



**PSQIA Case Law Alert:
Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital v. Azar**

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In September 2019, the U.S. District Court for the Northern District of Florida issued its opinion in the case of Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital v. Azar, 420 F. Supp. 3d 1300 (M.D. Fla. 2019).

Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital (“Tampa General”) initiated this action for declaratory relief, seeking a declaration that the Patient Safety and Quality Improvement Act of 2006 (“PSQIA”)¹ preempts the Florida Constitution, Amendment 7 (“Amendment 7”).² Tampa General also sought to enjoin Alex Azar, in his capacity as the Secretary of the U.S. Department of Health and Human Services (“HHS”), from imposing penalties for impermissible disclosures of patient safety work product (“PSWP”).³ This case was heavily focused on the federal law preemption of state laws that provide less privilege protection as compared to the privileges afforded under the PSQIA.

Background

Lawrence Brawley (“Brawley”) filed a medical malpractice lawsuit against Tampa General in Florida state court.⁴ In December of 2017, Brawley sought 241 documents from Tampa General.⁵ The request was based on Amendment 7, which gives individuals the “right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.”⁶

Tampa General is a member of a patient safety organization (“PSO”).⁷ The 241 documents at issue were created within Tampa General’s patient safety evaluation system (“PSES”) and submitted to its PSO.⁸ Therefore, documents are privileged PSWP under the PSQIA and not discoverable.⁹ If Tampa General did not produce the document, then it would have been subject to court sanctions.¹⁰ On the other hand, if Tampa General produced the 241 documents, then it would have been fined for knowingly disclosing identifiable PSWP.¹¹

The PSQIA provides for Secretary of HHS to impose civil monetary fines if identifiable PSWP is knowingly or recklessly disclosed in violation of the PSQIA’s confidentiality provisions.¹² The Secretary can impose fines of up to \$10,000 per act constituting a violation.¹³ Meaning, if Tampa General were to produce all 241

¹ Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C. §§ 299b-21 to 299b-26).

² Florida Health Sciences Centers, Inc. d/b/a Tampa General Hospital v. Azar, 420 F. Supp. 3d 1300 (M.D. Fla. 2019).

³ *Id.* at 1302.

⁴ *Id.* at 1304.

⁵ *Id.*

⁶ Fla Const., art. X, § 25(a).

⁷ *Tampa General*, at 1304.

⁸ *Id.*

⁹ *Id.* at 1306.

¹⁰ *Id.* at 1305.

¹¹ *Id.*

¹² 42 U.S.C. § 299b-22(f)(1); 42 C.F.R. § 3.402(a).

¹³ *Id.*

documents, then that would have constituted 241 separate acts of knowingly disclosing PSWP, thus equating to \$2.41 million in fines.

Tampa General filed a motion for a protective order in the state court action and sought a stay of discovery while Tampa General pursued this action in the U.S. District Court.¹⁴ The state court denied the motion and held Tampa General in contempt for failing to produce the documents.¹⁵ Consequently, the state court ordered Tampa General to pay \$100.00 per day until it complied with the order.¹⁶

Tampa General moved forward with this declaratory action in the U.S. District Court, seeking a declaration that the documents were protected by the PSQIA and that the PSQIA preempts Amendment 7. Tampa General also sought to enjoin the Secretary of HHS from imposing penalties for knowingly or recklessly disclosing identifiable PSWP in the event Tampa General produced the documents in state court.

District Court Opinion

The Secretary's only opposition to this action was that the U.S. District Court lacked subject matter jurisdiction because Tampa General did not face an imminent threat of enforcement.¹⁷ The Secretary argued that HHS was not obligated to impose civil monetary penalties for impermissible disclosures of identifiable PSWP.¹⁸ The U.S. District Court was not persuaded by this argument.

The U.S. District Court held that, notwithstanding the Florida Supreme Court's decision in *Charles v. South Baptist Hospital of Florida*, the PSQIA preempts Amendment 7.¹⁹ In the case of *Charles*, the Florida Supreme Court held that Amendment 7 preempted the PSQIA.²⁰ The U.S. District Court distinguished this case from *Charles* on the basis that the documents at issue in this case were reported to a PSO, whereas in *Charles* the documents at issue were not reported to a PSO.²¹ The U.S. District Court also noted that "preemption was not directly at issue" in *Charles*,²² meaning the preemption discussion in the *Charles* opinion amounted to dicta.²³

The U.S. District Court also held that the Secretary was enjoined from imposing penalties on Tampa General with regard to the state court action.²⁴ The U.S. District Court stated that:

"The federal statutory penalty is expressed in mandatory terms in both the Patient Safety Act and the HHS' implementing rule. . . In sum, because the Patient Safety Act and its regulations mandate enforcement – and the state court has initiated sanctions for contempt – TGH [Tampa General] is

¹⁴ *Tampa General*, at 1305.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.* at 1306.

