Understanding and Litigating the Federal Quality Assurance Privilege

James N. Martin, Jr.

In *Henderson Cty. Health Care Corp. v. Wilson* the Kentucky Supreme Court recently held the Federal Quality Assurance Privilege (FQAP) applies to nursing home malpractice litigation and protects nursing facility quality assurance committee documents from discovery. 612 S.W.3d 811 (Ky. 2020).

In the unanimous decision, the Court adopted a case-by-case approach which requires a trial court to determine how, why, and by whom a document was generated. This article will explain FQAP and its history. It will discuss the factors trial courts will consider when determining the privilege. Finally, the article will provide practice pointers for health lawyers advising clients on FQAP before litigation and for civil litigators once lawsuits occur. Many of these practice pointers involve familiarizing oneself with CMS regulations, as it is anticipated that the regulations will become increasingly important in FQAP disputes.

Nursing Home Litigation Against Kentucky Long-Term Care Facilities

The insurance claim costs needed to pay indemnity or expenses for Kentucky nursing facilities have risen steadily since 2014. This is according to the actuarial analysis reported in the 2020 Oliver Wyman and Marsh Professional and General Liability Benchmark for Long-Term Care Providers found at *https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/ltc-pl-gl-benchmark-2020.pdf.*

A *Kentucky Law Journal* article reports that punitive damages are much more likely to be awarded in nursing home litigation as compared to typical personal injury litigation. Punitive damages are generally awarded in only five percent of personal injury cases, but they are awarded in 20 percent of nursing home cases. Jamison, Hannah R. (2014) "Quality Assurance Privilege in Nursing Home Litigation: Why Kentucky Should Adopt the Narrow Approach," *Kentucky Law Journal*: Vol. 103: Iss. 2, Article 5. It is reported that at least one major nursing home provider left Kentucky altogether citing "frivolous lawsuits" as the reason for its departure. *Id.*

Litigation impacts even the highest quality facilities, not just lower performing ones. A study published in the *New England Journal of Medicine* examined the "Relationship between Quality of Care and Negligence Litigation in Nursing Homes." N Engl J Med 2011; 364:1243-1250. As one might expect, researchers found that nursing homes with more survey deficiencies and those with more serious deficiencies had higher odds of being sued. However, all these effects were relatively small. For example, nursing homes with the best deficiency records (10th percentile) had a 40 percent annual risk of being sued, as compared with a 47 percent risk among nursing homes with the worst deficiency records (90th percentile).

One key aspect of nursing home litigation involves the disclosure of the nursing facility's own internal reports of problems, incidents or concerns. Such reports may be extremely valuable to plaintiffs pursuing a negligence claim to show both the presence of a dangerous condition and to prove the key fact that a facility was aware of the dangers. Prior to the *Wilson* opinion, Kentucky courts lacked clear guidance on whether these reports were privileged or discoverable.

The Federal Quality Assurance Privilege

In 1987, Congress enacted the Federal Nursing Home Reform Act (FNHRA). The overarching goal of FNHRA was to improve the quality of care for nursing home residents and either to bring substandard facilities into compliance with federal requirements or to exclude them from the Medicaid and Medicare programs. *In re Subpoena Duces Tecum to Jane Doe, Esq.*, 787 N.E.2d 618, 620 (N.Y. 2003). To accomplish this goal, FNHRA established a system of "elaborate oversight and inspection of nursing homes." *Id.*

One of FNHRA's key mechanisms to improve quality of care is a universal requirement that all facilities create an internal quality assurance committee. 42 U.S.C. 1392r(b)(1)(B). Many facilities refer to these committees as Quality Assurance and Performance Improvement (QAPI) committees because CMS regulations use the QAPI acronym. 42 C.F.R. §483.75(g)(2). The *Wilson* opinion uses this QAPI abbreviation.

