IN THE SUPREME COURT OF FLORIDA
CASE NO.: SC15-2180

JEAN CHARLES, JR., as next Friend and duly appointed Guardian of his sister, MARIE CHARLES, and her minor children, ANGEL ALSTON, and JAZMIN HOUSTON, minors, and PERVIN ALSTON,

Appellants,

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC. d/b/a Baptist Medical Center-South, KRISTIN FERNANDEZ, D.O., YUVAL Z. NAOT, M.D., SAFEER A. ASHRAF, M.D., INTEGRATED COMMUNITY ONCOLOGY NETWORK, LLC, a Florida limited liability corporation, ANDREW NAMEN, M.D., GREGORY J. SENGSTOCK, M.D., JOHN D. PENNINGTON, M.D., and EUGENE R. BEBEAU, M.D.,

Appellees.
_____ /

L.T. Case Nos.: 1D15-0109
2012-CA-002677

ON APPEAL FROM THE DISTRICT COURT, FIRST DISTRICT, STATE OF FLORIDA

REPLY BRIEF OF APPELLANTS

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ARGUMENT

This brief makes four points in rebuttal. First, Baptist ignores the PSQIA's plain statutory text. *Infra* Point 1, at 1. Second, our argument does not nullify the PSQIA. *Infra* Point 2, at 6. Third, Baptist overlooks the critical role of Florida patients and courts in overseeing providers. *Infra* Point 3, at 12. Fourth, Baptist ignores the non-textual sources that contradict its interpretation. *Infra* Point 4, at 12.

1. Baptist's interpretation of subparagraph (B) contravenes the plain text.

This case hinges on a proper interpretation of subparagraph (B) of 42 U.S.C. § 299b-21(7). Baptist's argument contravenes this subparagraph's plain text:

> (i) Information described in subparagraph (A) [which defines PSWP] 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 [PSES]. Such separate information or a copy thereof reported to a [PSO] shall not by reason of its reporting be considered [PSWP].
>
> (iii) Nothing in [the PSQIA] shall be construed to limit—
>
> . . . .
>
> (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.

42 U.S.C.A. § 299b-21(7)(B).

The parties agree that clauses (i) and (ii) define the exceptions to PSWP (AB 17; IB 3-4, 39) and that, under clause (iii), the PSQIA does not excuse providers from complying with state reporting and recordkeeping laws (AB 24; IB 35). The parties, however, disagree on two critical sets of questions. First, under clause (ii), who or what determines whether certain information must be collected, maintained, or developed separately from the PSES and thus not qualify as PSWP? The provider? Or federal, state, and local reporting and recordkeeping laws? Second, under clause (iii), may a provider maintain state-mandated records as privileged PSWP within its PSES? Or must state-mandated records be maintained separately from the PSES? Baptist's interpretation of both clauses is unsupported by the text.

a. Clause (ii) cannot be reasonably read as authorizing providers to decide what is and is not non-privileged "separate information."

According to the First District, the PSQIA empowers a provider to unilaterally decide whether information is "separate" or not (and thus whether information is non-PSWP or PSWP) because, under the First District's reading of the PSQIA, the provider "determines how information is stored and reported." (R. 477.) This interpretation cannot be reconciled with clause (ii)'s second sentence: "Such separate information or a copy thereof *reported* to a [PSO] shall not by reason of its *reporting* be considered [PSWP]." 42 U.S.C.A. § 299b-21(7)(B)(ii); (IB 41-42).

Notwithstanding the irreconcilable conflict between the First District's interpretation and the plain language of clause (ii)'s second sentence, Baptist

embraces the First District's interpretation. After quoting just the first sentence of clause (ii), Baptist argues, "[Clause (ii)] asks a simple and objective question of fact: was the record collected, maintained, and developed—and does the record exist—within the provider's [PSES]? If so, it is protected. If not, it is not." (AB 18.) Though framing this "simple" question in the passive tense, it is clear that, according to Baptist, the provider unilaterally decides whether a state-mandated record is collected, maintained, and developed within the PSES or not.

An illustration given by Baptist on how, it thinks, clause (ii) should operate is very telling. Baptist reports that it "maintains the agendas and minutes of meetings of some of its quality-improvement committees outside of its PSE System;"[1] therefore, Baptist declares, the agendas and minutes are not PSWP. (AB 20.) But, under Baptist's interpretation of clause (ii), if Baptist later decides to collect, maintain, or develop these same agendas and minutes within the PSES, then they would become PSWP. Nothing in Baptist's brief refutes this assertion.

