Discovery: The Gatekeeper of Defense Verdicts

Amber K. Knouff, Esq.
Kathryn A. Eckert, Esq.

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OBJECTIVES OF PRESENTATION

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Objectives

- Overview of Privilege afforded to nursing homes in litigation and administrative matters
- Limitations of those privileges
- Current legal trends in broadening privilege through the Patient Safety Act
- Scope of PSA and limitations

Common Privileges

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Commonly Utilized Privileges

- Attorney Client: communications between attorney and client
- Work Product: documents created in anticipation of litigation
- Federal Quality Assurance Privilege

Federal Quality Assurance Privilege

- In an attempt to improve the quality of care afforded to nursing home residents, in 1987 Congress enacted the Federal Nursing Home Reform Act (FNHRA), of which FQAP was a subsection. 42 U.S.C. 1396r, et seq.; 42 U.S.C. 1395i–3, et seq.; 42 C.F.R. 483, et seq.
- Broadly, FQAP requires “skilled nursing facilit[ies]” and “nursing facilit[ies]” to establish a quality assessment and assurance committee in an attempt to ensure nursing homes are vigilant about the quality of care their residents are receiving. 42 U.S.C. 1395i–3(b)(1)(B); 42 U.S.C. 1396r(b)(1)(B).

Federal Quality Assurance Privilege

- FQAP 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. 1395i–3(b)(1)(B).

Federal Quality Assurance Privilege

- Kentucky has yet to determine a standard application of this privilege in its courts.
- “We have yet to have occasion to interpret FQAP's scope. In actuality, only two states and one federal court have had such an opportunity. From this paucity of case law, two rules have emerged: the Missouri Rule and the New York Rule. Richmond Health and Extendicare petition this Court to decide affirmatively between these two interpretations. Perhaps this is an important issue—no doubt it is enticing—but, for the reasons set forth below, we find it unnecessary to make the choice Richmond Health and Extendicare ask of us.” Richmond Health Facilities-Madison, LP v. Clouse, 473 S.W.3d 79, 84 (Ky. 2015).
  - Decided only two years ago. Didn’t reach application of privilege because the facility failed to show that FQAP applied—party asserting privilege has burden to do so.

Federal Quality Assurance Privilege

- Missouri Rule: The “Narrow” Approach
  - limits scope of privilege to the records of the QA committee; not extended to records and materials created outside committee and submitted to committee for review. State ex rel. Boone Retirement Center Inc. v. Hamilton, 946 S.W.2d 740, 742-3 (Mo. 1997).
- New York Rule: The “Broad” Approach
  - Held that federal statute does not restrict QA records to only those reports created by QA members themselves. “Records of such committee” encompasses within its parameters any reports generated by or at behest of quality assurance committee for quality assurance purposes. In re Subpoena Duces Tecum to Jane Doe, Esq., 787 N.E.2d 618, 623 (N.Y. 2003).

Federal Quality Assurance Privilege

- In the cases where the lower courts have taken up this FQAP application question, there is a split with applications of both interpretations. The Kentucky Supreme Court needs to answer this question so nursing homes can definitively move forward with their QA committees.

Why are we talking about Patient Safety Work Product?

- Kentucky issues with patient safety and adverse events/outcomes
- Rising costs of nursing home litigation in Kentucky along with large jury verdicts
- Some providers have considered this a hostile jurisdiction to provide long-term care and have left the state

New Considerations for Patient Safety

- OIG Recommendations for AHRQ and CMS to Raise Awareness of Nursing Home Safety (2014 Study)
- Recommendations in this report bring us to the discussion at hand: patient safety work product and reporting to patient safety organizations (PSOs)
- Quality Assurance and Performance Improvement (QAPI)—development mentioned in the report based on the requirements in the ACA—as you all are aware, this going into effect on November 28, 2017.

