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COLLEGE OF PHYSICIANS
& SURGEONS OF ALBERTA

STANDARDS OF PRACTICE

Disclosure of ~~Harm~~Unexpected Outcomes

Under Review: ~~No~~Yes

Issued ~~By~~by: Council: ~~January~~Jan. 1, 2010 *(Disclosure of Harm)*

Reissued by Council: [TBD]

Commented [CD1]: Title changed to encompass broader scope: not all events cause harm that needs to be disclosed, and sometimes there is no adverse event, but there is an unexpected outcome that needs to be actioned.

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The ***Standards of Practice*** of the College of Physicians & Surgeons of Alberta ("CPSA") are the **minimum** standards of professional behavior and ethical conduct expected of all regulated members registered in Alberta. Standards of Practice are enforceable under the *Health Professions Act* and will be referenced in the management of complaints and in discipline hearings. CPSA also provides **Advice to the Profession** to support the implementation of the Standards of Practice.

Note: a glossary of terms can be found at the end of this document. Glossary terms are indicated in teal with a "G" throughout this document.

PREAMBLE

Despite a regulated member's dedication and commitment to provide the best care possible, the delivery of care can sometimes result in unexpected outcomes[G] and exposes a patient to harm[G]/potential harm. Harm is not always preventable, nor is it necessarily an indicator of substandard care, but its impact can deeply affect patients and their families.[1]

Regulated members may also be significantly impacted when their patients experience negative healthcare outcomes. They may feel ill-equipped to disclose or discuss the harm that has occurred with patients and families and may also struggle to find the resources they need to conduct these conversations effectively.[1]

When the clinical outcome is not as anticipated, regulated members have an ethical, professional and legal obligation to disclose harm from healthcare delivery to patients.[2] It is also important to take steps to understand what factors contributed to the event and to mitigate a reoccurrence.[2] Part of the post-analysis involves an apology when appropriate. This is not an admission of error or liability: genuine concern will be appreciated by most patients and families and may prevent complaints or legal action.[3]

The purpose of this standard is to set out disclosure obligations for regulated members; the companion Advice to the Profession document provides additional guidance and resources to navigate this type of discussion. Related standards, additional information and general

Commented [CD2]: In development: will be available when updated standard is implemented.

[1] From CPSO's Disclosure of Harm Advice to the Profession (Aug. 2024).
[2] From CMPA's "Disclosure of patient safety incidents" Good Practices article (Apr. 2021).
[3] From CMPA's "Disclosing harm from healthcare delivery" (Mar. 2017).

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advice can be found in the companion resources listed at the end of this document.

STANDARD

Obligation to disclose

1. A regulated member **must** ensure adverse/harmful events[G] or unexpected outcomes are disclosed.[4] [5]

2. A regulated member **must** comply with the disclosure protocols of the institution(s) where they work.

   a. If a situation is ethically unclear, a regulated member **may** seek guidance from CPSA or the Canadian Medical Protective Association (CMPA).[6]

3. A regulated member **must** consider whether to disclose near-miss events[G], taking into account whether:

   a. the patient is aware of the event and if an explanation will reduce concern and/or promote trust;

   b. the patient should be educated to monitor for future similar incidents and/or issues that may be related; and

   c. a reasonable person in the patient's position would want to know about the incident.

To whom to disclose

4. A regulated member **must** disclose directly to the patient or the patient's substitute decision-maker if the patient is incapable with respect to treatment.

5. If a patient has died, a regulated member **must** disclose adverse/harmful events or unexpected outcomes to the patient's immediate family or to persons with whom the patient had a close personal relationship.

Commented [CD3]: From CPSBC's *Adverse or Harmful Events* Practice Standard: added to ensure regulated members are aware of their obligation to follow institutional requirements, as well as signal that seeking guidance is acceptable.

Commented [CD4]: From CPSO's *Disclosure of Harm* Policy and CPSS's *Disclosure of Adverse Incidents* Policy: added to address obligation to disclose harmful events and to consider disclosing "close calls" based on patient need/expectation.

Also clarifies to whom disclosure must be made if the patient is otherwise unavailable.

[4] From CPSO's *Disclosure of Harm* Policy (Dec. 2019).
[5] From CPSS's *Disclosure of Adverse Events* Policy (Sep. 2022).
[6] From CPSBC's *Adverse or Harmful Events* Practice Standard (June 2022).

