

Guide for the Iowa Candor Law



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. Medical providers and facilities in Iowa have a tool to utilize in these situations—the Iowa Candor Law.

Frequently Asked Questions

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 Colorado.

What are the origins of the Iowa Candor Law?

The Iowa Candor legislation was an initiative of the Iowa Medical Society working with the Iowa Association for Justice. The bill was passed unanimously by the Iowa General Assembly and was signed into law in 2015. The law was expanded in 2017 to allow more health care practitioners to use the Candor approach. It was again modified July 1, 2020, by extending the length of time a provider has to initiate the Candor process from 180 days to one year.

What types of incidents qualify under the law?

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

What types of medical providers and facilities can utilize the Iowa Candor Law?

Physicians, physician assistants, podiatrists, licensed practical and registered nurses, advanced registered nurse practitioners, pharmacists, and any other person who is licensed, certified, or otherwise authorized or permitted under Iowa law to administer health care in the ordinary course of business or in the practice of a profession.

In addition, hospitals, health care facilities, organized outpatient health facilities, outpatient surgical facilities, birthing centers, clinics, and community health centers are among the health facilities that can participate in Candor when an adverse health care incident occurs in the health facility.

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) or health facility 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.

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FAQs (From Page 1)

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 Iowa's Candor Law) with the patient. The notice must include specific details about the patient's rights and the nature of the communications and discussions under the Iowa Candor Law.

What should medical facilities/hospitals be aware of with the Candor process?

The Iowa Candor Law does not change the process for health facilities to review systems issues, the facility's quality improvement program, or the peer review of the professional services rendered by individual health care professionals. The law does not change any reporting requirements for adverse professional review actions or as otherwise required for health facilities.

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 Iowa Candor Law 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 law, 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 Iowa Candor Law?

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. They don't fall within a licensee's obligation to report to the licensing board every adverse judgment in a professional or occupational malpractice action to which the licensee is a party, and every settlement of a claim against the licensee alleging malpractice. They are also not considered a claim for purposes of medical malpractice insurers reporting open and closed claims filed during the reporting period against Iowa insureds during the preceding calendar year.

Patients participating under the Iowa Candor Law do not waive their right to file a complaint with the relevant licensing board or the Iowa Department of Inspections & Appeals, Health Facilities Division, which oversees health facilities. Where indicated, a health care professional's actions can be addressed through a hospital's or other health care entity's peer review process. The Candor Law does not change any reporting requirements for adverse professional review actions or as otherwise required for health facilities.



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 Iowa Candor Law.

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 Iowa Candor Law.

2. The written notice must be sent to the patient within one year of the incident.

This time period is defined as one year 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 Iowa Candor Law.

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;
- 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 by engaging in an open discussion unless all parties agree in writing;

- Notice that if the patient chooses to engage in an open discussion with the health care provider or health care facility, all communications made in the course of the discussion under the Candor law, including communications regarding the initiation of an open discussion, 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.

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 be advised in writing that the communications are privileged and confidential. The advisement must also indicate that communications and other materials, otherwise subject to discovery, that weren't prepared specifically for use in an open discussion are not confidential.

4. Under the Iowa Candor Law, health care providers and health 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.

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Candor Process (From Page 3)

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 or 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.
- 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, discussions and offers of compensation under the Candor law are privileged and confidential.

- Open discussion communications and offers of compensation made under the Candor law:
 - Do not constitute an admission of liability;
 - Are privileged, confidential, and shall not be disclosed;
 - Are not admissible as evidence and shall not be disclosed by any party in any subsequent judicial, administrative, or arbitration proceeding; and
 - Are not subject to discovery, subpoena, or other means of legal compulsion for release.
- Communications, memoranda, work products, documents, and other materials that are otherwise subject to discovery and not prepared specifically for use in an open discussion are not confidential.
- The limitation on disclosure includes disclosure during any discovery conducted as part of a subsequent adjudicatory proceeding, and a court or other adjudicatory body shall not compel a person who engages in an open discussion under the law to disclose confidential communications or agreements made as part of the open discussion.
- The law does not affect any other law, rule, or requirement with respect to confidentiality.

Considerations for Health Care Facilities/Hospitals

Hospitals and other health facilities 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.



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Considerations (From Page 4)

- **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.
- **Be conscious of the one year timeframe in which the initial written notice to the patient must be sent.**
- **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 registered nurse practitioners, pharmacists, and any other person who is licensed, certified, or otherwise authorized or permitted by Iowa law to administer health care in the ordinary course of business or in the practice of a profession.
- **Because Candor is "provider initiated," the facility or 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 Iowa Candor Law.**
- **Ensure the proper documentation is used at every step of the process.**
- **Educate medical staff about the Iowa Candor Law, and how it can be initiated and utilized.**

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

The Iowa Candor Law 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>