



COPIC GUIDE FOR THE COLORADO CANDOR ACT

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Nobody wants to see an adverse outcome in health care, yet despite best efforts, these types of incidents occur. How providers deal with them and address the needs of patients is important because the provider-patient relationship forms the foundation of health care. Now, medical providers and facilities in Colorado have a new tool to utilize in these situations—the Colorado Candor Act.

FAQs: Colorado Candor Act

WHAT IS CANDOR?

Candor can be defined as “the quality of being open and honest.” This term has been adopted in health care to describe a framework for addressing adverse medical incidents in a way that preserves the provider-patient relationship, allows for open communication, and supports improvements in patient safety.

The focus on Candor emerged out of efforts by the Agency for Healthcare Research and Quality (AHRQ). AHRQ developed a toolkit that promoted a shift to an environment that encourages open, honest conversations with patients after adverse outcomes occur. The process is also designed to investigate and learn from what happened, to address the patients’ needs alongside providers’ needs, and to disseminate any lessons learned in order to improve future outcomes.

Since then, the Candor framework has been utilized in various health care systems and demonstrated positive results. In addition, Candor-related legislation has been passed in Massachusetts, Oregon, and Iowa.

WHAT ARE THE ORIGINS OF THE COLORADO CANDOR ACT?

The Colorado Candor Act originated from discussions between the Colorado Academy of Family Physicians (CAFP) and legislators at the beginning of the 2019 state legislative session. CAFP served as a strong advocate for the health care community and its patients by highlighting the benefits of Candor. CAFP worked closely with other stakeholders, including the Colorado Trial Lawyers Association and patient safety advocates, to garner support for this bipartisan measure that eventually passed as legislation (SB 201).

WHAT TYPES OF INCIDENTS QUALIFY UNDER THE ACT?

Adverse health care incidents arising from or related to patient care resulting in the physical injury or death of a patient.

WHEN DID THE COLORADO CANDOR ACT TAKE EFFECT?

The Act went into effect on July 1, 2019.

WHAT TYPES OF MEDICAL PROVIDERS AND FACILITIES CAN UTILIZE THE COLORADO CANDOR ACT?

Physicians, physician assistants, podiatrists, licensed practical and registered nurses, advanced practice nurses, pharmacists, and others who are licensed, certified, registered or otherwise permitted to provide health care services in Colorado.

In addition, hospitals/health care facilities including clinics, community health centers, community mental health centers, surgical centers, and residential care or nursing homes are eligible to participate jointly with a health care provider involved in the adverse health care incident.

HOW DOES THE CANDOR PROCESS BENEFIT PATIENTS?

Patients who have an adverse incident, and their families, are able to engage in open discussions with the provider(s) involved. This helps them understand why the incident occurred and what is being done to prevent similar issues in the future. Patients become a part of the process by helping to identify and implement procedures designed to improve patient safety. The Candor process is also designed to expedite the process of addressing an adverse outcome and offering patients compensation when warranted.

HOW DOES THE CANDOR PROCESS BENEFIT PROVIDERS?

As with patients, the open discussions allow for providers to address concerns, offer their perspective on what happened and why, and work together to preserve the provider-patient relationship. The Candor process is meant to be non-adversarial. It allows providers to participate in and learn from the process without creating undue burdens that take the provider away from patient care.

HOW DOES THE CANDOR PROCESS START?

The process is initiated by the health care provider involved in the incident. The provider, or the provider jointly with the health facility, needs to provide the patient with written notice of the desire to enter into an open discussion (under the Colorado Candor Act) with the patient. The notice must include specific details about the patient’s rights and the nature of the communications and discussions under the Colorado Candor Act.

COPIC Guide to Colorado Candor Act

CANDOR FAQs (FROM PAGE 1)

WHAT SHOULD MEDICAL FACILITIES/HOSPITALS BE AWARE OF WITH THE CANDOR PROCESS?

The Colorado Candor Act does not change the process for health care facilities to review systems issues, the facility's quality management process, or the quality of care rendered by individual providers. The Act does not change the current process of reporting certain occurrences to Colorado Department of Public Health and Environment (CDPHE) or CDPHE's ability to investigate and access medical records and other information allowed under current law.

WHY ARE THE DISCUSSIONS CONFIDENTIAL AND PRIVILEGED?

To facilitate open communication between providers and patients in a way that is not hindered by the threat of these communications being used against the provider or facility in subsequent litigation.

CAN A PATIENT STILL FILE A LAWSUIT AFTER A CANDOR DISCUSSION?

