Legal Discovery and QAPI: A Tale of Two Risks A Systems RETHinking Approach

An Aging Services White Paper

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Legal Discovery and QAPI: A Tale of Two Risks
A Systems REThinking Approach

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A shift from quality assessment and assurance (QAA) to quality assurance and performance improvement (QAPI) is becoming a Centers for Medicare and Medicaid Services (CMS) regulatory reality for providers in the aging services continuum, affecting both home health and nursing centers. This new regulatory focus calls for a renewed discussion about how aging services providers may appropriately invoke privilege from discovery to protect quality improvement "work product" from disclosure in litigation. Why? Because the Federal Nursing Home Reform Act and its implementing regulations for QAPI programs for nursing facilities provide protection from disclosure as follows: "A state or the Secretary may not require disclosure of the records of [a QAPI] committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section" (42 USC § 1396r[b][1][B]; 42 CFR 483.75[o]).

The implementation of QAPI involves tools and methods through which providers identify, examine, assess, and candidly evaluate adverse events and quality of care, with the goal of taking action to mitigate harm and improve systems and processes. These activities are grounded on the premise that internal investigation and critical evaluation are essential processes for mitigating harm and improving quality of care.

The conduct of litigation involves a procedural tool referred to as "discovery" through which parties to a lawsuit may seek to "discover" information and material that are not privileged and that are relevant to the subject matter of the litigation. Discovery is grounded on the premise that litigation is a truth-seeking process that culminates in dispute resolution. Non-privileged information discovered in litigation is not automatically "admissible" as evidence in a court of law. Judges apply a jurisdiction's rules of evidence to determine what is admissible and for what purposes jurors may consider the evidence.

The processes and goals of QAPI and litigation discovery create a juxtaposition of two very real but seemingly opposing provider risks: harm to the organization if "problems" are discovered and QAPI information is used against the provider in litigation, versus harm to the

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organization from failure to act to prevent reoccurring incidents with common root causes. One result of these seemingly competing risks is that a fear of the first can inhibit practices that help to mitigate the second. Failure to operationalize QAPI practices also presents the risks associated with regulatory noncompliance for aging services providers participating in the Medicare and Medicaid programs. Effective management and mitigation of these risks are important for the persons served by provider organizations as well as for the organizations themselves.

American jurisprudence attempts to reconcile these important competing social interests by providing certain legal privileges from discovery. A privilege that protects quality improvement "work product" from discovery, for example, encourages providers to conduct thorough investigations, perform candid analyses, and recommend remedial actions by eliminating the risk that plaintiffs can discover such information and use it against providers in litigation.

However, a legal privilege is a narrow and rare exception to the general rule that favors broad discovery. A privilege may exist in common law or be provided in a statute. A party claiming a privilege must be able to demonstrate to the court that the privilege is recognized in the jurisdiction, that it applies to the information sought, and that the privilege has not been waived, as occurs when the information is communicated to someone outside the scope of the privilege. Accordingly, QAPI can be designed and structured to function in ways that optimize the chances that QAPI work product will satisfy privilege requirements. A systems thinking approach encourages us to address organizational problems and solutions in relation to the realities in which they exist.

Reality One

There is no guarantee that any document is protected by a privilege; courts determine whether privilege applies on a case-by-case basis. Courts typically attempt to construe discovery broadly enough to serve the purpose of truth finding in litigation yet narrowly and strictly enough to avoid unjustified "secreting" of relevant information.

Reality Two

A party claiming a privilege must demonstrate to the court that the privilege applies. Demonstrating by design, implementation, and adherence to practices that meet the intent and letter of the asserted privilege helps build a strong legal argument that privilege applies.

Federal and state case law provides real examples of lessons learned by litigants. Court opinions in privilege cases typically explain the facts, circumstances, and legal reasoning for

granting or denial of a privilege. Case law may also provide guidance that facilities can use to create QAPI processes that optimize conditions for the application of a privilege. (Neiman)