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6. A regulated member **may** wish to consider consulting CMPA prior to having a disclosure conversation with a patient.[6]

When to disclose

7. A regulated member's first priority after an adverse/harmful event or unexpected outcome **must** continue to be the provision of appropriate care.[6]

8. A regulated member **must** disclose as soon as possible and in the best interest of the patient.[4 5 6]

9. Disclosure is an ongoing obligation: a regulated member **must** disclose additional relevant information as soon as possible once it becomes available.[4 5]

What to disclose

10. A regulated member **must** consider whether an apology[G] is appropriate, taking into consideration the nature of the event or outcome and the consequences for the patient.[1 5 6]

    a. In accordance with the *Alberta Evidence Act*, an apology made by or on behalf of a person in connection with an adverse or harmful event does **not** constitute an admission of fault or liability.[7]

    b. A regulated member is **not** responsible for apologizing on behalf of another healthcare provider or organization.[8]

11. A regulated member **must** disclose in understandable, plain language:[6]

    a. the facts of the event or outcome, as they are known at the time;

    b. the consequences for the patient; and

    c. actions that have been taken and those that are recommended to address any actual or potential consequences to the patient, including:

        i. any steps the patient can take to monitor for potential consequences;

        ii. options for follow-up care;[4]

Commented [CD5]: From CPSBC: acknowledges resources available to members.

Commented [CD6]: From CPSBC: ensures members know the expectation is that patient care will continue to be prioritized.

Commented [CD7]: From CPSBC, CPSO, and CPSS: clarifies disclosure should not be delayed.

Commented [CD8]: From CPSO and CPSS: signals that patients must be kept advised as information becomes available.

Commented [CD9]: From CPSBC, CPSO, and CPSS: an apology is not an admission of wrong-doing - it is a key part of disclosure and can prevent legal action/complaints (e.g., "I am sorry this happened to you" vs. "I am sorry I did this to you").

Commented [CD10]: From CPSBC: ensures patients, substitute decision-makers, family, etc. understand what is being disclosed and why.

Commented [CD11]: Subclauses from CPSO: clearly identifies what to disclose.

[7] [7] From the Province of Alberta's *Alberta Evidence Act* (June 2024).
[8] From CMPA's "'I'm sorry this happened.' Understanding apology legislation in Canada" (Oct. 2021).

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d. who the patient can contact for further information; and

e. actions being ~~defined as~~ taken, if any, to avoid or reduce the risk of the incident recurring.[5]

12. A regulated member **must** avoid speculation and blaming others.[5 6]

Who must disclose

13. Where a sole regulated member is directly involved in the patient's care at the time of the event or outcome, that regulated member **must** disclose.[4 5 6]

14. Where multiple regulated health professionals are directly involved in the patient's care at the time of the event or outcome, a regulated member **must**:

    a. participate in determining who is the most appropriate health professional to disclose;

    b. ensure that disclosure occurs, regardless of who is determined to be the most appropriate health professional to disclose; and **Error! Bookmark not defined.** [4 5]

    c. plan for immediate and ongoing disclosure as new information arises.

Postgraduate trainees

15. A postgraduate trainee **must** inform the most responsible health professional (MRP) and their clinical preceptor of any harmful, no-harm, near-miss events or unexpected outcomes in a timely manner.[4 5]

Documentation

16. A regulated member **must** document the following in the patient's record:

    a. the facts of what occurred;

    b. a description of the cause(s) of the incident; and

    c. the relevant details of all discussions and communications with the patient, or their substitute decision-maker, relating to disclosure of the event or outcome.[4]

Commented [CD12]: Subclauses (d) and (e) from CPSS: provides patient with necessary information and reassurance.

Commented [CD13]: From CPSBC and CPSS: keeps disclosure fact-based.

Commented [CD14]: From CPSBC, CPSO, and CPSS: clearly outlines who must disclose/when and expectations in both solo and team-based scenarios.

Commented [CD15]: From CPSO and CPSS: provides expectations of trainees.

Commented [CD16]: From CPSO: clarifies importance of documenting adverse/harmful events.

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17. A regulated member **must not** make changes to the patient's record, except through an addendum, in accordance with the *Health Information Act* and the *Patient Record Content* standard of practice.[4 5]

Commented [CD17]: From CPSO and CPSS: emphasizes the importance of an accurate patient record and integrity of data entered.

Follow-up

18. A regulated member **must**:

a. reflect on what led to the event or outcome and consider ways to prevent similar incidents;

i. this includes participating in any available system(s) to prevent similar adverse/ harmful events or unexpected outcomes;

b. sharing learnings from the experience with others to prevent similar incidents; and

c. ensure that the regulated member (or another member of the healthcare team) is providing ongoing disclosure.

i. This includes engaging in a conversation with the patient, substitute decision-maker, immediate family or people with whom the patient has a close personal relationship to address what is being done to prevent similar adverse or harmful events.[4 5]

Commented [CD18]: From CPSO's *Disclosure of Harm* Policy and CPSS's *Disclosure of Adverse Incidents* Policy: added to address obligation to disclose harmful events and to consider disclosing "close calls" based on patient need/expectation.