²⁰ 209 So. 3d 1199 (Fla. 2017), cert. denied, 138 S. Ct. 129, 199 L. Ed. 2d 185 (2017).

²¹ *Tampa General*, at 1307.

²² *Id.*

²³ See Earl E. Googe, Jr., *Long and Winding Road: Federal Court Reasserts Supremacy of PSQIA Over Florida Amendment 7 in Medical Malpractice Discovery*, HEALTH ESOURCE, (Oct. 15, 2019), https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2019-2020/october-2019/winding-road/ (last accessed March 19, 2020).

²⁴ *Tampa General*, at 1307.

entitled to an injunction that enjoins the Secretary from enforcing the Patient Safety Act’s privilege and confidentiality provisions in the state court action.”²⁵

HHS has appealed this portion of the decision.²⁶

Key Takeaways from District Court Opinion

- This decision, along with the Illinois case *Daley v. Teruel*,²⁷ upheld that federal law preempts state laws that provide less protections – meaning the PSQIA preempts state laws that provide less privilege protections compared to the PSQIA.
- HHS affirmed in one of its motions that the PSQIA preempts state law.²⁸ This is the first time that HHS has stated that its position the PSQIA preemption of state law issue.
- While the U.S. District Court for the Northern District of Florida and its decisions are not binding on other federal courts or state courts, its decisions may have persuasive effect on other courts. The more courts that affirm the PSQIA preempts state laws that provide less privilege protections, the more likely this position will continue to be upheld by other courts.
- Ultimately, this case does not overturn the decision in *Charles*, but it certainly chips away at the decision which is unfavorable to PSOs.

Update: Circuit Court Opinion

HHS appealed the District Court’s decision to enjoin HHS from imposing penalties on Tampa General. On February 11, 2021, the 11th Circuit Court dismissed Tampa General’s lawsuit for lack of jurisdiction and vacated the District Court’s declarations and injunction.²⁹

At the time the District Court ruled that HHS was enjoined from imposing sanctions, it found that Tampa General faced an imminent threat from federal enforcement of the PSQIA penalties because Tampa General was facing state-court pressure to disclose PSWP, which would violate the PSQIA.³⁰ Since the District Court ruling, Tampa General’s circumstances changed: the state court stayed the contempt sanctions against Tampa General and dismissed the medical malpractice case filed by Brawley, thereby obviating any need for Tampa General to disclose PSWP.³¹

For Tampa General to face an imminent injury, the 11th Circuit Court explained the following conditions would have to be present:

1. Even though Brawley filed an appeal of his case, the state appellate court would have to reverse the trial court’s dismissal of his suit;

²⁵ *Id.* at 1305–1307.

²⁶ Defendant’s Notice of Appeal, Florida Health Sciences Centers, Inc. d/b/a Tampa General Hospital v. Azar, No. 8:18-CV-238-T-30CPT (M.D. Fla. Oct. 31, 2019).

²⁷ 107 N.E.3d 1028, 1045-46 (Ill. App. Ct. 1st Dist. 2018).

²⁸ *Tampa General*, at 1305 (stating “the Secretary ‘agrees that Amendment 7 is preempted by the Patient Safety Act.’”).

²⁹ Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital v. Secretary, U.S. Department of Health and Human Services, No. 19-14383 (11th Cir. Feb. 11, 2021).

³⁰ *Id.* at *2.

³¹ *Id.* at *1.

2. Brawley would have to request again the same PSWP;
3. The trial court must again compel disclosure;
4. Tampa General would have to acquiesce under the threat of contempt sanctions;
5. The Secretary of HHS must elect to pursue an enforcement action, even though it previously filed a statement of intent not to pursue sanctions;
6. Tampa General and Brawley must not settle the underlying case;
7. Relevant state and federal laws must remain untouched; and
8. The Florida Supreme Court must not revisit its interpretation of Amendment 7 preempting the PSQIA.³²

The 11th Circuit Court found that the threat of HHS' enforcement action against Tampa General no longer posed the sort of certainly, credibility, or substantiality required for an imminent injury and consequently found that the lack of imminent injury meant the court lacked jurisdiction over the case.³³ Consequently, the 11th Circuit Court dismissed Tampa General's lawsuit for lack of jurisdiction and vacated the District Court's declarations and injunction.

For information about how to join a patient safety organization, contact the Midwest Alliance for Patient Safety ("MAPS") at MAPSHelp@team-iha.org or 630-276-5657. MAPS is a federally certified patient safety organization and an IHA company.

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³² *Id.* at *3.

³³ *Id.*