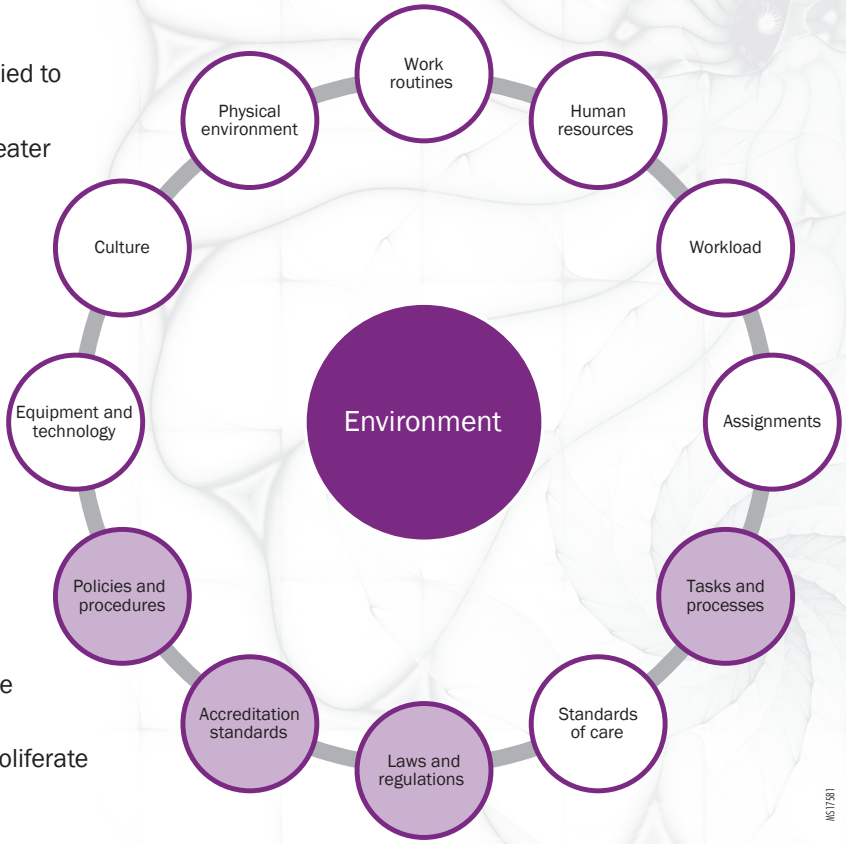
Keeping these realities in mind, aging services organizations should remember that "bundling" of practices strengthens their effectiveness for all stakeholders—persons served, employees, and the organization itself. Bundling can be achieved by designing and integrating risk management and QAPI practices in such a way as to reduce risks, improve quality, and increase safety. By continually developing a culture that values a common purposefulness and unity, a provider can create a new paradigm for addressing seemingly competing risks. In this new reality, implementing QI activity and processes designed to earn privilege protections effectively integrates otherwise competing interests. A paradigm is created whereby realistic efforts to earn protection from discovery coexist with ongoing improvement activities to prevent future similar events from occurring. That is, the paradigm shift no longer requires selecting one over the other, but instead includes one and the other, for a stronger bundled approach.

Systems Thinking Overview

A systems thinking approach pushes us to understand environments of all types through a greater appreciation of how all parts of a system interrelate—structures, processes, and people. Applied to care and service environments, systems thinking embraces the concept that the whole is greater than the sum of its parts. When various individual parts of a care and service environment are highly integrated (see Figure 1. Systems Thinking and Care and Service Environment), are aligned with the organization's mission and external environments, and act to support one another as part of daily and ongoing operations, it will be easier to establish and sustain an environment that inhibits adverse events and harmful or potentially harmful outcomes.

Conversely, when these processes are treated in a stand-alone fashion, fragmentation can occur, undermining cohesiveness, culture, and unity. These types of circumstances can lead to environments in which adverse events, poor outcomes, and harm proliferate

Figure 1. Systems Thinking and Care and Service Environment



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for all stakeholders, including persons served, families, visitors, individual members of the organization, and the organization itself.

By aligning complementary risk management and QAPI practices (e.g., adherence to policies and procedures, accreditation standards, and pertinent laws and regulations in completing all tasks and procedures) as part of the provider organization's overall health-care management system and daily operations, the organization betters its chances of maintaining an environment that best serves all stakeholders and furthers the organization's overarching purpose.

First Differentiate between Initial Investigations and Performance Improvement

Begin by increasing awareness about risk management and QAPI functions and the purposes they serve within the organization. Defining and mapping the differences between these two important functions will give staff a better understanding of where programs start and stop and why following process guidelines closely helps to integrate the functions and manage the risk that potential disclosure will inhibit efforts to improve quality and safety.

Risk management and QAPI functions are both vital to provider organizations. Exercising good organizational design and diligence can enable these processes to complement rather than compete with one another. Four important considerations can help in achieving an integrated systems thinking approach that encompasses both risk management and QAPI.

Consideration 1. Begin by establishing a clear definition of reportable incidents within the organization. Distinguish between initial investigation techniques, such as preparing incident reports and taking witness statements, and performance improvement analysis techniques, such as conducting interviews and performing root-cause analyses. The distinction between these techniques should be documented in written guidelines and policies and made operational.