Perhaps realizing its interpretation would effectively nullify clause (ii), Baptist proposes some limiting principles on its interpretation. (AB at 31-33.) These limiting principles are unsatisfactory. They would not stop Baptist from transforming into PSWP any state-mandated records, other than those records qualifying as original patient or provider records under clause (i).

[1] State law mandates some quality-improvement committees. (IB 15-16.)

Indeed, for its first limiting principle, Baptist points out that clause (i) prevents it from storing original patient or provider records in its privileged PSES. (AB at 31, 32-33.) Baptist is correct, but this point fails to address the question before this Court: What did Congress mean in clause (ii) when it expressly removed "separate information" from the definition of PSWP? Baptist's point suggests Congress wrote clause (ii) to be no different than the "original record" exception in clause (i). This, of course, cannot be so. In construing a statute, a court is "obliged to give effect, if possible, to every word Congress used." *E.g., Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979); *accord* (AB at 47).

For its second limiting principle, Baptist turns, ironically, to clause (iii). (AB 31-32, 42.) It notes that clause (iii) (in particular, subclause (II)) would not allow it to make privileged information that must be reported to the State. (AB 31-32, 42.) This argument is odd because, earlier in its brief, Baptist criticized us for "blend[ing]" clauses (ii) and (iii) and for our "fusion" of these two purportedly "distinct" clauses that are located side-by-side to one another in subparagraph (B). (AB 25.). Notwithstanding this internal inconsistency, we applaud Baptist's implicit recognition that clause (iii) is relevant to interpreting what is "separate information," and thus not PSWP, under clause (ii). (IB 38-39.) However, as explained next, Baptist has ignored clause (iii)'s plain text requiring providers to satisfy state-law reporting and recordkeeping obligations with information that is not PSWP.

b. Under clause (iii)'s plain text, providers must use non-privileged information outside of the PSES to satisfy state–law obligations.

Baptist admits that the PSQIA does not excuse it from complying with its state-law reporting and recordkeeping obligations. (AB 24.) Baptist, however, insists that it may store state-mandated records in its privileged PSES to satisfy its state-law obligations. (AB 6-7 ("The adverse incident reports that the State requires Baptist to create and maintain . . . are a subset of Baptist's occurrence reports," which "do not exist in any other place, separate and apart from the [PSES]."); *see also* AB 25-26.) But nowhere in its brief does Baptist try to reconcile this position with the plain text in clause (iii) that says just the opposite:

> (iii) Nothing in [the PSQIA] shall be construed to limit—
>
> . . . .
>
> (II) the reporting of information described in this subparagraph [B] 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 [B] under Federal, State, or local law.

"Information described in this subparagraph" means non-privileged information described in clauses (i) and (ii) of subparagraph B. (IB 5 & n.3, 38.)

Baptist admits that the information described in clauses (i) and (ii) of subparagraph is not PSWP. (AB 17.) Yet, Baptist insists that it can abide by its state-law obligations under clause (iii) by using privileged PSWP information locked away in a PSES. (AB 6-7, 25-26.) Clause (iii), however, plainly indicates a provider

must satisfy state-law reporting and recordkeeping obligations with non-privileged information described in clauses (i) and (ii) of subparagraph (B). And, thus, HHS instructs providers that information used for state-law obligations cannot be PSWP. (IB 6-7, 38 (citing 73 Fed. Reg. at 7042).).

2. Following the PSQIA's plain text, which preserves state reporting and recordkeeping laws, will not nullify federal law or the PSQIA's purpose.

Our initial brief described Florida's recordkeeping and reporting laws. (IB 13-17.) Baptist never disagrees that these laws are, in fact, recordkeeping and reporting laws. Our initial brief also argued these laws require providers to maintain state-mandated information separately from a privileged database. (IB 34-36.) Baptist never argues otherwise. Instead, it argues the PSQIA preempts these laws. Baptist's argument, however, rests on a faulty preemption analysis and misstatements.

a. Baptist overlooks that Congress expressly stated it did not intend to limit or preempt state-law reporting and recordkeeping laws.

