

Credentialing & Peer Review Legal Insider

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New PSO guidance raises questions over patient safety work product privilege

In May, the U.S. Department of Health and Human Services (HHS) published *Guidance Regarding Patient Safety Work Product and Providers' External Obligations* in the hopes of clarifying what documents are considered patient safety work product (PSWP) and thus protected from discovery during litigation. Because the guidance has far-reaching implications for the scope of the privilege and confidentiality protection, providers should consider reexamining their process for collecting information in the pursuit of improving patient safety.

Under the Patient Safety and Quality Improvement Act (PSQIA), providers collect and manage information through a patient safety evaluation system (PSES), which is then sent to a patient safety organization (PSO) for analysis and feedback. To motivate providers to participate in PSOs, PSQIA entitles the submitted information broad privilege and confidentiality protections.

According to **Michael R. Callahan, Esq.**, partner at Katten Muchin Rosenman, LLP, in Chicago, the

guidance may impact how discoverability disputes are handled in courts. To understand why, consider the three primary buckets of patient safety information:

- **Bucket one:** All mandated reports. For example, some states like New York and Florida require mandated adverse reporting if a wrong site surgery is performed. For these incidents, hospitals are required to prepare and submit a report to the state. Reports that fall within this bucket shouldn't be treated as PSWP.
- **Bucket two:** All reports that hospitals are required to collect and maintain pursuant to state and federal law, such as the Medicare *Conditions of Participation (CoP)*.
- **Bucket three:** All other information collected and maintained in a hospital's PSES to improve quality, safety, and patient outcomes. This information is PSWP.

Disputes will arise from reports that fall into bucket two, Callahan says. HHS's guidance stated that this type of information isn't PSWP, but not all

state and federal laws have crystal clear language defining what information hospitals need to collect and maintain.

“You will seldom find in the state and federal laws a specific list of documents which identifies the kinds of records and reports a provider is required to maintain and collect and to make available for inspection by a governmental authority. It is not that clear cut and hospitals use different terminology,” he says.

For example, Callahan points out that in the case *Tibbs v. Bunnell*, discussed later in this article, the dispute was over the question of whether an incident report collected and reported to a PSO by a defendant hospital was a bucket two document. “The language under Kentucky law obligated the hospital to maintain and collect ‘incident investigation reports’ but does this refer to the incident report, a resulting root cause analysis report or a peer review investigation report? Is it all or none of the above?”

The PSO guidance

The guidance, which was published in the *Federal Register* in May, clarifies what information can and cannot be called PSWP. Information can be PSWP if:

- A provider prepares it for reporting to a PSO and follows through in the reporting
- A PSO develops it for the conduct of patient safety activities
- A provider places it in a PSES to be reported to a PSO

Information that can't be PSWP includes:

- Patient medical records, billing and discharge information, or any other original patient or provider information
- Materials collected and maintained separately from a PSES
- Records mandated by federal and state law
- Information prepared to satisfy external obligations

One criticism of the guidance is its expansion of the concept of original patient and provider records, Callahan says. PSQIA states these records, such as medical records and billing information, can never be privileged. The guidance further clarified the scope of what these records include:

- Original records required of a provider to meet any federal, state, or local public health or health oversight requirements regardless of whether they are maintained inside or outside of the PSES

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- Copies of records that reside within a provider's PSES that were prepared to satisfy a federal, state, or local public health or health oversight record maintenance requirement if the records are maintained only within the PSES and any original records are either not maintained outside of the PSES or were lost or destroyed

Callahan takes issue with HHS' expansion of the definition of an original patient and provider record to include bucket one and bucket two documents, especially since it was put forth in guidance and not a final rule.

Requirements under the Administrative Procedure Act require a notice and comment period before a final rule is adopted. However, HHS chose to issue the guidance without following this procedure and therefore it should only be viewed as an interpretative rule, Callahan says. The U.S. Supreme Court decision earlier this year in the case of *Perez v. Mortgage Bankers Association* found that interpretive rules "do not have the force and effect of law."