- Initial investigation techniques are risk management techniques used to obtain facts about an incident, adverse event, or situation. These facts help improve other areas of organizational performance, such as the following:
  - Resident and family communication about incidents, harm, and potential harm
  - Licensing regulatory requirements to conduct postincident investigations
  - Human resource management after an incident
  - External reporting to licensing groups and authorities
  - Preparation for potential litigation

- Performance improvement techniques are QI techniques used to improve the organization, help prevent future incidents, and reduce opportunities for harm.

By establishing an appropriate degree of separation between risk management and QAPI processes, a provider organization can clarify and define associated risks and more effectively implement practices that contribute to risk mitigation. Delineation of the organization's risk management and QI processes and functions can help the provider appropriately segregate information for which it may claim a privilege from discovery, should the need arise.

To help distinguish between risk management and QAPI functions, consider the different nature of the assignments and documents utilized for the different purposes and goals of the two (fact finding or ongoing performance improvement). See Table. Differences between Risk Management and QAPI Documents. It is wise to begin by assuming that fact-finding documents such as incident reports, witness statements, and timelines may not meet the definition or intent of QI work product and therefore do not typically enjoy protection from discovery.

Table. Differences between Risk Management and QAPI Documents

Risk Management	QAPI
Initial investigation: investigating an incident or near miss after the fact	**Systems improvement:** preventing the next similar incident
Incident reports (basic facts about the incident)	Performance gap analyses (desired versus actual performance)
Witness statements (objective facts about what was observed—avoid opinions)	Witness or employee interviews
Incident timelines	Other root-cause analysis tools, such as fishbone diagrams
Review of the resident medical record for resident-related incidents	Executive summaries with improvement recommendations

Consideration 2. Next, remember that just because a QAPI or QAA committee uses a particular document for QAPI activities does not mean that a court will conclude that the document automatically is a quality assurance document, protected from discovery. Some jurisdictions place limitations on privilege in clear statutory or regulatory language. In Pennsylvania, for example, "information, documents or records otherwise available from original sources are not to be construed as immune from discovery or use in any such civil action merely because they were presented during proceedings of such committee" (Horty Springer "Pennsylvania Peer Review Statute").

Consideration 3. Recognize that a clear distinction between initial investigations and QAPI activities allows for effective use of QAPI committees and clarifies their purpose. When a chartered QAPI committee directs and executes certain efforts in a manner consistent with QAPI intent, it creates a more favorable foundation for building an argument for privilege protection. For example, an interview directed by the QAPI committee that is designed to obtain information to help better understand a process and how it may have contributed to an incident or adverse event differs from a witness statement taken with the purpose of obtaining the basic facts (who, what, where, and when) associated with a specific incident. In this instance, a QAPI-driven interview might best include employees from within the organization who were not directly involved in a particular incident, but who can describe how

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something is done day to day. This approach to QAPI focuses on systems design and performance improvement rather than on establishing individual fault and assigning blame. It can also help to avoid certain types of bias that can occur as a result of including persons who were directly involved in an incident. For instance, if an employee involved in an incident is asked to describe a process, the fear of discipline or of getting someone else in trouble may influence his or her description in an undesirable way.

Additionally, the effects of bias should be considered from two perspectives, the interviewer and the interviewee. For example, if a direct supervisor is conducting an interview, the interviewee may be less apt to accurately describe how a process or task is usually completed—especially if the interviewee knows his or her description deviates from organizational guidelines or policy. When done correctly, QAPI interviews can be a very effective tool in identifying and defining gaps between desired and actual organizational performance and behavior; when conducted as intended, such interviews may very well reveal that a poorly designed process, rather than an individual employee, created a situation where failure was likely.

Consideration 4. Recognize that QAPI work product should demonstrate a primary purpose of improvement and thus should reflect efforts to prevent future episodes of harm. QAPI work product therefore should include performance improvement recommendations.

Designing Integrated Risk Management and QAPI Functions

A written risk management plan and a written QAPI plan that serve as blueprints for an organization's risk management and QAPI committee activities provide an effective first step in developing and implementing practices that address these issues. These written plans should identify important elements such as committee membership, procedures, and the role and scope of each program.

By doing so, the plans formally state the scope of authority, purpose, and responsibilities of each committee as approved by the provider organization's leadership. In addition, written plans illustrate design and function by identifying standing committee membership, defining roles, establishing the frequency and manner in which the committee will meet, and describing committee activities to be conducted on both a regular and episodic basis, as circumstances dictate.

Federal and state statutes or regulations related to quality assessment and assurance programs convey expectations about quality assurance committee membership, procedures, and scope. CMS provides a QAPI description and background page

with additional information about the QAPI function at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapidefinition.html.

CMS requirements of participation on a federal level require quality assurance committee membership to include a physician designated by the facility, the facility's director of nursing, and at least three other members (42 CFR § 483.75[O][i-iii]).