Also clarifies to whom disclosure must be made if the patient is otherwise unavailable.

GLOSSARY

Adverse/ harmful event: an incident that has resulted in harm to the patient. For specific examples, please refer to the Advice to the Profession document [TBD].[4 5]

Apology: an expression of sympathy or regret, a statement that one is sorry, or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault.[7]

It is important to avoid the use of words that express or imply legal responsibility (e.g., negligence, liable, fault, or failed to meet the standard of care): legal responsibility is complex and up to the courts and Colleges to make such determinations.[8]

Disclosure: the acknowledgement and discussion of an adverse or harmful event, a no-harm event or a near-miss event with the patient, substitute decision-maker or the

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patient's immediate family or to persons with whom the patient had a close personal relationship.[4 5]

~~1.~~ **Harm:** an outcome that negatively affects ~~the~~a patient's physical or mental health ~~and/~~or quality of life~~, the responsible regulated member **must** ensure that the patient receives disclosure of that information~~.
[5] and extends beyond physical harm to include the impact on a patient's life, which is determined by the patient. This includes negative effects even if they are not known to the patient.[9] Harm may also be compounded because of how it is handled. Examples of harm include, but are not limited to physical, psychological, power imbalances, systemic oppression (e.g., racism, ableism, ageism, sexual and gender discrimination), and socioeconomic inequities.[10]

~~a. if the regulated member is the only healthcare professional treating the patient, then it is the regulated member's responsibility to disclose that information to the patient;~~

~~b. in a team setting, the regulated member must cooperate with other members of the team (in the hospital setting this will also include the administration) to identify the most suitable person(s) to disclose that information to the patient; and~~

~~c. in all settings, disclosure of harm is to be considered part of a process that will also address the patient's immediate and future medical needs, the investigation (if required) of the circumstances that led to the patient suffering harm, and necessary steps to prevent recurrence of the harm if an untoward and avoidable event occurred.~~

~~2. Disclosure **must** occur whether the harm is a result of progression of disease, a complication of care or an adverse event and whether the harm was preventable.~~

Commented [CD19]: Clause 1 of current version of standard.

Commented [CD20]: New clause 13.

Commented [CD21]: New clause 14.

Commented [CD22]: New clause 3(b).

Commented [CD23]: New clause 18(a).

Commented [CD24]: New clause 18(c)(i).

Commented [CD25]: New clause 1.

[9] From The Health Foundation's "Evidence Scan: Levels of Harm" (Nov. 2011).
[10] From Healthcare Excellence Canada's "Rethinking Patient Safety" (Oct. 2023).

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Near-miss events: incidents with the potential for harm that did not reach the patient due to timely intervention or good fortune (also known as a "close call"). For specific examples, please see the Advice to the Profession document [TBD].[4 5]

Unexpected outcomes: the outcome of a medical treatment/procedure that differs from the expected result[11] (e.g., a patient has an unexpected cardiac arrest and dies when in the ER for a minor injury, like a broken toe). Unexpected outcomes do not always involve adverse events and can be the result of risks inherent in treatment, system issues, human error or a patient's underlying medical condition.[12]

ACKNOWLEDGEMENTS

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RELATED STANDARDS OF PRACTICE

- *Informed Consent*
- *Patient Record Content*
- *Responsibility for a Medical Practice*

COMPANION RESOURCES

- Advice to the Profession documents:
  - Disclosure of Unexpected Outcomes [TBD]
  - Informed Consent for Adults
  - Informed Consent for Minors

[11] From Law Insider (n.d.).
[12] From CMPA's "Learning from adverse events: learning from a just culture of safety in Canadian hospitals and healthcare institutions" (2009).

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  - Legislated Reporting & Release of Medical Information
  - Responsibility for a Medical Practice
- Advice to Albertans: Disclosure of Unexpected Outcomes [TBD]
- Canadian Medical Protective Association:
  - Disclosing harm from healthcare delivery
  - Disclosure of patient safety incidents
  - "I'm sorry this happened." Understanding apology legislation in Canada
- Health Quality Council of Alberta:
  - A guide to disclosure of harm: A resource for healthcare providers
  - Checklist for disclosure team discussion
  - Resources for improvement: disclosure of harm
  - When something goes wrong: Information for patients who've been harmed during healthcare
- Healthcare Excellence Canada:
  - Canadian disclosure guidelines: Being open with patients and families
  - Canadian incident analysis framework
  - Patients for Patient Safety Canada: Principles of disclosing harm
  - Patient safety and incident management toolkit: Disclosure

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