Baptist wrongly asserts that we seek a "broad, unwritten exception" to "nullify federal law." (AB 28.) In fact, Congress has defined two broad, written exceptions to PSWP in clauses (i) and (ii), *see* 42 U.S.C.A. § 299b-21(7)(B). And Congress clearly expressed an intent in clause (iii) that these written exceptions be construed to preserve, **not** preempt, state reporting and recordkeeping laws. *Id.*

Baptist cites a hodgepodge of preemption principles to support its "nullification" argument. (AB 28-31.) It overlooks the cardinal preemption

principle: the "ultimate touchstone" for determining the scope of a federal statute's pre-emptive effect is Congress's intent as expressed in the statute. *E.g.*, *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008). Congress indicates its preemptive intent through either: (1) the statute's express language or (2) the statute's structure and purpose. *E.g.*, *id.* Baptist's analysis erroneously focuses on the latter method to infer the PSQIA's preemptive scope. But, here, Congress expressly wrote into the statute the PSQIA's preemptive scope. *See* 42 U.S.C.A. § 299b-21(7)(B)(iii); *id.* §299b-22(g)(2)&(5). When Congress has written a provision explicitly addressing the scope of preemption, a court should not infer an intent to pre-empt state laws from the legislation's substantive provisions; instead, it should follow the express provision. *E.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992).

The recent U.S. Supreme Court ERISA case cited by Baptist illustrates the erroneous nature of Baptist's preemption analysis. (AB 30-31 (discussing *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936 (2016)). In *Gobeille*, the Court reiterated the "starting point" for any preemption analysis is the preemptive intent that Congress itself expressly wrote in the statute. *See* 136 S. Ct. at 943. The federal ERISA statute at issue in *Gobeille* had an express preemption provision that broadly, comprehensively, and plainly preempted many state laws. *See id.*; *see also id.* at 947 (Thomas, J. concurring) (noting ERISA "contains what may be the most expansive express pre-emption provision in any federal statute"). Specifically, in ERISA,

Congress expressly preempted "any and all State laws insofar as they may now or hereafter related to any employee benefit plan." 29 U.S.C. § 1144(a).

In contrast, here, the PSQIA does not have any express preemption provision, much less a broad provision like ERISA. Instead, the PSQIA has the polar opposite – an anti-preemption provision (also called a savings provision). *See* 42 U.S.C. § 299b-21(7)(B)(iii); *id.* §299b-22(g)(2)&(5). Ironically, *Gobeille* perfectly demonstrates how the existence of an anti-preemption provision (like the PSQIA has) may be dispositive of a statute's preemptive scope. In *Gobeille*, the Court accepted a preemption argument based on ERISA, but it was skeptical of an alternative preemption argument based on another federal statute, ACA, because ACA has an anti-preemption provision.[2] 136 S. Ct. at 946-47. Similarly, this Court rejected a prior preemption attack on Amendment 7, based on the HCQIA, because that statute had anti-preemption provisions. *See W. Florida Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1, 20-21 (Fla. 2012).

b. The PSQIA will not be a "dead letter." Our interpretation promotes, rather than undermines, the PSQIA's purpose.

Baptist engages in hyperbolic, misleading argument when it asserts our position undermines Congress's intent, makes the PSQIA a "dead letter," and results in no record being privileged. (AB 27-29.) Congress's express will was to preserve,

[2] The Court ultimately declined to decide the ACA preemption issue given its holding that ERISA preempted the state statute. *Gobeille*, 136 S. Ct. at 946-47.

not pre-empt, state reporting and recordkeeping laws. *Supra* at Argument 2.a., at 6-8. We merely ask this Court to honor this congressional intent. Doing so will not strip away PSQIA protections from all records. Providers still may voluntarily keep privileged information not collected, maintained, or developed for state, local, or federal recordkeeping and reporting obligations. And preserving these obligations will achieve the PSQIA's purpose – as stated by Baptist and its amici (*e.g.*, AB 32) – of ensuring patients have access to the facts of adverse medical incidents.

Baptist is flat out wrong when it argues that, under our interpretation, states may nullify the PSQIA's privilege by merely enacting laws that allow access to all of a provider's records. (AB 27.) To overcome any protection that the PSQIA may provide to a record, the state law must do more than simply mandate access to the record; the state law must also mandate the information in the record be collected, maintained, or developed.[3] Of course, providers are free to collect, maintain, and develop any other information – the collection, maintenance, or development of which is not mandated by state law – and voluntary keep that information privileged in the PSES. But providers may not use the voluntary PSES to hide information that state law already mandates be collected, maintained, or developed.

[3] This requirement distinguishes our argument from *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. Ct. 2012) (IB 35), because, as Baptist admitted below, "there was no contention in *Walgreen* that state law required the pharmacy to create or maintain the contested reports." (R. 31.)