The Colorado Candor Act does not limit a patient's ability to use the legal system. Patients can choose to withdraw from the Candor process at any time. However, the discussions and communications that occurred during the Candor process, including any offers of compensation, remain privileged and confidential. Under the Act, an offer of compensation does not constitute an admission of liability. In addition, if a patient chooses to accept an offer of compensation, a provider or facility may require a patient to sign a release of liability, so he or she cannot bring a subsequent lawsuit.

WHAT REPORTING REQUIREMENTS APPLY TO THE COLORADO CANDOR ACT?

Because no payments are made as a result of a written complaint or claim demanding payment based on a practitioner's provision of health care services, incidents handled through the Candor process are not required to be reported to the National Practitioner Data Bank.

Patients participating under the Colorado Candor Act do not waive their right to file a complaint with the relevant licensing board or the Colorado Department of Public Health and Environment, which oversees health care facilities. Where indicated, a provider's actions can also be addressed through Colorado's professional review process for physicians, PAs, APNs, or a facility's quality management process for other licensed health care professionals.

States outside of Colorado may require notification of incidents where there is compensation under the Candor process for providers who are licensed in those states, including through the Interstate Medical Licensure Compact.

WHAT ARE SOME OF THE OTHER BENEFITS OF THE COLORADO CANDOR ACT?

A health care provider/health facility that participates in open discussions under the Act may provide de-identified information about an adverse health care incident to any patient safety-centered nonprofit organization for use in patient safety research and education. Such a disclosure does not constitute a waiver of the privilege for open discussions and is not a violation of the Act's confidentiality requirements.

Overview of the Candor Process

1 The process is initiated by the health care provider.

A health care provider involved in the adverse health care incident, or the provider jointly with the health facility, needs to provide the patient with written notice of the desire to enter into an open discussion under the Colorado Candor Act.

As with all incidents, COPIC insureds should call a COPIC occurrence specialist nurse during business hours, 8am–5pm (Mountain time), Monday through Friday, by calling (800) 421-1834. The occurrence specialist nurse will evaluate the incident with our internal team to determine if it is appropriate to utilize the Colorado Candor Act.

2 The written notice must be sent to the patient within 180 days of the incident.

This time period is defined as 180 days after the provider knew or should have known about the incident.

3 The notice must include specific details about the patient's rights and the nature of the communications and discussions under the Colorado Candor Act.

The notice must include the following:

- The patient's right to receive a copy of the medical records related to the incident and to authorize the release of the records to any third party;
- The patient's right to seek legal counsel and have legal counsel present during any open discussions;
- A copy of the relevant statute of limitations with notice that the time for a patient to bring a lawsuit is limited and will not be extended merely by engaging in an open discussion;

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CANDOR PROCESS (FROM PAGE 2)

- If the health care provider or health facility is a public entity or public employee, a copy of the deadline for filing under the Governmental Immunity Act, which won't be extended by engaging in an open discussion;
- Notice that if the patient chooses to engage in an open discussion with the health care provider or health facility, all communications made in the course of the discussion under the statute are:
 - Privileged and confidential,
 - Not subject to discovery, subpoena, or other means of legal compulsion for release, and
 - Not admissible in evidence in a judicial, administrative, or arbitration proceeding arising directly out of the adverse incident.
- An advisement that communications, work product, documents, and other materials that are otherwise subject to discovery and not prepared specifically for use in an open discussion are not confidential.

If the patient agrees in writing to engage in an open discussion, the patient, health care provider, or health facility engaged in the discussions may include other persons in the open discussion, who must acknowledge in writing that the communications are privileged and confidential.

4 Under the Colorado Candor Act, health care providers and facilities may investigate, disclose, and communicate about how the incident occurred and what steps are being taken to prevent a similar outcome in the future.

The health care provider/facility that agrees to engage in an open discussion may:

- Investigate how the incident occurred and gather information regarding the medical care.
- Disclose the results of the investigation to the patient.
- Communicate to the patient the steps that will take place to prevent future occurrences of the incident.

5 As part of their assessment, health care providers and facilities can determine whether or not an offer of compensation is warranted.

If no offer of compensation is warranted, the provider/facility shall orally communicate that decision with the patient.

If the provider or facility determines that an offer of compensation is warranted, the provider or facility shall provide the patient with a written offer of compensation.

- If an offer is made and the patient is not represented by legal counsel, the provider/facility is required to:
 - Advise the patient of the patient's right to seek legal counsel regarding the offer of compensation; and
 - Provide notice that the patient may be legally required to repay medical and other expenses that were paid by a third party, including private health insurance, Medicare, or Medicaid.
- A health care provider/facility may require the patient, as a condition of an offer for compensation, to execute all documents and obtain any necessary court approval to resolve an adverse health care incident.