"The guidance is simply an interpretation provided by HHS. While it certainly expresses the position of HHS, the Office of Civil Rights and the Agency for Healthcare Research and Quality (AHRQ) from a regulatory enforcement standpoint, it is not binding on state or federal courts," he says.

As a result, different interpretations of PSQIA will likely lead to continued challenges to court orders to turn over documents hospitals believe to be PSWP. Some of these discoverability disputes have made their way to state supreme courts.

Southern Baptist Hospital of Florida v. Charles

In a case that will go before the Florida Supreme Court later this year, *Southern Baptist Hospital of Florida v. Charles*, the PSO guidance may play a role in determining whether occurrence reports—reports that hospital collects and maintains for events that are inconsistent with its routine operations or care of patients, or that could result in an injury—are PSWP.

The plaintiff sued Southern Baptist Hospital of Florida, claiming his sister suffered a catastrophic neurological injury due to negligence. During discovery, the plaintiff requested documents related to adverse medical incidents and the conduct of

physicians who worked at the hospital. This request was made pursuant to Amendment 7 of the Florida Constitution, which provides patients with the right to access "any records made or received in the course of business by a healthcare facility or provider relating to any adverse medical incident."

Although the hospital produced some of the requested documents, it declined to turn over occurrence reports that were collected within its PSES and reported to its PSO, claiming they were PSWP and therefore privileged and confidential under PSQIA.

The plaintiff argued that PSQIA only protects documents generated exclusively for submission to a PSO, so anything collected to also satisfy a state law is not PSWP. The circuit court agreed, finding that information collected for dual purposes was not PSWP and ordered the hospital to produce the documents.

This order was later reversed by an appellate court, which said the documents were PSWP because they were collected in the hospital's PSES and reported to a PSO. Further, documents can simultaneously be PSWP and meet a state reporting requirement. The plaintiff appealed to the state supreme court, which will hear the case in October.

Since the documents in question fall into bucket two, the plaintiff will likely cite the guidance to support a position that the reports can't be treated as PSWP and therefore are discoverable, says Callahan. However, the argument can be made that the guidance is not legally binding on the courts.

Tibbs v. Bunnell

The release of the PSO guidance likely contributed to the U.S. Supreme Court's denial to hear *Tibbs v. Bunnell*. The case would have provided a nationwide interpretation of the scope of privilege and confidentiality protections under PSQIA for reports submitted to PSO, as well as whether PSQIA preempted state laws.

In *Tibbs*, a patient's estate brought a wrongful death and medical malpractice suit against three surgeons employed by University of Kentucky Hospital. The plaintiffs sought to discover a post-incident event report generated by a surgical nurse through the hospital's PSES and subsequently sent to its PSO.

At trial, the hospital argued that the report was protected under PSQIA and therefore not subject to

discovery. However, the trial court ruled that the report was not protected under PSQIA. The hospital appealed.

Although the appellate court found that the privilege provided by the PSQIA did preempt the Kentucky state law, it stipulated that protections afforded by PSQIA only apply to documents that contain “self-examining analysis,” meaning those in which the provider analyzes his or her own actions. The court then sent the matter back to the trial court for evaluation of whether the report contained self-examining analysis.

The hospital appealed to the Kentucky Supreme Court, arguing that the appellate court erroneously limited the scope of privilege protections under PSQIA. The Supreme Court reversed the Court of Appeals’ interpretation of PSQIA, finding it too narrow. However, it also ruled that the incident report was not protected under PSQIA because its creation, maintenance, and utilization was required in the regular course of the hospital’s business, as well as under Kentucky state law. Therefore it cannot be collected within the hospital’s PSES and treated as PSWP.

In response, the hospital filed a petition for the U.S. Supreme Court to review the Kentucky Supreme Court’s decision. The petition had the support of more than 50 PSOs, hospitals, and health systems from across the country, as well as the American Hospital Association, AMA, and The Joint Commission. Last October, the court asked the U.S. solicitor general to file a brief on his views of the case and whether the petition should be granted or denied.

