IN THE SUPREME COURT OF FLORIDA

JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, and children, ANGEL ALSTON and JAZMIN HOUSTON, minors, and PERVIN ALSTON,

Appellants,

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Appellee.

Case No. SC15-2180
L.T. Case No. 1D15-0109
L.T. Case No. 2012-CA-002677

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PRELIMINARY STATEMENT

Appellee, Southern Baptist Hospital of Florida, Inc. ("Baptist"), adopts the following shorthand:

- "Act" means the federal Patient Safety and Quality Improvement Act of 2005.
- "Guidance" refers to the "Guidance on Patient Safety and Quality Improvement Act of 2005," 81 Fed. Reg. 32,655, issued by the U.S. Department of Health and Human Services on May 24, 2016.
- "HHS" means the U.S. Department of Health and Human Services.
- "PSE System" means "patient safety evaluation system," as defined at 42 U.S.C. § 299b-21(6).
- "PSO" means "patient safety organization," as defined at 42 U.S.C. § 299b-21(4).
- "PSWP" means "patient safety work product," as defined at 42 U.S.C. § 299b-21(7).
- "RCA" means root-cause analysis, as identified in 42 U.S.C. § 299b-21(7)(A)'s definition of "patient safety work product."
- "Supp. Opp." refers to Appellants' Response Opposing Appellee's Motion for Leave to File Supplemental Brief, dated June 29, 2016.

The appendices at Tabs A, B, and C of the record on appeal are cited by tab and page number (*e.g.*, Tab A 421).

ARGUMENT

This case concerns three distinct types of safety and quality data: information providers report to the state, information that states require providers to record but not report, and information not covered by state regulations. The Act affects the three categories differently. So does the Guidance—despite Charles' attempt to apply it across the board.

First, information not subject to state regulations—RCAs and other internal documents swept into the trial court's order—is not addressed by the Guidance and is privileged under the Act's plain terms. *Second*, information actually reported to the state is *not* privileged—which is why it was not withheld from Charles and is not at issue here. *Third*, information that satisfies the federal definition of PSWP, and that is maintained in connection with state recordkeeping rules, is privileged despite the Guidance's attempt to rewrite the binding statutory and regulatory text.

I. RCAs AND OTHER INFORMATION NOT COVERED BY STATE REGULATIONS ARE PRIVILEGED EVEN UNDER THE GUIDANCE.

The trial court ordered Baptist to produce "*all* . . . reports . . . create[d] or maintained pursuant to *any* statutory, regulatory, *licensing, or accreditation requirements*." Tab A 503 (emphasis added). This overbroad order compelled production of more than 50,000 documents, including RCAs and other internal quality documents that Baptist prepared (i) in compliance with accreditation requirements imposed by a non-governmental accrediting organization; or (ii) voluntarily in

connection with licensing. State law does not require providers to report—or even create—these documents. Nothing in the Guidance, much less the Act, supports the trial court's radical constriction of the privilege to exclude them. RCAs are clearly covered by Congress's two-step analysis for provider records:

1. *Is this type of information eligible for the privilege?* "[D]ata, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that "could result in improved patient safety, health care quality, or health care outcomes" may be protected. 42 U.S.C. § 299b-21(7)(A). The Act expressly identifies analyses "such as root cause analyses" as examples of what "the term 'patient safety work product' means." *Id*. § 299b-21(7)(A). RCAs do not fall within the "original record" exception for "a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id*. § 299b-21(7)(B)(i). They are not conducted contemporaneously with treatment, but rather after an adverse or near-miss incident is identified and analyzed for safety and quality improvement. Congress could hardly have been clearer in protecting RCAs.