New Considerations for Patient Safety

- OIG recommended that the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) coordinate their efforts to reduce harm to residents by methods similar to those used to promote hospital safety. OIG, February 2014, Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries.

New Considerations for Patient Safety

- OIG further recommends that AHRQ and CMS encourage nursing homes to report adverse events to Patient Safety Organizations (PSO).
  - AHRQ has designed PSO reporting formats for nursing homes
- On the other hand, OIG recommends that CMS instruct surveyors to examine evidence that a facility identified and reduced adverse events.

New Considerations for Patient Safety

- PSQIA confidentiality provision may be in conflict with CMS compliance requirements that allow surveyors access to facility QAA actions and reports.
- AHRQ and CMS should collaborate to remove any barriers to nursing home reporting due to possible conflicts between QAPI provisions that require nursing homes to share event information with stage agency surveyors and PSO provisions that require confidentiality of reported information

Patient Safety and Quality Improvement Act of 2005 (PSA)

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PSA Purpose

- The purpose behind this protection is to encourage healthcare providers to share information enabling evaluation of healthcare treatment, including failures, to improve patient safety and quality of care without fear of liability.

Benefits of Enrollment

- Patient Safety Organizations (PSOs) created through PSA afford avenue of dialogue between healthcare facilities to improve patient care
- Provides federal and state legal privilege and confidentiality protections to information created and reported to PSO
- Limits use of patient safety information in proceedings and imposes penalties for any violations (monetary and equitable)

Benefits to Enrollment

42 U.S.C.A. § 299b-22(a): Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—

- (1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
- (2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;
- (3) subject to disclosure pursuant to section 552 of Title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

Benefits to Enrollment

42 U.S.C.A. § 299b-22(a): Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c) of this section, patient safety work product shall be privileged and shall not be—

- (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or
- (5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

Penalties for Disclosure of PSWP

- 42 U.S.C.A. § 299b-22(f)
- (1) Civil monetary penalty:
  - Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) of this section shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.
- (4) Equitable relief
  - (A) In general Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) of this section and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

Who is a Provider Under the PSA?

42 U.S.C.A. § 299b-21(8): The term "provider" means—

- A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—
  - (i) a hospital, **nursing facility**, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, **long term care facility**, behavior health residential treatment facility, clinical laboratory, or health center; or

Who is a Provider Under the PSA?

42 U.S.C.A. § 299b-21(8): The term "provider" means—

- A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—
  - (ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or
- B) any other individual or entity specified in regulations promulgated by the Secretary.

What is Patient Safety Work Product (PSWP)

- 42 U.S.C.A. § 299b-21(A): Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements- (i) which-
  - (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
  - (II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or
  - (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

What is NOT Patient Safety Work Product (PSWP)

- 42 U.S.C.A. § 299b-21(B) Clarification:
  - (i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.
  - (ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

What is NOT Patient Safety Work Product (PSWP)

- 42 U.S.C.A. § 299b-21(B) Clarification:
  - (iii) Nothing in this part shall be construed to limit—
    - (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
    - (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or
    - (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

What is Patient Safety Work Product (PSWP)

- 42 U.S.C.A. § 299b-21(5) Patient safety activities
  - (A) Efforts to improve patient safety and the quality of health care delivery
  - (B) The collection and analysis of patient safety work product.
  - (C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
  - (D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk

What is Patient Safety Work Product (PSWP)

- 42 U.S.C.A. § 299b-21(5) Patient safety activities
  - (E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.
  - (F) The provision of appropriate security measures with respect to patient safety work product.
  - (G) The utilization of qualified staff
  - (H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

Patient Safety Evaluation System (PSES)

- The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization. 42 U.S.C.A. § 299b-21(6)

Patient Safety Organization (PSO)

- 42 U.S.C.A. § 299b-21(4): The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 299b-24(d) of this title.
- The data compiled by the various PSOs is eventually reported to the Secretary for Health and Human Services who has "facilitate[d] the creation of, and maintain[ed], a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities." 42 U.S.C. § 299b–23(a).