Just as the guidance was published, the solicitor general filed his brief to the court. The brief recommended that the court deny the petition in light of the guidance issued by HHS and because hearing the case would be premature until it is seen how the lower courts interpret and apply the guidance.

In June, the U.S. Supreme Court denied the petition without comment and without remanding the case back to the Kentucky Supreme Court to take the guidance into consideration. This leaves the Kentucky Supreme Court’s ruling in place, although the decision is only binding on Kentucky courts.

Carron v. Rosenthal

Regardless of the U.S. Supreme Court’s denial to hear *Tibbs*, discovery disputes are still playing out in other courts. The Rhode Island Supreme Court

will be hearing an appeal of an order for a hospital to produce incident reports in *Carron v. Rosenthal*. In this case, the plaintiff is suing her obstetrician and Newport Hospital for medical malpractice after her newborn baby suffered irreversible brain damage following a failed labor induction and died days later.

Two nurses prepared incident reports known as Medical Event Reporting System (MERS) reports, which were submitted to the hospital’s PSO. The hospital also produced separate state-mandated adverse event reports.

Later during discovery, the nurses were deposed but had difficulty remembering what had happened, so the plaintiffs asked that the hospital produce the MERS reports. The hospital objected, citing PSQIA and the Rhode Island Patient Safety Act.

According to Callahan, much of the plaintiff’s argument was based on the Kentucky Supreme Court’s decision in *Tibbs* that reports required by state statutes can’t be treated as PSWP. However, Newport Hospital argued that in *Tibbs*, the University of Kentucky Hospital collected state mandated reports in its PSES. At Newport Hospital, state mandated reports are collected separately. The MERS reports were separate reports distinguishable from the mandated reports and therefore were PSWP, according to the hospital.

Despite this argument, the trial court ruled in favor of the plaintiff and order the hospital to show the MERS reports to the nurses—but not the plaintiff—to refresh their memories before they were to be deposed again. The hospital appealed and, because Rhode Island does not have an appellate court, the state supreme court exercised its discretion to hear the hospital’s appeal. A decision is expected later this year.

What can providers do?

With the U.S. Supreme Court declining to hear *Tibbs*, and ongoing confusion in regards to the guidance, providers that participate in a PSO have a few options for how to proceed.

Providers can choose not to do anything and simply maintain the status quo as they wait for further regulatory or judicial developments, says Callahan. “We have these other cases before state supreme courts and it’s conceivable one of those will be appealed. It doesn’t mean the U.S. Supreme Court is going to accept one of

these other ones, but that's a development that providers may want to wait on."

PSOs will also likely have questions about the guidance and will reach out to AHRQ for additional guidance, so providers will want to wait to see if there is any further clarification, he says.

Providers that choose to comply with the guidance will need to determine if any information they were previously collecting in their PSES for reporting to their PSO is no longer considered PSWP. These providers will need to review state and federal laws, including the Quality Assurance and Performance Improvement standards set forth in the Medicare *CoP*, to ensure the information doesn't fall into buckets one or two, Callahan says. Anything that's determined to fall into those two buckets will require modifications to the provider's PSES policy.

Since the guidance is an interpretive rule, some providers may choose to fight requests to turn over disputed documents, Callahan says. Providers would choose this path if they believed a court would be more likely to side with their interpretation of PSQIA.

More drastically, providers could simply decide to abandon their PSOs altogether. However, there are several factors to consider before making that move, says Callahan.

The Affordable Care Act requires hospitals with more than 50 beds that want to provide healthcare services to patients enrolled in a state insurance exchange to be enrolled in a PSO. This was modified to allow hospitals to meet the requirement by contracting with a hospital engagement network (HEN) or quality improvement organization (QIO).