2. *Was this information in fact created and maintained in a PSE System for reporting to a PSO?* There is no dispute that Baptist assembled and developed its RCAs and other information at issue as part of its PSE System, and no dispute that Baptist reports such information to its PSO. *Id*. § 299b-21(7)(A)(i)(I). It was not "collected, maintained, or developed separately," nor does it "exis[t] separate-

ly," from the PSE System. *Id.* § 299b-21(7)(B)(ii).[1]

RCAs easily satisfy this two-part test. They involve precisely the sort of "feedback and assistance to effectively minimize patient risk" that Congress intended providers to create, share, and learn from. *Id.* § 299b-21(5)(D). Because RCAs are often "create[d] or maintained pursuant to . . . accreditation requirements," the trial court compelled their production. Tab A 503. But the Act does not exclude accreditation materials from the privilege.[2] To the contrary, it directly addressed—and included—RCAs prepared in connection with accreditation within the definition of PSWP, and therefore within the privilege. The Act expressly allows disclosure of PSWP to an accrediting body without destroying the privilege, 42 U.S.C. § 299b-22(c)(2)(E), (c)(3), even though privileged PSWP normally "shall not be disclosed," *id.* § 299b-22(a)–(b). If data "maintained pursuant to . . .

[1] Information becomes protected PSWP as soon as it is collected in the provider's PSE System, even before submission to the PSO. 42 C.F.R. § 3.20(1)(i)(A) (definition of PSWP); Answer Br. 4. "[T]he Department will presume the intent to report information in the patient safety evaluation system to the PSO is present, absent evidence to the contrary." 73 Fed. Reg. 70,732, 70,741 (Nov. 21, 2008).

[2] The trial court's reference to "licensing and accreditation requirements" apparently derived from an inapposite portion of the rulemaking. HHS clarified that the PSE System "would resid[e] alongside but . . . not replace" accrediting and licensing requirements. Tab A 500 (quoting 73 Fed. Reg. at 70,742). In discussing this passage, neither the rule, 73 Fed. Reg. at 70,742, nor the Guidance, 81 Fed. Reg. at 32,657, identified accreditation as a reason the privilege would not apply. Elsewhere, in fact, the rule made clear it did not "include accreditation or licensure activities as examples of regulatory activities." 73 Fed. Reg. at 70,749.

accreditation requirements" could never be PSWP, as the trial court erroneously concluded, Tab A 503, Congress would have had no need to exempt disclosures to accrediting bodies from the Act's confidentiality requirements.

It is unsurprising, therefore, that nothing in the Guidance calls into question RCAs' eligibility for protection. The Guidance cites the disclosure exemption for accrediting bodies with approval. 81 Fed. Reg. at 32,660. It does not identify RCAs among the materials HHS contends are ineligible for the privilege. Indeed, the Guidance includes only one passing mention of RCAs, *id.* at 32,655 n.3, in the context of *state* regulations. Regardless of any weight given the Guidance, the First DCA's decision to quash the trial court's overbroad order must be affirmed with respect to RCAs and other materials, not required by the state, that Baptist created and maintained in its PSE System.

II. INFORMATION ACTUALLY DISCLOSED IS NOT PRIVILEGED—AND NOT IN DISPUTE.

The Guidance, Charles' submissions, and the trial court order spill considerable ink over an uncontroverted point: providers may not disclose PSWP to satisfy state *reporting* obligations without sacrificing the privilege. *E.g.*, Initial Br. 5, 7–8; 81 Fed. Reg. at 32,655–56; Tab A 500. The Act makes clear that the privilege does not preempt federal, state, and local reporting obligations, 42 U.S.C. § 299b-21(7)(B)(ii), and that PSWP "shall not be disclosed" absent a statutory exception, *id*. § 299b-22(a)–(c). Baptist has never failed to report information required by the

state on the ground that the information was PSWP, nor has it ever withheld information from Charles that it has reported to the state. Answer Br. 41–43. Baptist has already disclosed its Annual Reports and Code 15 Reports to the state and to Charles. Arguments that PSWP cannot be used to satisfy external reporting requirements, *e.g.*, 81 Fed. Reg. at 32,656, are beside the point.