6 To facilitate open communication under the Colorado Candor Act, discussions and offers of compensation under the Act are privileged and confidential.

- Open discussion communications and offers of compensation made under the statute:
 - Do not constitute an admission of liability;
 - Are privileged and confidential and shall not be disclosed; and
 - Are not admissible as evidence in any subsequent judicial, administrative, or arbitration proceeding arising directly out of the adverse health care incident.
- Communications, memoranda, work product, documents, and other materials that are otherwise subject to discovery and not prepared specifically for use in an open discussion are not confidential.
- The limitations on disclosure includes disclosure during any discovery conducted as part of a subsequent adjudicatory proceeding arising directly out of the adverse health care incident, and a court or other adjudicatory body shall not compel a person who engages in an open discussion under the Act to disclose confidential communications or agreements made as part of the open discussion.
- The Act does not affect any other law, rule, or requirement with respect to confidentiality.

Considerations for Health Care Facilities/Hospitals

Health care facilities and hospitals follow the same Candor process as individual health care providers. However, they should examine internal systems and what adjustments should be made to integrate the Candor process. This may include the following considerations and/or “best practices”:

- **Establish a Situation Management Team (SMT) to ensure a timely and effective response:**
 - An SMT is responsible for managing how a facility responds to an adverse outcome in a coordinated approach among various stakeholders within a facility.
 - The key responsibilities of an SMT are to conduct an analysis, notify the involved providers (if they are not already aware) and provide support to them, determine what type of communication with the patient is appropriate, and evaluate if compensation is warranted.
 - Members of the SMT can include risk managers, patient safety specialists, patient representatives, and medical and nursing staff leadership.

For COPIC insureds, the SMT should include members of COPIC’s Candor Team. Our 20+ years of experience in dealing with communication after an adverse outcome provides expertise to guide facilities through every step of the Candor process.

- **Recognize the key exclusions that make an incident ineligible for the Candor process.**
 - A summons or complaint was received.
 - There is a written demand for compensation.
 - There is no physical injury to the patient.

- **Remember that physicians are not the only providers who can participate in the Candor process.**
 - Besides physicians, eligible providers include physician assistants, podiatrists, licensed practical and registered nurses, advanced practice nurses, pharmacists, and others who are licensed, certified, registered or otherwise permitted to provide health care services in Colorado.
- **Be conscious of the 180-day timeframe in which the initial written notice to the patient must be sent.**
- **Because Candor is “provider initiated,” the facility/hospital should work with the involved provider(s) to discuss how to speak with the patient and walk through the Candor process.**
 - The Candor framework recognizes that patients want to hear from the provider(s) who was involved with their care as opposed to an administrative representative from the facility.
- **Establish a clear contact who will work directly with the patient throughout the entire Candor process.**
- **Develop patient communication pieces designed to help them understand the Colorado Candor Act.**

COPIC has developed a Patient FAQs and Program Overview, which is available for insured facilities/hospitals to use.

- **Ensure the proper documentation is used at every step of the process.**
- **Educate medical staff about the Colorado Candor Act, and how it can be initiated and utilized.**

The Colorado Candor Act framework shares underlying principles with Seven Pillars¹, another recognized approach to addressing adverse events in health care facilities and systems. The components of Seven Pillars are:

- 1) Patient safety incident reporting**—Reinforce a culture that encourages timely reporting.
- 2) Investigation**—Conduct a preliminary review of the incident to determine if patient harm occurred and if a root cause analysis should be performed; the investigation should examine the system as well as provider performance.
- 3) Communication and disclosure**—Maintain ongoing communication with the patient and family throughout the process; providers involved should be trained in

communication skills required in these situations such as empathy, sincerity, active listening, patience, and tact.

- 4) Apology and remediation (if appropriate)**—Ensure that when patient harm did occur, saying “we’re sorry” includes subsequent action such as explaining what is being done to prevent similar outcomes and offers of compensation, if warranted.

- 5) System improvement**—Identify and implement system improvements aimed at preventing a recurrence;

patients and families may be invited to participate in this aspect of the process.

- 6) Data tracking and performance evaluation**—Collect data associated with the incident and utilize this for internal quality assurance, research, and dissemination to relevant stakeholders.

- 7) Education and training**—Build a robust education platform based on analysis of adverse events, and utilize case-based, interactive education for all members of the health care team.

¹ <https://www.ncbi.nlm.nih.gov/pubmed/20194217>