However, contracting with a HEN or QIO doesn't offer providers the same privilege protection received from participating in a PSO. Those providers would still have their state law protections, but those vary and some states may not have any protections at all or limited protections, Callahan says.

Providers considering leaving their PSO will need to evaluate their state protections, including the scope of protected activities and entities.

"Using Illinois as an example, [state law protections] only generally apply to hospitals, surgery centers, and managed-care entities. The statutes do not apply to physicians, physician groups, labs,

pharmacies, home health, or other licensed providers. So if you have formed a clinically integrated network with all these different provider boxes, only the hospital—for all practical purposes—will be protected," Callahan says.

Providers should also check to see if it's possible under state law to inadvertently waive the privilege if protected information is not handled correctly (e.g., information is disclosed improperly). Under PSQIA, the protections afforded to PSWP can never be waived.

Callahan also notes it's important for providers to know that state privilege protections only apply in state courts or state claims. So, for example, if a physician is terminated but falls under a protected class (race, age, sex, religion, etc.), he or she can file a federal claim. The physician can then request access to protected peer review documents. Although the hospital may try to argue that they are privileged and confidential under the state peer review statute, state privilege statutes cannot be asserted to preempt federal claims. However, if the documents were collected in a PSES and reported to a PSO, they would not be undiscoverable.

"The PSQIA has many advantages to offer. Part of the problem, however, is that there are not many appellate court interpretations of the law and most of those decisions have only involved medical malpractice cases" Callahan says. "Unfortunately, because the U.S. Supreme Court denied the petition in *Tibbs*, these disputes will have to be decided on a state-by-state basis. This is great for the attorneys but not helpful for PSOs and participating providers." ❏

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Please email Associate Editor Son Hoang at shoang@hcpro.com if you would like to contribute a column or just have a story idea for a future issue of the newsletter.

Case summary

Texas Supreme Court grants writ of mandamus for peer review committee records

The Supreme Court of Texas (the “Court”) recently held that a trial court failed to adequately review allegedly privileged documents—to determine if they were disclosable pursuant to an exception to the state’s peer review statute—before issuing an order compelling Christus Santa Rosa Health System to produce them. As a result, the Court granted a petition for writ of mandamus filed by Christus, ordering the lower court to inspect the documents in question.

The documents concerned a peer review committee convened to review an unsuccessful surgery performed by Gerald Marcus Franklin, MD, in March 2012 to remove the left lobe of a patient’s thyroid gland. Franklin instead removed thymus gland tissue, requiring the patient to undergo a second surgery.

According to Franklin’s deposition, several weeks after the failed surgery he met with a three-member medical peer review committee to provide a verbal report. He said that complications arose due to an abundance of scar tissue, which made it difficult to distinguish between thymus and thyroid tissue. The unavailability of a cryostat machine, a critical piece of equipment that Franklin would have used during the surgery to diagnose the removed tissue, led him to end the surgery. During the meeting, the committee concluded that Franklin’s actions were reasonable and the committee chose not to take action.

As a result of the failed surgery, the patient filed a malpractice lawsuit against Franklin and his medical group in March 2013. Franklin subsequently filed a motion to designate Christus as a responsible third party, alleging that the unavailability of the cryostat machine was responsible for the surgery’s failure. The patient went on to add Christus as a defendant in the suit.

In March 2014, Franklin served Christus with a request to produce documents from its medical peer review file. Christus objected, arguing that the documents were protected from discovery under the medical peer review committee privilege provided by the Texas Occupations Code section 160.007(a), which states, “[E]

ach proceeding or record of a medical peer review committee is confidential, and any communication made to a medical peer review committee is privileged.”

Following an *in camera* review, the trial court ordered Christus to produce the documents under a protective order that mandated that they be disclosed only to Franklin and his attorneys.

Christus filed a motion to reconsider, which the trial court denied. Christus then filed a petition for writ of mandamus in the court of appeals, which was also denied, leading to it filing the petition with the state supreme court.