III. INFORMATION KEPT UNDER STATE RECORDKEEPING RULES MAY BE PRIVILEGED.

The only data reasonably in dispute, therefore, are occurrence reports that are maintained—but not reported—in compliance with state regulations. The statute clearly distinguishes reporting requirements from recordkeeping requirements. *E.g.*, 42 U.S.C. § 299b-21(7)(B)(iii)(II)–(III). The Act bars providers from disclosing PSWP outside the organization absent a specific exception, *id*. § 299b-22(a)–(d), but it does not contain a similar prohibition on the internal use of PSWP for recordkeeping. Yet Charles and the Guidance repeatedly conflate these obligations, concluding that *any* material subject to *any* state regulatory requirement cannot be privileged. *E.g.*, Reply Br. 4–11; 81 Fed. Reg. at 32,655–56.

Congress's definition of the federal privilege, *supra* pp. 2–3, does not turn on state law. It does not even mention state law—though it easily could have, had that been Congress's intent. Rather, Congress's goal was a uniform privilege, 42 U.S.C. § 299b-22(a); 73 Fed. Reg. 8,112, 8,113 (Feb. 12, 2008), that preempted inconsistent state privilege laws without disrupting state oversight law, *compare* 42

U.S.C. § 299b-22(a)–(b) (preemption), *with id.* § 299b-21(7)(B)(iii) (preserving state reporting and recordkeeping obligations). The Act does not shield a provider that violates a state requirement from state-law repercussions, 73 Fed. Reg. at 70,742 (state-law violations remedied in "the same manner as" before the Act)—but neither does it allow states to pierce the federal privilege by authorizing disclosure of protected materials. The Guidance and Charles advocate, in essence, state nullification of federal law, and defend this upside-down result by asserting that state-regulated records were never privileged to begin with. But this just begs the question. Nothing suggests the Act preempts only what states declined to regulate.

The contrary view is incompatible with the statutory text. This is best illustrated by the contradictory interpretations of the trial court, Charles, and Guidance.

1. *The trial court's ruling* rested on the Act's preservation of state reporting and recordkeeping requirements. *See* Tab A 499–500. As noted above, *supra* pp. 5–6, those state rules do not define the scope of the federal privilege; they merely subject providers to potential *state* liability if they cannot satisfy regulatory obligations without disclosing PSWP. *S. Baptist Hosp. of Fla., Inc. v. Charles*, 178 So. 3d 102, 109 (Fla. 1st DCA 2015).

2. *Charles' appellate submissions*, *e.g.*, Initial Br. 33, contrary to their position in the trial court, argued that state-recordkeeping information is not privileged because it is "information that is collected, maintained, or developed sepa-

rately, or exists separately, from a [PSE System]." 42 U.S.C. § 299b-21(7)(B)(ii). But "exists separately" does not mean "separately required." And Baptist's occurrence reports were not maintained separately from its PSE System in any event. Charles' argument depends on two additional unsubstantiated premises: Florida law requires Baptist to maintain records in an unprivileged database, and violating this hypothetical state regulation would destroy the federal privilege. Initial Br. 28, 33. No evidence, text, or logic supports either position. *See infra* p. 9 and note 5.

3. *The Guidance*, unable to locate a "state-law" exception in the statute, offers two possible interpretations in support of its preferred outcome. Privileged information purportedly must be "prepared solely for reporting to a PSO," 81 Fed. Reg. at 32,657, because PSWP is defined in part as material "assembled or developed by a provider for reporting to a [PSO]." 42 U.S.C. § 299b-21(7)(A)(i). This interpretation would exclude materials that serve any other purpose, such as satisfying state recordkeeping rules, or even internal quality improvement. But that reading only works if the word "solely" is inserted into the statutory text, contrary to the language Congress actually enacted. The Act's other provisions, moreover, squarely foreclose reading "for" as "solely for." Its confidentiality exceptions authorize the use of PSWP "for a variety of purposes," H.R. Rep. No. 109-197, at 14 (2005): for "patient safety activities," for authorized "research" and "demonstration projects," "to an accrediting body," "for business operations," and to law en-

forcement, 42 U.S.C. § 299b-22(c)(2)(A)–(G). This dual-purpose material remains privileged PSWP. *Id.* § 299b-22(d)(1). Under the Guidance's approach, by contrast, the material was never PSWP in the first place—which would render Congress's list of exceptions pure surplusage.[3]

The Guidance also posits that information subject to state recordkeeping and reporting obligations are "original provider records" excluded from the definition of PSWP. 81 Fed. Reg. at 32,658. This alternative reading of the statute—which Charles has never asserted—is novel, unsupported, and unpersuasive. *See id.* at 32,658 n.32. "Original provider record" means contemporaneous clinical and administrative materials. Such "traditional health care operations or record keeping" include "medical records, billing records, guidance on procedures, physician notes, hospital policies, logs of operations, records of drug deliveries, [and] primary information *at the time of events*." H.R. Rep. No. 109-197, at 14 (emphasis added). Quality and safety reports developed *after the fact* are not original records.

