an

administrative or civil action simply from monitoring the data, sharing and analyzing it, and having the discussion. The CPRA allows innumerable educable moments like these to occur among health care providers daily. It is undeniable that patients directly benefit from the candid, thoughtful and thorough analysis the CPRA permits.

Since enactment of the CPRA in 1975, Colorado physicians, hospitals and other health care providers have relied on the CPRA's protections as a cornerstone to build a culture of patient safety within the Colorado health care community for the direct benefit of patients.

Professional review currently arises from a number of sources, including physician self-reports, peer reports, and reports from patients and other health care providers. With the CPRA intact, the trend in the number of reports is steadily increasing as reflected in the 230% increase in the number of professional review investigations between 2013 and 2017. There are substantial benefits of the CPRA in eliminating a fear among health care providers to report events or to participate in professional review which led to its enactment in the first place.

Physician self-reporting, as promoted by the CPRA, is vitally important to preserve and protect patient safety. Ending the CPRA would have a chilling effect on such self-reporting.

4. **Should DORA require timely investigation of every adverse event, including full reporting to the patient, CDPHE and Medical Board so accurate statistics can be developed and tracked to specific facilities?**

Response: CMS does not believe that the reporting of every adverse event to the agencies will benefit consumers, providers or the agencies. Current regulations already in place mandate the reporting of many categories of adverse events to CDPHE by facilities. Under those regulations, following appropriate investigation and analysis, certain information is already made available to the public. A requirement to report these same events to CMB would only create unnecessary duplicate reporting.

It is also paramount to note that "adverse event" is not a synonym for medical negligence. Adverse events are not a defined term under the law. Many adverse events are caused by known risks and consequences of medical conditions, procedures, medications and other health care treatment. Investigating and reporting adverse events by the Medical Board will confuse patients. This data will make it appear that the individual provider licensed by the Medical Board was negligent when in fact the adverse event may have been a known and disclosed complication.

We also have a real concern that this requirement will lead to adverse patient selection. In other words, providers would be incentivized to avoid adding patients with complex medical conditions who carry a higher risk for an adverse patient outcome to their panels. Physicians may also be discouraged from practicing in high-risk areas, such as in-vitro fertilization practice among reproductive endocrinologists.

Finally, CMB's investigative process is currently complaint-driven, which ensures that the state's valuable resources are being used to investigate and address patient concerns. The investigatory function for adverse events is already delegated to professional review entities since they are far better able to investigate events in their own facility or within their own group.

Current law already mandates reporting to the CMB by those professional review entities. Further mandatory investigation and reporting is unnecessary.

We support the evolution of required reporting to reflect how care is delivered today (see discussion on page two above) and the current availability to the public of the de-identified and aggregate data of professional review activities. We support reporting that affirms for DORA and patients that professional review is improving care safety and holding providers accountable through robust use of the professional review mechanism.

5. **Should DORA require mandatory reporting for all adverse events and publicly report by facility and provider?**

Response: Please see the response to question 2 above and recommendations about what could be reported publicly by professional review entities to give the public greater assurance that the system is working to make care safer and to hold providers accountable.

6. **Should patients and families have unfettered access to medical records and other information that has been withheld from their records. This includes factual information, investigative reports, data, or interviews gathered in the course of investigating an adverse event – even if a review committee uses the information during its deliberations assessing the motives and judgment of a practitioner?**

Response: This question raises many of the same issues as question one above. We incorporate that response here as we believe that unfettered access would equally undermine the core purpose of professional review. If detailed information gathered in the course of investigating an adverse event is subsequently shared with patients, then providers will be less likely to self-report and may hesitate to fully participate in the professional review process. In addition, patients and, with the patient's consent, a family member already have a qualified right of access to the patient's medical records. Federal law, through HIPAA, provides specific definitions of medical records, which is already incorporated and followed in existing Colorado law. The medical record includes the information used in treatment or diagnosis of the patient's medical condition. A retrospective analysis of patient care, the kind of analysis done in professional review, is not part of the medical record. The purpose of the retrospective analysis is to improve future care, but this analysis does not impact the individual patient's plan of care. The law already provides that all information related to the patient's plan of care be included in the medical record.

7. **Should DORA prohibit Peer Review Committees if the member of the panel have a financial interest in the outcome of any review?**

Response: We believe that this issue is adequately addressed in existing law. The CPRA requires a professional review process that is in accordance with procedures that, under the circumstances, were fair to the [licensee]. C.R.S. § 12-36.5-105(2)(d). If not followed, the governing board loses immunity from suit and liability for damages in any civil or criminal action, including antitrust actions, brought by the individual under review. C.R.S. § 12-36.5-105(2). As a practical matter, in group practices and smaller communities, it may impair

professional review activities to have a blanket prohibition which would then preclude even obtaining a waiver from the licensee under review.

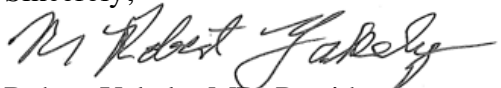
8. **Should a member of the public unconnected to the hospital, entity, and practitioners be required to be a part of all Professional Review Committees to ensure that errors and misconduct are not kept from the patient?**

Response: We believe that this issue is also adequately addressed in existing law. Under current law, having a public member on a professional review committee is optional, encouraged and often utilized when possible. Governing boards, particularly in the hospital setting, also often have community members. To further evolve public involvement, we would suggest that professional review entities report whether a public member is participating in their process. In addition, we strongly promote candid disclosure and discussion between physicians and patients when adverse patient events occur.

We wish to emphasize our goal to continue to work closely with your office to continue to use the sunset process to enhance the system of patient safety and quality care through evolution of professional review. We would be pleased to address any questions you may have about the foregoing responses. If you would like to meet personally with our panel of physician experts, we would be pleased to facilitate a discussion.

Please do not hesitate to call on us.

Sincerely,



Robert Yakely, MD, President
CMS President

Colorado Academy of Family Physicians
Colorado Chapter - American College of Emergency Physicians
Colorado Society of Osteopathic Medicine
Colorado Society of Anesthesiologists
Rocky Vista University, College of Osteopathic Medicine

Attachments:
(1) Roster: CMS Expert Panel on Professional Review-MPA Sunset
(2) July 2011 CMS-CHA Recommendations; Professional Review Sunset

Cc:
CMS Expert Panel on Professional Review Sunset
Deb Parsons, MD, President-elect
Katie Lozano, MD, Immediate Past President
Alethia Morgan, MD, Chair, Council on Legislation
Susan Koontz, JD, General Counsel, Senior Director of Government Relations
Chet Seward, Senior Director, Division of Health Care Policy
Jerry Johnson, CMS Public Affairs Consultant