State variations may include additional requirements, so it is important to design the organization's QAPI processes in a way that meets expectations set at both the federal and state level. Examples of state variations include the following:

- In Maine and North Carolina, pharmacists must be included in efforts to make recommendations relating to pharmaceutical services.
- In Maryland, the quality assurance committee must include a director of nursing, an administrator, a social worker, a medical director, a dietitian, and a geriatric nursing assistant employed at the facility.
- In Virginia, one of the three staff members rounding out the committee must be someone who demonstrates an ability to represent the rights and concerns of residents.

The written QAPI plan shapes the role and the scope of the QAPI program. It should distinguish between regular activities and interim activities and identify regularly scheduled meeting times and the circumstances under which the committee will be convened to direct interim QAPI activities, such as after incidents or adverse events have occurred that have a high severity or high potential for harm. Having a written QAPI plan can strengthen the organization's performance improvement practices and provide a foundation for a claim of privilege. A written QAPI plan should clarify the activities and types of QAPI work product that are maintained as confidential and that fall within a statute's privilege protection.

Another important organizational function involves postincident response and when to add QAPI committee direction. Timely involvement of the QAPI committee allows the committee to direct certain efforts and assign certain performance-improvement-related tasks after an incident occurs. This in turn, can create a stronger environment for the argument of protection. Therefore, postincident response practices should act to accomplish three important items:

- First, provide for timely notification and incident reporting inside the organization to mobilize risk management functions
- Second, provide for effective initial investigations and fact gathering necessary for ongoing risk management and QAPI efforts

- Third, identify incidents based on severity (e.g., incidents resulting in harm and near-miss incidents with the potential for harm) in order to introduce QAPI committee direction in the right time and measure

The provider organization's processes should account for timely internal and external notifications. Therefore, they should be designed to reflect the organization's size, complexity, decision-making structures, and chain of command (see Figure 2. Postincident Response Algorithm). The example above reflects how the processes may behave in a multisite provider organization that has risk, quality, and safety functions at the campus level and at the corporate or home office level. In a single-site provider organization, the tasks identified in the "Risk/Quality Management (Campus)" box and the "Corporate Risk Management" box may be combined to reflect the consolidated organizational structure.

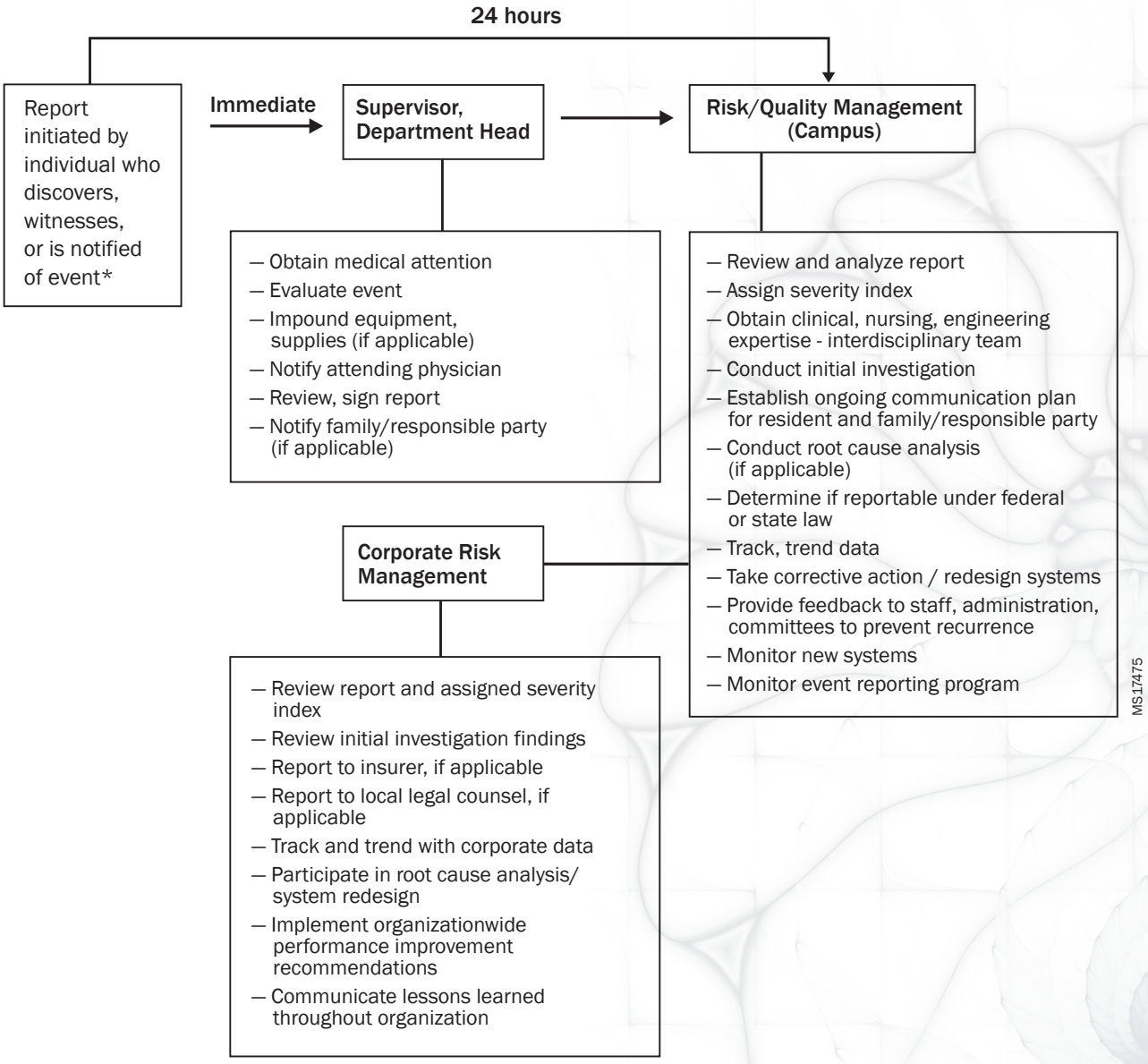
Timely external notifications include reporting to the organization's general and professional liability insurer; use of the severity index can help identify incidents that meet external reporting thresholds. As also noted in the "Corporate Risk Management" box, determination of which incidents to report, timeframes for reporting, and identification of the person or persons who have the authority and responsibility to report certain incidents to the organization's local legal counsel should also be included in the written guidelines.