The fallacy of Baptist's hyperbolic arguments is best exemplified by the information required for the state-mandated 3-day incident reports, which Baptist unlawfully conceals as part of its "occurrence reports" in its privileged PSES. A provider must collect the following information for the 3-day reports:

> (a) The patient's name, locating information, admission diagnosis, admission date, age and sex;
> (b) A clear and concise description of the incident including time, date, exact location; and elements as needed for the annual report . . . ;
> (c) Whether or not a physician was called; and if so, a brief statement of said physician's recommendations as to medical treatment, if any;
> (d) A listing of all persons then known to be involved directly in the incident, including witnesses, along with locating information for each;
> (e) The name, signature and position of the person completing the reports, along with date and time that the report was completed.

Fla. Admin. Code R. 59A-10.0055(2). After collecting this mandatory information, a provider also may voluntarily collect, maintain, or develop additional information about the incident. And the provider may permanently keep this additional, voluntarily collected information in its PSES for reporting to the PSO. (IB 35-36.)

But the same is not true for state-mandated information, like the information collected, maintained, or developed under Rule 59A-10.0055(2) or section 395.0197(1)(a), Florida Statutes (2014).[4] A provider must keep this state-mandated

[4] Baptist emphasizes that section 395.0197(1)(a) does not use the words "root-cause analysis." (AB 46.) The particular words used are not important. What is important is that section 395.0197(1)(a) requires providers to investigate and analyze adverse incidents. Under the "separate information" exception in 42 U.S.C.A. § 299b-21(7)(B)(ii), Ms. Charles is entitled to any information collected, maintained, or developed under an investigation or analysis mandated by section 395.0197(1)(a).

information separate from the privileged PSES in a manner accessible to patients and regulators. (IB 34-40.) Granted, during the initial collection of information, providers often may have difficulty sorting out what is and is not state-mandated information. For this reason, HHS granted providers a generous accommodation by allowing them to temporarily store all collected information in the PSES until the provider can assess which information must be removed from the PSES to satisfy its obligations under state reporting and recordkeeping laws. (IB 6-7, 43-44.) Baptist, however, has abused this generous accommodation. It dumps into its PSES all the information that state law requires it to collect, leaves the information there, and then charges patients, like Ms. Charles, exorbitant amounts to extract the information to which they are constitutionally entitled.

Even Baptist and its supporting amicus, the Joint Commission, admit the PSQIA's purpose is not to hide the facts.[5] Preserving state reporting and recordkeeping laws will bolster, not undermine, this purpose. For example, the information required for 3-day incidents reports is intensely factual. *See* Fla. Admin. Code R. 59A-10.0055(2) (quoted at 10.) Yet, for seven months, Baptist concealed in its PSES the incident reports on Ms. Charles. (IB 23.) Contrary to the lofty

[5] Baptist states, "[T]he Act . . . does not shield facts." (AB 32.) The Joint Commission states, "The [PSQIA] does not supplant or interfere with state required incident reports or the patient's right to know . . . ." (Amicus Br. 19; *see also id.* at 5-6 ("The information not in the [PSES], such as the factual basis for the issues in a particular case, is available for a states' review and may be reported in an incident report.")

purposes for the PSQIA detailed in its brief (AB at 1-2), Baptist's actual conduct shows it is abusing the PSQIA to hide factual information from patients, contrary to Congress's intent. (IB at 11 & n.11.)

3. Florida patients and courts have a critical role in overseeing providers.

Baptist is wrong to argue that a provider's storage of state-mandated information in a PSES will not frustrate the state's oversight of providers. (AB 33-35.) Granted, if Baptist's primary regulator, AHCA, demands state-mandated records, Baptist may promptly produce the records, even if they are stored in its PSES, because AHCA may revoke its license. § 395.003(1)(a), Fla. Stat. (2014). However, in Florida, state agencies do not stand alone in overseeing providers. Patients also oversee providers. Specifically, under Amendment 7, patients may inspect a variety of state-mandated records, even records unrelated to their own care. *See* Fla. Const., Art. X, § 25; (IB 16-17.) Yet, unlike AHCA, patients need the courts to carry out their oversight role. Baptist's distorted interpretation of the PSQIA obstructs the oversight role of Florida's patients and courts. (IB 22-24.)

4. After relying heavily in the First District on non-textual sources, Baptist ignores the parts of those sources that contradict its narrative.

a. Introduction. Unquestionably, the PSQIA's plain statutory text is paramount. (IB 31.) The text shows no intent to preempt. *Supra* Point 2, at 6-12. In the court below, however, Baptist's narrative was based on non-textual sources. It cited fifteen times the HHS regulatory preamble (R. 11, 13-15, 34-36), which it now

says is due no judicial deference (AB 39; *but see* IB 31 n.14). Baptist explained the PSQIA with two pages attributable solely to a 2003 Senate committee report, which it cited a dozen times. (R. 9-13.) It also cited a House committee report (R.13-15, 30) and congressional testimony (R. 43-44). The First District was persuaded. It relied heavily on the Senate report and the HHS preamble. (R. 467-69, 476.)