Kentucky Interpretation of PSA and PSWP Protection

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Kentucky's Interpretation of Privilege under PSA

- 42 U.S.C.A. § 299b-22 (g) Rule of construction Nothing in this section shall be construed-
  - (2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;
- Since the inception of this Federal Act, Kentucky Courts have battled over the scope of this privilege and application under Kentucky law for medical providers. In fact, in the last year alone, there have been 4 cases heard on this issue the most recent of which was less than a month ago.

Kentucky's Interpretation of Privilege under PSA

- Tibbs v. Bunnell, 448 S.W.3d 796, 806 (Ky. 2014), as corrected (Sept. 10, 2014)
  - Tibbs held that information provided as part of mandatory state reporting efforts could not be privileged solely because it was used in conjunction with a patient safety evaluation system.
  - "The decision [in Tibbs] caused much concern among patient safety advocates and healthcare providers, who contended that the decision ran contrary to the Patient Safety Act and would have a chilling effect on patient safety efforts." Id. at 347–48.
    - Zara Airapetian, Federal Privilege Under Patient Safety and Quality Improvement Act: The Impact of Tibbs v. Bunnell, 11 J. Health & Biomedical L. 345, 345 (2016).

Kentucky's Interpretation of Privilege under PSA

- Frankfort Reg'l Med. Ctr. v. Shepherd, 2016 WL 3376030, at *8 (Ky. June 16, 2016)
  - It does not necessarily follow that the regulation required the interviews and other investigative steps undertaken …simply because they were ultimately used to prepare the Root Cause Analysis. It is theoretically possible that the investigation might have been undertaken in a different manner if its only purpose was to prepare the Root Cause Analysis.
  - "Whether a particular communication is privileged depends (absent waiver) not on what use was ultimately made of the communication, but on the facts and circumstances under which the communication was made." Lexington Public Library, 90 S.W.3d at 59.

Kentucky's Interpretation of Privilege under PSA

- Baptist Health Richmond, Inc. v. Clouse, 497 S.W.3d 759, 766 (Ky. 2016)
  - The existence of the Act does not relieve providers from fulfilling their statutory and regulatory reporting obligations. As long as a provider fulfills those obligations, the trial court has no reason to review the information in the provider's patient safety evaluation system.
  - However, if a provider fails to fulfill those obligations, the court can conduct an in camera review of the documents in the provider's patient safety evaluation system. In conducting that review, the court should separate the information that is usually contained in state-mandated reports from information that is not usually contained in those reports.
  - Because the provider is claiming the privilege, it bears the burden of proving that it complied with the statutory and regulatory reporting requirements. If the provider fails to meet that burden, the party seeking the information then bears the burden of establishing what information is generally contained in state-mandated reports.

Kentucky's Interpretation of Privilege under PSA

- Univ. of Kentucky v. Bunnell, 2017 WL 4712408 (Ky. Ct. App. Oct. 20, 2017)
  - Judge Acree -"Consequently, and particularly in light of this regulation, circuit courts remain uncertain how to proceed when a medical provider seeks application of the privilege under the Patient Safety Act."
  - Seeks to provide guidance and reconcile the prior opinions

Univ. of Kentucky v. Bunnell

- To be entitled to the privilege under the federal Act, medical providers must "voluntarily associate and communicate privileged patient safety work product (PSWP) among themselves through in-house patient safety evaluation systems (PSES) and with and through affiliated patient safety organizations (PSO)…." Tibbs, 448 S.W.3d at 800. Tibbs suggests "the first analysis to undertake when a party asserts the Act's privilege is to determine whether the information satisfies the statutory definition for patient safety work product as established by the Act [.]" Id. at 803.

Does the Purported Document qualify as PSWP?

- Judge Acree outlined a 3 part test in making this determination:
  - What is it?
  - Why was it generated?
  - Might it improve overall patient care?