Under the FNHRA, a QAPI committee meets at least quarterly to "identify issues" in the facility and "develops and implements appropriate plans of action to correct identified quality deficiencies." 42 U.S.C. 1392r(b)(1)(B). It is this portion of the FNHRA which contains a single sentence creating the FQAP. The statute states, "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 subparagraph." 42 U.S.C. 1392r(b)(1)(B). This same language can be found in the federal regulations at 42 C.F.R. §483.75(h).

Prior to *Wilson*, litigants questioned whether the FQAP applied to malpractice litigation whatsoever in Kentucky. On its face, the privilege applies to "states" and "the Secretary," which is the U.S. Secretary of Health and Human Services. 42 U.S.C. 1301(a)(6). Some plaintiffs argued that the privilege was meant to apply only in the regulatory process, not civil litigation. They reasoned that the provision had no applicability in federal court since federal courts are clearly not "the state" or "the Secretary." As such, a facility would have no privilege if a plaintiff's malpractice complaint were removed to federal court. Plaintiffs argued that it was easier to believe that the privilege was meant to apply only in regulatory matters and not intended to apply in any courts, federal or state.

The scope of the privilege was also vague, with mere reference to "records of such committee." As such, trial courts had little guidance on the exact types of documents the privilege would protect. *Wilson* provides this guidance and holds that the FQAP is applicable to malpractice and includes materials created by outside consultants "at the behest of" the QAPI committee.

The Privileged Reports Were Created Outside of the QAPI Committee

The plaintiff in *Wilson* allegedly suffered multiple injuries at the defendant nursing facility, including serious bedsores. *Wilson*, 612 S.W.3d at 815. During the discovery process, the plaintiff requested all "reports from any consultant or management personnel hired to evaluate the adequacy of care rendered to residents." *Id.* at 815. The facility refused to turn over so called nurse consultant reports. It was undisputed that the reports were created by outside consultants, not actual members of the QAPI committee. Therefore, the question to answer was whether records created "for" the QAPI committee constituted records "of" the QAPI committee.

The reports consisted in three basic categories. First, "chart audits" contained reviews of the residents' medical charts. Second, "compliance rounds" were observations of the facility staff duties. Third, statistical data was reviewed and summarized. *Id.* at 815-816. The express purpose behind the reports was "to evaluate the facility's quality of care and provide guidance where care can be improved." *Id.* at 815.

The *Wilson* Court acknowledged the reports could be very valuable to a plaintiff's case, since such reports might contain "highly relevant information about the dangerous conditions" at the facility. The Court acknowledged that the reports might reveal the facility's "potential knowledge of those conditions." *Id* at. 820.

The trial court ruled that the nurse consultant reports were not privileged and ordered that they be produced. It reasoned that the nurse consultant reports were not records of the QAPI committee because the reports were not actually authored by the QAPI committee. *Id.* at 816.

The facility then filed a petition for a writ of prohibition in the Court of Appeals. The Court of Appeals denied the writ, holding that the trial court was correct in finding the documents were not protected by the FQAP, as they "were not generated by [the facility's] quality assurance committee, 'nor were they minutes, internal papers or conclusions of' the committee." *Id.* at 816. The facility appealed to the Kentucky Supreme Court.

In construing the scope of the FQAP the *Wilson* court considered the legislative purpose of the FQAP but was also keenly aware of the longstanding precedent that all privileges be narrowly interpreted. The court considered both Kentucky caselaw and cases from other states and federal jurisdictions.

i. The Legislative Purpose of the FQAP

The *Wilson* court placed significant emphasis on the legislative intent behind the FQAP. It found that congress intended QAPI committees to be "key internal mechanisms that allow nursing homes opportunities to deal with quality concerns in a confidential manner and can help them sustain a culture of quality improvement." *Id.* at 817–18 The court recognized the privilege was "designed to encourage thorough and candid peer review and thereby improve the quality of care." *Id.* at 18. The Court did not want nursing facilities to "shy away from self-critical analyses and improvements for fear that the same can be used against them in a civil suit." *Id.* at 820–21.

ii. Privileges Must Be Interpreted Narrowly

Kentucky law has long held that privileges must be construed narrowly. The *Wilson* opinion acknowledges this by citing the case of *Sisters of Charity Health Sys., Inc. v. Raikes*, 984 S.W.2d 464, 468 (Ky. 1998). *Wilson*, 612 S.W.3d at 817. The *Sisters of Charity* case involved Kentucky's peer review privilege in KRS 311.377(2). Peer review is the process by which a hospital investigates physician qualifications. The process depends on candid evaluations of a physician's skills by the physician's colleagues.