Remember that even though a QAPI committee may use initial investigation documents as part of its analysis, a prudent assumption that fact-finding documents such as incident reports and witness statements typically fall outside of discovery protection may best serve the organization. Exceptions to this assumption may exist in specific circumstances where attorney–client privilege may apply, such as when the incident report and witness statements are prepared at the specific request of the provider's attorney for purposes of preparing a legal defense. Applicable circumstances such as attorney–client privilege are discussed in "Six QAA or QAPI Guidelines to Consider."

Be aware that documentation that an organization is required to generate for a regulatory compliance purpose is not shielded from those regulators just because the documentation was prepared by a member of a QAPI committee or was reviewed or analyzed by a QAPI committee. This lesson is explained in a precedent-setting opinion from the 3rd Circuit U.S. Court of Appeals. In that matter, state surveyors relied on information contained in a facility's incident reports as a basis for issuing deficiency citations (*Jewish Home of Eastern PA v. Centers for Medicare and Medicaid Services*). The facility claimed that the incident reports were privileged quality assurance documents.

Federal regulations require skilled nursing facilities to investigate and report to state survey agencies all allegations of resident mistreatment, neglect, or abuse and misappropriation of resident property. The incident reports at issue in Jewish Home included factual information

Figure 2. Postincident Response Algorithm



*Serious events reported immediately to supervisor and risk manager

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Five QAA or QAPI Guidelines to Condider

1. Any review of quality indicators should be directed by the QAA committee. Reports or documentation detailing the QAA committee's findings should be authored by or at the behest of a member of the QAA committee.
2. Reports and documents should not raise issues of compliance with regulations. Records of a QAA committee are not privileged if related to compliance of the QAA committee with the requirements of the regulations.
3. Reports or documentation generated by or at the behest of the QAA committee should clearly state that the report is prepared for purposes of quality assurance. The substance of the documents must analyze and evaluate quality of care.
4. Quality assurance discussions should be held within a formal committee and documents should be kept confidential. Importantly, sharing quality assurance documents with the Board of Directors does not operate as a waiver of the privilege and is encouraged by CMS.
5. QAPI documents should not be utilized for non-QAPI purposes. Avoiding "mixed uses" decreases the likelihood of inadvertently waiving the QAA Privilege.

Reprinted with permission from Buchanan Ingersoll & Rooney PC., Pittsburgh, Pennsylvania. Maintaining Privilege for Quality Assurance Performance Improvement (QAPI) Documents and Reports*. 2017 Aug 8 [cited 2017 Aug 9] http://www.bipc.com/maintaining-privilege-for-quality-assurance-performance-improvement-(qapi)-documents-and-reports*

that federal regulations require be reported to state survey agencies. The court noted that it would be strange if the documentation that a facility was required to generate for a regulatory purpose were shielded from those very regulators whenever such documentation has been reviewed by a quality assurance committee. Consequently, the court held that the statute did not protect the facility's incident reports from use by surveyors as a basis for citing a deficiency because the incident reports were generated for regulatory compliance purposes and did not constitute "minutes, internal papers, or conclusions generated by the quality assurance committee." The court clarified that internal deliberations by the QAPI committee and its minutes and internal working papers and conclusions are protected from disclosure.