At issue was the interpretation and scope of an exception provided by Texas Occupation Code section 160.007(d), which states, “If a medical peer review committee takes action that could result in censure, suspension, restriction, limitation, revocation, or denial of membership or privileges in a healthcare entity, the affected physician shall be provided a written copy of the recommendation of the medical peer review committee and a copy of the final decision, including a statement of the basis for the decision.”

Franklin argued that the documents were subject to disclosure under the exception because, even though the committee opted not to take any action, the medical peer review committee had the opportunity to recommend discipline.

The Court disagreed with Franklin’s interpretation of the privilege: “Looking to the intent of the Legislature, as we must, we conclude that the Legislature intended a medical peer review committee do more than simply convene for review for the exception to apply.”

The Court found that applying this interpretation would require disclosure of a medical peer review committee’s documents every time it conducted a review, regardless of its outcome.

“Under this interpretation, it is difficult to conceive of an instance where the physician would not be entitled to the documents and the documents would remain privileged. This would in turn enfeeble confidentiality and prevent physicians from engaging in candid


and uninhibited communications, which is essential for improving the standard of medical care in the state,” the Court wrote.

The Court also found that the trial court did not review the documents in camera sufficiently to determine if the medical peer review committee took any actions that could result in one of the disciplinary

actions listed in the exception to the medical peer review committee privilege, such as censure, suspension, or denial of privileges.

The trial court judge had stated he went through the documents page by page only to ensure that patient’s health information and social security numbers were not disclosed and didn’t look at the documents “closely enough” to determine whether the committee had taken any actions. Christus had argued that an in camera inspection of the documents would clarify if the exception applied.

The Court concluded that the trial court abused its discretion when it ordered Christus to produce the medical peer review committee documents; and ordered the trial court to vacate its order compelling production of the documents and to review the documents further to see if the exception applies.

Source: In re Christus Santa Rosa Health Sys., No. 14-1077 (Tex. May 27, 2016). 

What does this mean for you?

J. Michael Eisner, Esq., of Eisner & Lugli in New Haven, Connecticut: The Court’s decision stands for the fundamental proposition that a court must comply with the plain meaning of the statutes that it is interpreting. While this may seem to be a “no brainer,” too many courts ignore the plain meaning of statutes and act as if they were legislative bodies. Here, the statute required that disclosure only be made if the peer review committee recommended certain actions. According to the Texas Supreme Court, in spite of the clear wording in the statute, the trial court ordered disclosure without making the requisite determination(s). The Supreme Court sent the matter back to the trial court, ordering it to follow the statute.

This case was reviewed by Michael Eisner, Esq. (meisner@jmeisner.com) of Eisner & Lugli in New Haven, Connecticut. Case summaries are prepared for informational purposes only and should not be considered legal advice.

Legal and regulatory news roundup

Find out what’s happening in the world of federal healthcare regulations by reviewing some recent headlines from across the country.

Senate Finance Committee aims to reform Stark Law

The Senate Finance Committee hopes to introduce legislation to reform the federal physician self-referral law, commonly referred to as the Stark Law. During a recent hearing, Chairman Orrin Hatch (R-Utah) said the committee would take some action by the end of 2016 but did not elaborate on what that might be.

In June, Hatch released a white paper discussing potential reforms to the Stark Law. Several commenters suggested repealing the law in its entirety. Others suggested changes to the law that would allow providers to implement new payment models.

In a statement released with the white paper, Hatch said the Stark Law is “a real burden for hospitals and doctors trying to find new ways to provide high quality care while reducing costs as they work to implement recent healthcare reforms.”

Hundreds charged with healthcare fraud in nationwide sweep

More than 300 physicians, nurses, and other medical professionals across the country allegedly involved in healthcare fraud schemes face criminal and civil charges following what the U.S. Department of Justice called the largest coordinated takedown in history. The Medicare Fraud Strike Force in 36 federal districts led the sweep, which also involved 23 state Medicaid Fraud Control Units and 26 U.S. Attorney’s Offices.