The peer review process has similar features to the QAPI since openness and transparency are believed to improve patient safety and care. Moreover, *Sisters of Charity* involved whether the privilege should be applied in malpractice litigation. As such, the case was a natural place to look for guidance on interpreting the scope of privileges.

The peer review statute in *Sisters of Charity* contained a very broad privilege for all civil litigation. It stated that peer review documents "shall be confidential and privileged and shall not be subject to discovery, subpoena, or introduction into evidence, in any civil action in any court." *Sisters of Charity*, 984 S.W.2d at 471 (Stephens, C.J., dissenting). Despite this otherwise clear language, the *Sisters of Charity* court held that the peer review privilege did not apply in malpractice litigation. The court believed applying the peer review privilege to malpractice cases would be an unreasonable result that could not have been intended by the legislature. Such a privilege "tilts the legal playing field against [plaintiffs], who have not waived any rights pursuant to the statute to the advantage of Appellants, who, as defendants in a medical malpractice suit, were not intended to benefit from the statute's privilege." *Sisters of Charity*, 984 S.W.2d at 470.

iii. The Kentucky Case of *Clouse*

The Kentucky Supreme Court addressed the FQAP previously, in *Richmond Health Facilities-Madison, LP v. Clouse*, 473 S.W. 3d 79, 84 (Ky. 2015). In *Clouse*, the majority opinion declined to define the scope of the FQAP privilege because "the parties asserting the privilege failed to produce the documents for an in camera review." *Wilson*, 612 S.W.3d at 818. However, *Clouse* contained a concurring opinion. Justice Barber, writing for himself, Justice Cunningham, and Justice Venters, analyzed the two different approaches which emerged regarding interpretation of the scope of FQAP. *Clouse*, 473 S.W.3d at 86 (Barber, J., concurring).

The narrower interpretation of the FQAP held that only those documents actually

authored by the QAPI committee could be entitled to protection. This is the so-called "Missouri Rule" based on the Missouri case of *State ex rel. Boone Ret. Ctr. v. Hamilton*, 946 S.W.2d 740 (Mo.1997). *Clouse*, 473 S.W.3d at 87 (Barber, J., concurring). The more expansive approach held that documents could be privileged even if they were not actually authored by the QAPI committee so long as they were created "at the behest of" the QAPI committee for QAPI purposes. Clouse, 473 S.W.3d at 88 (Barber, J., concurring). This is known as the "New York Rule" after the New York case of *In re Subpoena Duces Tecum to Jane Doe, Esq.*, 787 N.E.2d 618 (2003). *Clouse*, 473 S.W.3d at 88 (Barber, J., concurring).

The *Clouse* concurrence concluded that because the Missouri Rule was a narrower interpretation, it was more consistent with the precedent in *Sisters of Charity Health Systems*. *Id.* at 89. Justice Barber ultimately explained that he would adopt the narrow approach "and hold that only documents generated by a nursing home's quality assurance committee fall within the scope of the FQAP." Id. at 87.

Wilson *Rejects the Narrow Rule and Provides Guidance*

Ultimately, the *Wilson* court weighed the competing interests and rejected the Missouri rule that FQAP only protects documents authored by the QAPI committee members. *Wilson*, 612 S.W.3d at 821. It found that the nurse consultant reports were used by QAPI committee "to improve care at the facility" *Id.* at 822. Under the system in place, the outside consultants were effectively agents of the QAPI committee. *Id.* at 822.

