Privacy, Security, Confidentiality, and Privilege Considerations for Patient Safety and Quality Improvement Activities

Before you begin, check with the appropriate point of contact in your organization to:

- Confirm that all participants in the improvement activity are authorized to access and use patient information for this purpose.

- Determine if any confidentiality or privilege protections are available for information generated in planning and conducting the improvement activity and, if protection is desired, be ready to meet all requirements that apply before, during, and after the activity.

- Confirm and be able to explain to participants whether information generated by the activity might be shared and used within your organization and for what purposes.

- Confirm that plans for storing and securing information related to planning and conducting the activity meet all applicable security requirements. Systems used for storing patient information may not meet all of the requirements for storing confidential and privileged patient safety or quality improvement information.
Protecting Patient Information

The privacy and security of patient information that is subject to the Federal Health Insurance Portability and Accountability Act Privacy and Security Rules must always be protected as required. State and local laws and organizational policies may also apply.

- Having access to patient records for patient care and treatment purposes does not necessarily mean access is authorized for other purposes.
- To protect patient privacy, healthcare organizations are likely to have policies and procedures that specify the workforce roles that require access to patient records, the conditions under which access is permitted, and limitations on access. They must also meet security requirements and monitor for unauthorized access. All files and documents with patient information must be stored in designated locations so they can be secured as required.

Protecting Information Generated by Patient Safety and Quality Improvement Activities

Another consideration in planning any patient safety or quality improvement activity is psychological safety. Individual personnel and/or the organization might want the information the activity will generate to be confidential and privileged.

Different Federal, State, and local laws create confidentiality and privilege protections. Each has its own specific requirements. The nature and extent of such protections can be very different.

Note that organizational policies may determine how confidential information can be used within the organization. For example, it may be up to the organization to decide whether it will – or will not – use confidential patient safety or quality improvement information for performance evaluations that can affect employment or professional privileges. Policies regarding how such information might be shared and used within the organization and for what purposes should be clearly communicated.

It is also important to consider in advance that if information is designated as confidential or privileged for improvement purposes, it may not be able to be used for other purposes, such as for research or to meet regulatory requirements.

Confidentiality and privilege protections for patient safety and quality improvement work are often available, but they are not automatic. If such protections are available and desired, it is likely they will only apply if specific requirements are followed.

What do the terms confidentiality and privilege mean?

Generally, if information is confidential, there is an obligation to restrict access to it and prohibit disclosure of it except as authorized. Authorized access to confidential information is typically limited to specified circumstances, purposes, and recipients.

In the legal realm, a privilege refers to the right to not disclose information during a legal proceeding. If information meets the requirements for a legal privilege to apply, the privilege can be asserted to defend against a demand to produce the information for use in certain legal matters. Some privileges apply to discovery requests or subpoenas in relation to a civil or criminal case in a court; some may apply in administrative agency matters, such as a professional licensing board investigation or disciplinary proceeding; and some may apply to Federal Freedom of Information Act requests or similar laws.

Ultimately, if there is a dispute over whether a privilege applies, a court would have the final word.

Examples of confidentiality and privilege protections:

- Some are created by State or local laws (sometimes referred to as “peer review” or “quality assurance” protections). The circumstances under which they apply, the kinds of information they protect, and the legal situations in which they can be used differ significantly from place to place.

- Uniform Federal law protections are available for certain information for individual and organizational healthcare providers that choose to work with a federally listed patient safety organization.

- Additional Federal confidentiality and privilege laws apply to certain improvement activities conducted in healthcare systems operated for or by the Veterans Health Administration, the Department of Defense, Indian health programs, and urban Indian organizations.