The government's attempts to recast the text Congress enacted deserve no judicial deference. Charles concedes the Guidance, which was promulgated with-

[3] It also would necessitate a subjective inquiry into a provider's *true* purpose, "result[ing] in widely varying applications" of the privilege. *See Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981). Under the Guidance's amorphous standard, *see* 81 Fed. Reg. at 32,657, a hospital employee who creates a record will seldom know at the time the record is created whether the record will qualify as PSWP, and that uncertainty will deter the voluntary reporting on which the Act relies.

out notice and comment, is ineligible for *Chevron* deference, Supp. Opp. 7, but suggests *Auer* deference may apply to HHS's interpretation of its own regulations. That is incorrect. The Guidance identifies no ambiguity in the relevant regulatory language that it purports to clarify. Nor could it. The final rule took a clear position, after notice and comment rulemaking, that is diametrically opposed to what the Guidance now endorses: in 2008, HHS interpreted the PSWP privilege to apply regardless of whether a state recordkeeping requirement applied.[4] Despite years of provider reliance on that rule, the Guidance retroactively replaced that interpretation with one that undermines Congress's core purpose of "encourag[ing] providers to share [PSWP] without fear of liability." 73 Fed. Reg. at 70,732. Although Charles is correct that government interpretations advanced in litigation are not *categorically* ineligible for deference, Supp. Opp. 8, no deference is due a "post hoc rationalization" or "inconsistent" interpretation like this one. *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166 (2012); *see* Supp. Opp. 7 (interpretation not controlling if "inconsistent with the regulation") (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)).[5]

[4] The 2008 final rule presupposes that PSWP may include state-regulated records. It explained that disclosure of PSWP "*even to a State entity* . . . must have an applicable disclosure permission," and "a State *may not require* that patient safety work product be disclosed." 73 Fed. Reg. at 70,743–44 (emphases added).

[5] Even more glaring is HHS's about-face that providers must maintain PSWP separately from other state-regulated information. Under the 2008 final rule, "providers

Even if this Guidance deserved some deference with respect to federal law, it plainly cannot determine what if any activities violate state recordkeeping requirements. In this Court (but not below), Charles has repeatedly accused Baptist of violating state recordkeeping requirements, *e.g.*, Initial Br. 42–43, Supp. Opp. 6, and framed the entire appeal around these false and unsupported allegations. Those allegations are wrong and irrelevant: wrong because the state has never identified any violation related to Baptist's compliance, which has been diligent and comprehensive; and irrelevant because neither PSWP preemption nor state discovery obligations turn on state regulatory violations.

The Guidance cannot help Charles' case on this crucial point: Baptist's compliance has not been adjudicated and was not known to HHS, which has no authority to interpret state law in any event. *See* Initial Br. at 38. And despite Charles' insinuations, the PSWP privilege does not shield *facts* about Charles' case. As envisioned by the Guidance, 81 Fed. Reg. at 32,657 n.21, Charles has had full discovery into this treatment, including the occurrence reports. The voluminous discovery it now seeks is neither justifiable nor allowable.

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need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations." 73 Fed. Reg. at 70,740–42 (emphasis added); *accord id.* at 70,794. Yet the Guidance now says HHS has "*reiterated* that a provider *should* maintain at least two systems or spaces: a [PSE System] for [PSWP] and a separate place where it maintains records for external obligations." 81 Fed. Reg. at 32,659 (emphases added).

Respectfully submitted this twenty-first day of July, 2016.

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I certify that the foregoing brief complies with the font requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

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