The court reasoned that the outside consultants did not inhibit the goals of FNHRA. The outside consultants were compared to experts consulted by attorneys as part of the attorney-client relationship. The court found that "contracting for assistance" does not inhibit the FQAP goals, "just as an attorney contracting with an outside expert does not inhibit the confidential relationship between the attorney and his client. *Id.* at 822. The court instructed that if a document "is generated for the express purpose of aiding the committee in its work, then it will likely be privileged." *Id.* at 821.

The court showed concern that nursing facilities may attempt to expand the privilege beyond the intentions of the FNHRA. To protect litigants from this overreach, the court instructed trial courts to take a case-by-case approach and determine at how the document was generated, why it was generated and by whom it was generated. *Id.* at 821. Factors for trial courts to consider are as follows:

- Mere review by a QAPI committee does not protect documents. *Id.* at 821.
- Documents "for purposes unrelated to the committee are not protected by the FQAP." *Id.* at 822.
- Documents kept "in the ordinary course of business" are not privileged. *Id.* at 821.
- Documents that are "kept as a part of the patient's medical record" are not privileged. *Id.* at 821.
- Documents "required to be generated pursuant to other legal requirements" are not privileged. *Id.* at 821.

Practice Pointers

Wilson may dramatically change discovery in nursing home litigation. Below are considerations and practice pointers for attorneys, including those who advise clients prior to litigation and those who litigate for either defense or plaintiff. Several of the recommendations involve familiarizing oneself with CMS regulations to determine whether reports are QAPI related or not. It is anticipated that federal regulations will become increasingly important to FQAP interpretation.

i. QAPI Committee Membership Considerations.

Attorneys should determine precisely who is on the QAPI committee. In advance of litigation, defense counsel may advise facilities to consider whether outside pharmacy, nursing or dietary consultants should be included on the QAPI committee. While the *Wilson* opinion explicitly states that membership on the committee is not required for FQAP protection, delineating the QAPI committee removes any uncertainty as to whether the author of a document is a committee member.

ii. Mark QAPI Documents as Privileged.

Defense counsel may consider advising clients of this best practice prior to litigation. The *Wilson* opinion states that the burden of proving FQAP "rests on the party claiming its benefit." *Id.* at 817. Explicitly stating the privilege in the document itself is one powerful way proving privilege.

iii. Avoid Combining QAPI and Business Reports

Defense counsel may consider advising clients to avoid combining QAPI materials with reports of general business matters. Combined reports may be more efficient for facility operations, but could create ambiguity in litigation as to whether the reports were generated "in the ordinary course of business" or were generated for the purpose of "aiding the committee."

Conversely, Plaintiff's counsel will want to establish with witnesses what financial purposes are included in various documents. *Wilson* does not define "ordinary course of business" but presumably, plaintiffs attorneys will have greater success proving the non-privileged status of financial documents. Plaintiff attorneys may ask if reports contain census, payor source, open positions or staffing information.

iv. Determine Which Reports are Regulatory Requirements

Both plaintiff and defense counsel should familiarize themselves with CMS regulations found in 42 C.F.R. 483 and make note of all reports required to be kept therein. *Wilson* states that reports kept for "other legal requirements" are likely unprivileged. *Id.* at 821. This increases the importance of CMS regulations in discovery disputes.

Plaintiff's counsel will likely want to depose facility witnesses to confirm that various reports are regulatorily required in support of plaintiff's arguments. Some examples of reports described in the regulations include resident council minutes and facility responses thereto as found in 42 C.F.R.48310(f)(5)(iv)(A), annual emergency preparedness training as found in 42 C.F.R 483.73(d)(1)(iii), and reports of suspected crimes as found in 42 C.F.R. 483.12(b)(5)(i)(A). This is not an exhaustive list and many other reports are required by the regulations.

v. Compilation Documents Increase Likelihood of Privilege

Defense counsel should advise facilities that medical records cannot be cloaked with privilege by simply "funneling" them to the QAPI committee. Instead, documents that compare and compile information from various medical sources are more likely to receive protection. *Id.* at 820.

vi. Plan for Waiver Arguments

Prior to litigation, defense counsel should consider advising facilities that disclosing QAPI reports to persons outside of the QAPI committee may be deemed a waiver of the FQAP. Waiver was not explicitly addressed in *Wilson*, but the opinion states that the nursing consultant reports were provided to the QAPI committee and there is nothing in the opinion to indicate that the reports were shared outside of that committee. *Wilson* compares the FQAP to the attorney client privilege. There is ample caselaw indicating that waiver of the attorney client privilege occurs if communications are shared with unnecessary third-parties. *Lexington Public Library v. Clark*, 90 S.W.3d 53, 61 (Ky. 2002).