But Baptist's non-textual narrative was inaccurate. For instance, the 2003 Senate report concerned a prior version of a never-enacted bill that did not have any language similar to the enacted language in § 299b-21(7)(B)(iii), which, of course, preserves state reporting and recordkeeping laws. (R. 229-32; IB 9 n.4.) Baptist's narrative also omitted portions of the Senate and House reports that showed: (i) no congressional intent to preempt state law and (ii) Congress's intent for the public to have access to the same information it could access before the Act. (IB 12-13.)

After winning with a misleading non-textual narrative, Baptist now denounces the non-textual sources. (AB 36-45.) It argues the PSQIA's language is unambiguous and resort to non-textual sources is unnecessary. (AB 36, 40.) We agree. The PSQIA unambiguously does not preempt Amendment 7. But, if this Court finds the PSQIA is ambiguous, it may consider the non-textual sources. (IB 31.)

b. HHS regulatory preamble. A preamble may contribute to a "general understanding" of the text, although it cannot trump unambiguous text.[6] *Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 237 (D.D.C. 2014) (cited at AB 39)(quoting *Nat'l Wildlife Fed. v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002)). Courts may rely on a preamble even when the text is unambiguous. For example, though recognizing that it defers to a preamble only when the text is ambiguous, the Second Circuit relied on a preamble to "bolster" its reading of unambiguous text. *Ramos v. Baldor Specialty Foods, Inc.*, 687 F.3d 554, 559 & n.3 (2d Cir. 2012). The nonbinding preamble was "persuasive because it rest[ed] on a body of experience and informed judgment to which courts and litigants may properly resort for guidance." *Id.* at 561 (internal quotation omitted); *see also Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) (noting that a preamble, though not controlling, shows the drafter's "contemporaneous understanding" of the text). Finally, even if the *Chevron* doctrine does not apply, this Court may owe some deference to HHS's preamble under the *Skidmore* doctrine. (IB 31 n.14.)

c. Floor statements. Baptist's characterization – the floor statements reflect only three members' views (AB 32) – is neither accurate nor fair. The primary

[6] The text to be interpreted is statutory, the PSQIA. However, the HHS's rule defining PSWP largely parrots the PSQIA's statutory definition. *Compare, e.g.*, 42 C.F.R. § 3.20, *with* 42 U.S.C. § 299b-21(7)(B)(same). Thus, the regulatory preamble, 73 F.R. 7032-01, should be instructive of both the statute and the rule.

floor statements in our brief were by the PSQIA's chief architect and Senate sponsor (Sen. Jeffords) and the Senate committee chairman who reported the bill (Sen. Enzi). (IB 9-11.) The House sponsor and others made consistent statements. (R. 228; Tab C, Supp. App. 464.) These statements are an "authoritative guide," meriting "substantial weight" in construing the PSQIA.[7] They do not amend the PSQIA's text. *Cf. Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 457 (2002).

Also without merit is Baptist's complaint about floor statements made one day after the Senate's passage but before the House's passage. (AB 37.) The timing of the statements here distinguishes this case from cases cited by Baptist. *See, e.g.*, *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 240-42 (2011) (faulting the dissent for relying on legislative history from a subsequent session of Congress). More importantly, the post-passage statements are consistent with pre-passage statements and the committee reports. (IB 11-13& n.8; R. 228; Tab C, Supp. App. 440, 464.) Thus, if the Court disregards the post-passage statements, the result will be the same.

CONCLUSION

The Court should reverse and grant the relief requested in the initial brief.

[7] *N. Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 526-27 (1982) (holding a sponsor's remarks, though not "controlling," are an "authoritative guide"); *Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (holding a sponsor's statement should "be accorded substantial weight"); *see Boumediene v. Bush*, 553 U.S. 723, 738 (2008) (holding lower court was correct to rely on floor statements in construing a statute); *cf. United States v. McKesson & Robbins, Inc.*, 351 U.S. 305, 313-14 (1956) (cited at AB 37) (giving little weight to statement of member who was not "in charge of the bill" or "a member of any committee that had considered it").

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished, via electronic mail, to the following on this 20th day of May, 2016:

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that the foregoing brief is in Times New Roman 14-point font and complies with the font requirements of Rule 9.210(a)(2), Florida Rules of Appellate Procedure.

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