To support a claim of privilege for bona fide quality assurance documents, consider adding statutory citation numbers that correspond to applicable federal and state QAPI and quality assurance statutes when marking documents as confidential and privileged quality improvement work product. For example, indicate "Privileged and confidential: quality improvement work product as defined and protected by [federal statute name and number] and [state statute name and number, if applicable]." The section below on federal and state peer review laws provides references that may help determine what protections might be available for your organization. However, recognize that marking a document "privileged" or

"confidential" does not in itself confer any privilege on the document. Courts will not exalt form over substance.

Just as important as creating integrated and complementary risk management and QAPI functions, provider organizations must consistently go about doing the risk management and QAPI functions as described in the written programs and guidelines. Risk and QAPI practices should become part of daily operations. It is also good practice to document execution of these activities, recording their completion and illustrating adherence to the practices.

Writing and preserving meeting minutes is an important QAPI committee activity. Meeting minutes that document assignments and the purposes for assignments—such as delegating a committee member to conduct a witness interview to find differences between an organization's desired versus actual function—can help make a stronger argument for privilege from discovery because the purpose of the assignment is recorded as being directly connected to the QAPI committee's scope and work. Nevertheless, a good practice is to avoid including extraneous information in meeting minutes; instead, include information that would be required to avail a privilege (e.g., attorney Ms. XYX was invited and is in attendance). Minutes can also tie assignments and activities to PI recommendations developed for the primary purpose of decreasing future risk, improving quality, and increasing safety for those served by the organization and those who serve in the organization.

Avoid overextending asserted protection to documents that fall outside of QI activities. Providers should also work to avoid situations of "mixed uses" of documents between fact-finding and performance improvement activities, which may act to undermine applicable protection for eligible work product for the latter by opening the door to arguments that the documents were not utilized for the sole purpose of analysis and performance improvement. Documents or reports created for QAPI purposes should not address regulatory compliance or raise questions about regulatory noncompliance, for example, because such records are not subject to the disclosure restrictions provided in the Act and its implementing regulations.

Building on the example given above in "Consideration 3," an organization should have separate documents for a "witness statement," which might be part of the initial investigation tools after an incident, and an "interview form," which might be associated with a provider organization's QAPI tools. These documents should be given different titles, and the titles should be used consistently in oral and written communications throughout the organization. If a provider organization uses the title phrase "witness statement" interchangeably to describe the two documents, difficulties may be created in defending these documents from discovery—even if they meet the definition and spirit of the QAPI process and available protections.

Attorney–client privilege may also protect documents from discovery. When using a provider organization's QAPI function to analyze and develop performance improvement recommendations after a specific incident or near-miss event, request direction from the organization's legal counsel or from defense counsel for those efforts.

Finally, conducting annual reviews of the risk management plan, QAPI plan, initial incident response, and initial incident investigation practices is also vital to program efficacy as it helps to ensure that these guidelines and daily operational activities are consistent with applicable laws and regulations. These reviews also provide valuable feedback necessary to identify gaps between desired and actual performance within the organization. Bundling regular plan review and revision with other associated practices helps to demonstrate a provider's diligence and helps substantiate arguments that the organization has an active QAPI program in place.

QAPI Resources from CMS. CMS makes available various resources (materials or websites) to support QAPI implementation for nursing home providers. These resources are also helpful for other service lines throughout the aging services continuum of care and can be accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapiresources.html.

Discovery and Admissibility

Discovery and privilege. Discovery in civil lawsuits is a tool guided by a jurisdiction's rules of civil procedure. Generally, discovery rules permit litigants to discover nonprivileged information or material that is relevant to the subject matter of the litigation. A party to the litigation may resist discovery by claiming a specific legal privilege and demonstrating to the court that the privilege exists and that the information or material sought is privileged from disclosure. When a privilege is provided by a statute, the words of the statute define the scope of the privilege. When the language of the statute is ambiguous, courts interpret the application of the privilege by considering the jurisdiction's public policy and the intent of the legislature in enacting the statute. Courts must also follow relevant legal precedent in the jurisdiction as established by higher courts, such as the state's supreme court.

Admissibility. A statute that provides a privilege from discovery may explicitly provide that privileged information shall not be offered or received into evidence at trial, or the statute may be silent on the issue of admissibility. The admissibility of evidence at trial is typically governed by the rules of evidence in a jurisdiction. Rules of evidence address many legal issues, including "relevancy" and its limits, and the application of privileges. Information or material that is admitted into evidence must be admitted for a specific purpose permitted by the rules of evidence. Once information is admitted into evidence, a jury may consider it for the purpose for which it was admitted (for example, to show fault). Disputes over the admissibility of evidence are managed by a trial judge or magistrate.