Plaintiff's counsel should ask facility witnesses whether reports are posted at the nurse's station or used in facility wide training. For facilities in a corporate conglomerate, plaintiff's counsel may ask if the reports are available to nearby facilities either via email or intranet. Also, are the documents in question provided to state surveyors, local police or adult protective services? Note again, the CMS regulations and CMS's guidance to surveyors often describe what documents must be provided to outside agencies. If so, plaintiffs may argue that the privilege has been waived.

The regulations can also benefit facilities. For example, to the extent that QAPI documents are shared with corporate ownership, facilities can argue that such sharing does not waive FQAP since the QAPI committee is required to make reports to the facility's governing body under 42 C.F.R. 483.75(g)(2).

vii. Provide Documents to the Court for Inspection

Once a motion to compel has been filed, defendants should provide QAPI documents to the trial court for in camera inspection along with sufficient affidavits to enable the trial court to evaluate the claims of privilege. In *Clouse*, the defendant's failure to provide the trial court with documents or a detailed description thereof warranted automatic denial of the FQAP. *Wilson*, 612 S.W.3d at 818.

viii. Assert the FQAP as Found in CMS Regulations

When asserting the FQAP, defense counsel should consider emphasizing that the FQAP is found not only in federal statute, but also in the federal regulations. Under the supremacy clause of the United States Constitution, state laws that conflict with federal agency regulations are preempted. *City of New York v. F.C.C.*, 486 U.S. 57, 64 (1988). As such, the FQAP found in 42 C.F.R. §483.75(h) is binding in state court. The *Wilson* opinion generally references federal regulations at 42 C.F.R. 483 and notes that the FQAP is a subsection thereof. *Id.* at 815. However, *Wilson* focuses heavily on the FNHRA statutory text. The vagueness of the statutory text may lead to narrow interpretations since privileges are to be construed narrowly.

Defense counsel can combat the vagueness of the statute by pointing to the QAPI regulations at 42 C.F.R. 483.75. The regulations describe in detail the exact types of data and reports QAPI committees must review and create. This may be particularly important in the area of incident reports, which are always hotly contested in litigation.

Wilson mentions incident reports indirectly by explaining that one jurisdiction found that incident reports were part of the medical record. *Id.* at 819. Defense counsel in Kentucky may want to argue based on federal regulations that incident reports are required for QAPI purposes, not for medical records purposes. Support for this position can be found at 42 C.F.R. 483.75(e)(2), which states that the QAPI must track "medical errors" and "adverse resident events." If the defendant has already made clear that it intends to enforce the FQAP as found in CMS federal regulation it will be easier to argue that the surrounding QAPI regulations shape the scope of that privilege.

Conclusion

The *Wilson* case has clarified that FQAP is a powerful tool for protecting QAPI materials. This is true even though QAPI reports may contain highly relevant and damaging information. Counsel must be aware of the factors courts will use in determining the privilege. Because many of these factors are implicated by CMS regulations, it is important to have a good grasp of what those regulations require.

Disclosure: The appeal and underlying litigation in *Henderson County Health Care Corporation v. Wilson* was handled by Steptoe & Johnson attorneys, Craig L. Johnson and James N. Martin Jr.

James N. Martin, Jr. is an attorney in the Louisville office of Steptoe & Johnson, PLLC. Licensed in Kentucky and Indiana, the bulk of his practice is devoted to medical negligence defense. He is a member of the LBA and the Kentucky Association of Health Care Facilities (KAHCF). ■