The individuals charged are suspected of collectively submitting approximately \$900 million in fraudulent

billing to Medicare and Medicaid. They face multiple healthcare fraud-related charges, including conspiracy to commit healthcare fraud, aggravated identity theft, money laundering, and violations of the anti-kickback laws for schemes in which they submitted claims for medically unnecessary treatments. Often the treatments were never provided. In some cases kickbacks were paid to Medicare beneficiaries, patient recruiters, and other co-conspirators in return for providing beneficiary information to providers to use in submitting fraudulent billing.

Some of the highlights of the sweep include:

- One-hundred defendants from southern Florida were charged for their alleged involvement in schemes that resulted in \$220 million in fraudulent billings for home healthcare, mental health services, and pharmacy fraud.
- Eleven defendants in southern Texas were allegedly responsible for \$47 million fraudulent billing, including one physician who allowed unlicensed individuals to perform services and then billed Medicare as if he had performed them.
- Twenty-two defendants in central California allegedly defrauded Medicare of \$162 million. One physician is believed to be responsible for nearly \$12 million through fraudulently billing for medically necessary vein ablation procedures.

In an announcement of the arrests, Attorney General Loretta E. Lynch said, “The wrongdoers that we pursue in these operations seek to use public funds for private enrichment. They target real people—many of them in need of significant medical care. They promise effective cures and therapies, but they provide none. Above all, they abuse basic bonds of trust—between doctor and patient; between pharmacist and doctor; between taxpayer and government—and pervert them to their own ends.”

Cardiologist agrees to pay \$2 million to settle kickback, false billing lawsuit

Asad Qamar, MD, of the Institute of Cardiovascular Excellence (ICE) of Ocala, Florida, has agreed to pay \$2 million to resolve a lawsuit alleging he paid kickbacks to patients and improperly billed Medicare, Medicaid, and TRICARE—a healthcare program of the U.S. Department of Defense Military Health System. Qamar will also release any claim to \$5.3 million in suspended Medicare funds and

agreed to a three-year exclusion from participating in any federal healthcare program. This will be followed by a three-year integrity agreement with the Department of Health and Human Services Office of the Inspector General.

According to the U.S. Department of Justice, the lawsuit against Qamar claimed that he and ICE billed for peripheral artery interventional services and other related procedures, many of which were medically unnecessary according to the patients’ medical histories or records, or by the severity of their symptoms.

The lawsuit also alleged that Qamar and ICE persuaded patients to agree to the unnecessary procedures by routinely and indiscriminately waiving the 20% Medicare copayment. The copayment is typically used to help patients be smarter healthcare consumers and deter them from unnecessary procedures.

According to *The Wall Street Journal*, following a legal effort by the paper, CMS made public Medicare payment data which showed that Qamar had collected more than \$18 million from Medicare in 2012. That ranked him second highest paid among all physicians in the country and four times more than the third highest paid cardiologist.

The settlement resolves two consolidated lawsuits originally filed under the whistleblower provision of the False Claims Act. The two individuals who originally brought the suit will receive about \$1.3 million for their share of the settlement.

Former Warner Chilcott president acquitted on anti-kickback charge

W. Carl Reichel, former president of Warner Chilcott, was found not guilty of conspiring to pay kickbacks to physicians to induce them to prescribe its drugs.

The government’s case against Reichel alleged that he encouraged members of the sales force to provide physicians with payments, meals, and other rewards. According to court documents, Reichel was acquitted on grounds that there wasn’t insufficient evidence to suggest that he had ever given the sales team any such direction.

Last October Warner Chilcott agreed to plead guilty before a federal judge in U.S. District Court for the District of Massachusetts to a felony healthcare fraud charge and pay \$125 million to settle criminal and civil liability related to illegal marketing of several of its drugs. This included paying kickbacks to physicians throughout the country to encourage them to prescribe their drugs. 