What is the document?

- To qualify as PSWP:
  - It must be data, reports and the like, including even oral reports or statements. Univ. of Kentucky v. Bunnell, 2017 WL 4712408, at *5 (Ky. Ct. App. Oct. 20, 2017)
  - Also includes deliberations or analysis of reporting

Why was it generated?

- When a provider participates in this voluntary program, the data it generates for that program must be superfluous to the documentation necessary for patient care or regulatory compliance. Additionally, the report eventually must be submitted to a PSO, whereupon it will be permanently unavailable for the separate purpose of complying with government regulation of the provider's activities. Univ. of Kentucky v. Bunnell, 2017 WL 4712408, at *6 (Ky. Ct. App. Oct. 20, 2017)
- Intention often established by affidavit of individual involved in collection

Might it Improve Overall Patient Care?

- The report must relate to events impacting patient medical care and not, for example, ethical breaches of a physician-patient relationship. Univ. of Kentucky v. Bunnell, 2017 WL 4712408, at *6 (Ky. Ct. App. Oct. 20, 2017)
- Guidance issued by Agency for Healthcare Research and Quality (AHRQ), Office for Civil Rights (OCR) and Department of Health and Human Services (HHS): "reporting pathway" it must be information that could improve patient safety, health care quality, or health care outcomes and be assembled or developed by a provider for reporting to a PSO and be reported to a PSO. Guidance at 32656.

Does An Exception to Privilege Apply?

- **Exceptions of the First Kind**: patient's medical record, billing and discharge information, or any other original patient or provider record. 42 U.S.C. §299B-21(7)(B)(i)
- **Exceptions of the Second Kind**: hospital records created because they satisfy an external obligation, i.e. information kept internally or reported externally that is either mandated by law or is a mandatory condition of participation in a government sanctioned voluntary program. 42 U.S.C. §299B-21(7)(B)(iii)(II) and (III)

Does An Exception to Privilege Apply?

- **Exceptions of the Third Kind**: business records existing outside a PSES that are neither required by law nor as a mandatory condition of voluntary participation in a government-sanctioned program, but which the hospital's governing authority nevertheless deems necessary to be kept in the ordinary course of its business. [42 U.S.C. § 299b–21(7)(B)(i) ("other … provider records"); (7)(B)(ii) ("exist[ing] separately, from a patient safety evaluation system")]. Univ. of Kentucky v. Bunnell, 2017 WL 4712408, at *9 (Ky. Ct. App. Oct. 20, 2017)

Exceptions of the First Kind

- 902 KAR 20:048 Section 3(3) -Administrative records
  - (3)(3)(d) – incident reports. Notably, Judge Acree found that this did not create an affirmative reporting duty
- 902 KAR 20:048 Section 3(11)
- May decide to create other records not required by law but which its governing authority deems necessary or useful to patient care – not privileged
- 902 KAR 20:300

Exceptions of the Second Kind

- Highlights importance of intent in assessment of PSWP designation
- **Two Types**:
  - **Mandatory External Obligations**: compelled by police powers AND
  - **Voluntary External Obligations**: When a provider voluntarily participates in a certification program or accreditation process, there will be obligations imposed as a condition of that voluntary participation.

Exceptions of the Second Kind

- **Mandatory External Obligations**: First question is what state laws regulate a particular medical provider's licensure
  - Kentucky **does not** have adverse medical events reporting obligations
  - KRS §215.590: reporting active tuberculosis;
  - KRS §620.030: duty to report suspected abuse or neglect
  - 902 KAR 2:020: duty to report array of ailments including HIV and other STDS.