Case Review (Illinois):

Quality Improvement Process: Timing and Direction of Investigation

In 2017, an Illinois court of appeals reasoned that whether a statutory privilege from discovery applies to information gathered in a nursing home's investigation of a resident's fall depends on when and why the information was prepared. The court held that an incident report and witness statements prepared pursuant to the facility's quality assurance practices were not privileged because the report and witness statements were prepared before the facility's quality assurance process began. The Illinois Nursing Care and Quality Improvement Act provides that "proceedings and communications" of a peer review or quality assessment and assurance committee of a long-term care facility shall be privileged and confidential.

In this case, the plaintiff asked the facility to disclose all investigation reports regarding a resident's fall. The facility refused to turn over an incident report and written witness statements prepared during its internal investigation, maintaining that the documents were privileged by the Act because they were prepared for its quality assurance committee.

The trial court examined the records in an in camera review, along with an affidavit from the facility's administrator explaining the facility's quality assurance process. The facility's process required the completion of quality assurance investigation reports regarding incidents involving injury to a resident and required that such reports be prepared for the purpose of consideration by the quality assurance and/or falls committee. The trial court found that the report in the fall incident in question contained facts but no recommendations for improvement, and no indication that any quality assurance or falls committee had reviewed the report or the statements. The court concluded that the records were not privileged and ordered their disclosure. The dispute was ultimately resolved on appeal.

In order to determine whether the privilege applied, the appeals court followed the legal reasoning of the state's highest court in a case involving an identical privilege in the state's Medical Studies Act relevant to hospitals. In that case, the high court held that the Act's privilege does not extend to information generated before a peer review process begins, regardless of whether the information is later used by the facility for corrective action. The high court reasoned that if the simple act of furnishing a quality improvement committee with earlier-acquired information were sufficient to cloak that information with a statutory privilege, a hospital could effectively insulate all adverse facts from discovery except for those in the patient's medical records. Accordingly, the appellate court held that the disputed records were discoverable, rejecting the nursing home's argument that if not for the existence of its quality assurance committee, the investigative report and witness statements would never have been created. (*Lindsey v. Butterfield Health Care II*)

Suggestion: Establish facility policy and procedure that align with privilege requirements. For example, establish a quality assurance committee process that is triggered by the committee's receipt of a report of an adverse event. Establish policy that encourages and requires reporting of an adverse event or incident to the committee and establishes the committee's next steps, such as routing to a specific committee (e.g., a falls committee) for investigation and analysis; determining whether to perform an analysis of the event and its contributing causes; taking remedial action; and providing recommendations for improvements to mitigate future risk.

Protection and Privilege

Attorney–client privilege. Attorney–client privilege protects from disclosure to third parties the confidential communications between an attorney and client that are conducted for the purpose of obtaining and providing legal advice. The scope of attorney–client privilege and how the privilege is applied to particular circumstances vary among jurisdictions.

Attorney–work product privilege. Attorney–work product privilege protects from disclosure to third parties materials that are prepared for legal counsel in anticipation of litigation. The privilege protects materials prepared by legal counsel in preparation of the claims or defenses of a client's legal case, such as documents reflecting the attorney's litigation strategy. The privilege is not ironclad; jurisdictions differ on the application of the privilege.

Privilege of self-critical analysis. A few jurisdictions (for instance, New Jersey) recognize the common law privilege of self-critical analysis, a qualified privilege based on public policy considerations and intended to encourage honest critical self-evaluation in light of a problem or incident.

Federal Peer Review and Quality Assessment and Assurance Law

The Healthcare Quality Improvement Act (HCQIA). In 1986, Congress concluded that "the increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems . . . [that] can be remedied through effective peer review" (42 USC § 11101[1-3]). Thus, it enacted the Healthcare Quality Improvement Act (HCQIA) with two stated goals: improving the quality of medical care and eradicating the problem of incompetent physicians and dentists. HCQIA promotes these goals by encouraging "healthcare entities" to engage in professional review action, including credentialing determinations, by providing limited immunity from liability to the entities and individuals performing review in accordance with the act's standards. "Healthcare entities" include hospitals, group medical practices, and health maintenance organizations that provide healthcare services and follow a formal peer review process for the purpose of furthering quality healthcare. HCQIA does not provide a privilege from discovery.

The Affordable Care Act of 2010. The Affordable Care Act of 2010 requires nursing homes to have an acceptable QAPI plan within a year of the promulgation of a QAPI regulation. Federal regulatory requirements for QAPI programs for nursing facilities provide protection from disclosure as follows: "A state or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section" (42 § CFR 483.75).