Exceptions of the Second Kind

- **<u>Mandatory External Obligations</u>**: First question is what state laws regulate a particular medical provider's licensure
  - KRS §216.155(1) All health care facilities and services licensed under this chapter, with the exception of personal care homes, family care homes, and boarding homes, shall develop comprehensive quality assurance or improvement standards adequate to identify, evaluate, and remedy problems related to the quality of health care facilities and services. These standards shall be made available upon request to the public during regular business hours and shall include:

Exceptions of the Second Kind

- **Mandatory External Obligations**: First question is what state laws regulate a particular medical provider's licensure
  - KRS §216.155(1)
    - (a) An ongoing written internal quality assurance or improvement program;
    - (b) Specific, written guidelines for quality care studies and monitoring;
    - (c) Performance and clinical outcomes-based criteria;
    - (d) Procedures for remedial action to correct quality problems, including written procedures for taking appropriate corrective action;
    - (e) A plan for data gathering and assessment;
    - (f) A peer review process; and
    - (g) A summary of process outcomes and follow-up actions related to the overall quality improvement program for the health care facility or service.

Exceptions of the Second Kind

- **<u>Mandatory External Obligations</u>**: First question is what state laws regulate a particular medical provider's licensure
  - Current federal or state regulations which address quality assurance and quality improvement requirements for nursing facilities, intermediate care facilities, and skilled care facilities shall suffice for compliance with the standards in this section. – Inclusion of PSA and reporting to PSOs

Exceptions of the Second Kind

- **<u>Voluntary External Obligations</u>**: When a provider voluntarily participates in a certification program or accreditation process, there will be obligations imposed as a condition of that voluntary participation. Univ. of Kentucky v. Bunnell, 2017 WL 4712408, at *21 (Ky. Ct. App. Oct. 20, 2017). Examples Include:
  - Joint Commission
  - Medicare and Medicaid

Exceptions of the Second Kind

- **<u>Voluntary External Obligations</u>**:
  - Medicare and Medicaid
    - HHS expressly states: CMS [the Center for Medicare and Medicaid Services] does not require submission of a PSWP, and hospitals have choices with regard to what to place in a patient safety evaluation system as a PSWP, to what extent the hospital will use any of the exceptions provided in the PSQIA [the Act] as noted above, and to what extent the hospital will seek to demonstrate compliance with the CoPs [Conditions of Participation] through the provision of other information. 46 79 FR 49854–01 at 50340.

Exceptions of the Second Kind

- External Obligation after PSES placement
  - If before submitted to PSO:
    - Drop Out Provision
  - If after submitted to PSO
    - Do new analysis without PSWP to satisfy requirement

How Courts Determine Close Calls

- A circuit court's in camera review of information in the provider's PSES would only be justified if the party seeking the information carries her burden to demonstrate:
  - (1) what information should be in a state-mandated report that the provider has failed to create; and
  - (2) that such information does not exist outside the provider's PSES.
- If that burden is met, the circuit court's in camera review would be appropriate to determine if information necessary to satisfy an external obligation exists within the PSES.

What does this mean for the Future?

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Future Predictions/Trends

- CMS' official response in the 2014 study highlights what it sees as the "challenges" involved with utilizing the PSO framework.
- CMS notes that it has encountered situations where facilities claimed they could not demonstrate compliance with Medicare's Conditions of Participation without disclosing information believed to be protected because it was submitted to a PSO.
- CMS claims it would be "impossible" to assess a facility's adverse event identification and reduction process if it could not examine a facility's internal incident reporting system.

Future Predictions/Trends

- It remains to be seen how the recommendations regarding voluntarily reporting adverse events to PSOs is harmonized with CMS' requirements regarding a facility's quality assurance committee and certain mandatory reporting and investigation requirements.
- AHRQ and CMS are working together on the 11th Scope of Work for Quality Improvement Organizations specifically to resolve issues related to nursing home event reporting (expected release 2019).

Any questions?

Amber K. Knouff
Office: 859-231-8780, ext. 224
aknouff@mmlk.com

Kathryn A. Eckert
Office: 859-231-8780, ext. 186
keckert@mmlk.com

www.mmlk.com

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