Case Review (Iowa):

Quality Improvement Process: Capture and Routing of Incident Reports

In 2017, the Supreme Court of Iowa held that a hospital's "Patient Safety Net" (PSN) materials, including an incident report, were protected by a privilege in the state's "morbidity and mortality" statute and thus were not discoverable in a medical negligence lawsuit. The plaintiff claimed that he sustained a shoulder injury because of the hospital's negligent handling of him during transport and during an abdominal scan. A hospital employee filed an incident report in the PSN system about the occurrence after staff found a problem with the patient's left shoulder following the scan. The patient sued the hospital and requested the incident report and related documents.

The hospital resisted the request to produce the information, claiming privilege under the state's morbidity and mortality statute. The statute provides a privilege from discovery for information used in the course of any study intended to reduce morbidity and mortality rates in hospitals and nursing homes. Iowa law also requires hospitals to have quality improvement programs and to implement written quality improvement plans. The hospital demonstrated to the court that it had established an electronic reporting system that allows it to track incident reports and route them to an appropriate department for resolution and remedial action. The hospital demonstrated that its policy encourages employees to use the system to file a form for adverse events and other concerns regarding the health, care, and safety of its patients. The court found that the hospital's PSN system aligned with the intent of the legislature in enacting the morbidity and mortality statute and concluded that the incident report and related documents were privileged under the statute as "morbidity and mortality" information. (*Willard v. State of Iowa*)

Suggestion: Although this case involved a hospital, the legal lessons are applicable to long-term care. The Iowa case illustrates one state court's approach to a privilege granted by the state's morbidity and mortality statute. Be aware that most state jurisdictions do not provide a statutory privilege that encompasses incident reports. Courts generally treat incident reports as nonprivileged records that document the facts of an incident or event and that are maintained in the ordinary course of business. Obtain the advice of legal counsel in your facilities' jurisdiction(s) to determine whether a state statutory privilege may be available to protect incident and adverse event reports from discovery, and if so what best practices can be set in place in policies and procedures to earn the privilege. If no statutory privilege is available, determine whether a common law privilege, such as attorney–client privilege and/or attorney–work product privilege, might be available, and if so, what policies and procedures the facility might implement to support the privilege.

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The Patient Safety and Quality Improvement Act of 2005 (PSQIA) (Pub. L. No. 109-41). Through PSQIA, Congress authorized the creation of patient safety organizations (PSOs), establishing for the first time a protected legal environment in which providers in all states and U.S. territories may share certain information about patient safety events and quality without the threat of information being used against them. The Act provides that long-term care facilities (including state-licensed or state-authorized assisted-living residential care facilities that provide healthcare services and other community-based care providers) are eligible to participate in a PSO.

By participating in a PSO, providers may voluntarily and confidentially report their patient safety and quality information for aggregation and analysis and in return receive recommendations, protocols, best practices, expert assistance, and feedback to improve their patient safety activities. PSO participants benefit from a broad federal legal privilege that protects "patient safety work product" from subpoena and discovery and use in civil and criminal litigation against providers in any state or federal court and other tribunals, subject to a few narrow exceptions. The information that flows between providers and PSOs, and providers' deliberations about whether and what to report, as well as the fact of reporting, are privileged and confidential.

State Peer Review and Quality Assurance Laws

Information on states with quality assurance protection laws can be found at the following sources:

- https://www.hortyspringer.com/peer-review-statutes-by-state/ (Horty Springer "Peer Review Statutes by State")
- http://www.butlersnow.com/wp-content/uploads/pdfs/attorney_publications/case-law-a-fifty-state-survey-of-the-medical-peer-review-privilege.pdf (Modak-Truran)

In Summary: *Earning* and Asserting Privilege from Discovery for Quality Improvement Work Product

Designing integrated risk management and QAPI systems that complement each other can help support an argument to protect certain documents, discussions, and activities should the need arise. Designing an integrated risk and quality platform with guidelines to direct activities; bundling practices that strengthen each other; and following those practices consistently creates an environment that helps defense counsel construct a legal argument for protection of certain items on an organization's behalf.

Risk management and QAPI processes can be designed to optimize the chances that a legal privilege will be applicable in the event of litigation. By understanding the nature of various risk management and QAPI functions as well as the spirit and letter of quality assurance and peer review laws, and by exercising diligence to make those practices part of daily operations, the provider will be better positioned to claim an applicable legal privilege from discovery if needed. Just as importantly, when provider organizations work to strengthen organizational functions such as resident and patient safety, risk management, and quality improvement, they do so for the greatest of reasons: to provide the best care possible for the persons served.

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