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.
- "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).

The record on appeal is cited as "R", followed by the volume and page numbers (*e.g.*, "R3 464"), except that the appendices at Tabs A, B, and C of the record are cited by tab and page number (*e.g.*, Tab A 421). Finally, Appellants' Initial Brief, dated February 10, 2016, is cited as "Br.", followed by the page number (*e.g.*, Br. 42).

STATEMENT OF CASE AND FACTS

The Patient Safety and Quality Improvement Act

In 1999, the Institute of Medicine reported that as many as 98,000 Americans die each year from preventable medical errors, most of which are caused not by isolated mistakes, but by "system failures." S. Rep. No. 108-196, at 2 (2003). The report noted that "society's long-standing reliance on the threat of malpractice litigation discourages health care professionals and organizations from disclosing, sharing, and discussing information about medical errors." *Id*. It recommended the creation of a protected system in which information might be shared and errors might be identified and evaluated without fear of blame and litigation. *Id*. at 1–2.

In 2005, Congress responded to the Institute of Medicine report and enacted the Patient Safety and Quality Improvement Act of 2005. In passing the Act, Congress sought to "promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a 'culture of safety' that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors." *Id*. at 3.

Under the Act, each provider establishes a system—the PSE System—to collect, manage, and analyze patient-safety information. *See* 42 U.S.C. § 299b-21(6). Providers like Baptist collect information through their PSE Systems and

transmit the information to federally listed PSOs. *Id*. § 299b-21(4). To the extent possible, providers transmit information to PSOs in a standardized manner to enable valid comparisons of similar cases among similar providers. *Id*. § 299b-24(b)(1)(F). PSOs assess the information and present "feedback and assistance to providers to effectively minimize patient risk." *Id*. § 299b-24(b)(1)(G). Information reported to PSOs may then be anonymized and aggregated in the National Patient Safety Database and made available to providers as an "evidence-based management resource." *Id*. § 299b-23(a). In this manner, information gathered from the errors and best practices of one provider can be disseminated to educate and improve the practices of both participating and non-participating providers nationwide.

Congress recognized that a comprehensive system of information collection and analysis cannot be effective without the voluntary participation of health care providers. To engender the trust and cooperation of providers, Congress declared all "patient safety work product"—PSWP—privileged and confidential. *Id*. § 299b-22(a)–(b). It defined PSWP broadly to mean, in relevant part, "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" that (1) are assembled or developed by a provider for reporting to a PSO; (2) are in fact reported to a PSO; and (3) could result in improved patient safety, health care quality, or health care outcomes. *Id*. § 299b-21(7)(A)(i).

Congress enacted a provision of express preemption, providing the PSWP is privileged and confidential "[n]otwithstanding any other provision of Federal, State, or local law." *Id.* § 299b-22(a), (b). The federal privilege is not limited to hospitals, but extends to almost all health care providers. *Id.* § 299b-21(8).

Congress also provided two exceptions to the definition of PSWP. PSWP does not include "a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* § 299b-21(7)(B)(i). Nor does it include "information that is collected, maintained, or developed separately, or exists separately," from the provider's PSE System. *Id.* § 299b-21(7)(B)(ii). Information that exists outside the PSE System may be submitted to a PSO, but it does not acquire protection as a result of that submission. *Id.*

Congress made clear that the Act does not limit the reporting and record-keeping obligations of providers. *Id.* § 299b-21(7)(B)(iii)(II)–(III). The Act expressly permits additional analysis by a PSO or a PSE System of "issues identical to or similar to those for which information was reported to or assessed," *id.* § 299b-22(h), and authorizes certain limited disclosures of PSWP, *id.* § 299b-22(c). For example, a provider may disclose PSWP, including its specialized analyses called root-cause analyses, to its accrediting body consistent with, and without a waiver of, the confidentiality that the Act confers. *Id.* § 299b-22(c)(2)(E), (d)(1).

Finally, Congress imposed fines and other remedies to ensure that participants do not make unauthorized disclosures of protected information. *Id*. § 299b-22(f).

In 2008, the U.S. Department of Health and Human Services adopted final regulations to implement the Act. The regulations clarified two essential points. First, the Act's protections attach upon collection of the information in the PSE System, even while those records await submission to the PSO—not merely when the information is reported to a PSO. Br. 6; 42 C.F.R. § 3.20(1)(i)(A) (defining PSWP to include "information that is documented as within a [PSE System] for reporting to a PSO"). Second, providers need not maintain separate systems for the collection of information that must be reported to the State. Br. 6. Rather, a provider may collect information in its PSE System and then, before its submission to a PSO, remove information that must be reported to the State. *Id*. Once "removed" from the PSE System, information is "no longer considered" PSWP. 42 C.F.R. § 3.20(2)(ii) (definition of PSWP). It then "exists separately" from the PSE System and may be disclosed. *See* 42 U.S.C. § 299b-21(7)(B)(ii). In combination, these regulations avoided the administrative burdens and duplication of labor that would have encumbered the operation of separate systems, and thus removed a potential barrier to voluntary provider participation.

Baptist's Establishment of a Confidential PSE System

The undisputed evidence before the trial court clearly showed that Baptist had established a PSE System in reliance on the Act. Baptist established its PSE System soon after the Act's adoption in 2005. Tab A 419 ¶ 7. It began to collect, manage, and analyze information within its PSE System in early 2006 and began to label information as PSWP in July 2006. *Id*. ¶¶ 8–9. Since 2006, in reliance on the Act, Baptist has instructed its employees to enter information into the PSE System with an assurance of confidentiality. *Id*. ¶ 12.

Soon after PSOs were first listed in 2009, Baptist joined a PSO named the Patient Safety Organization of Florida ("PSOFlorida"). *Id*. ¶ 10. PSOFlorida was listed as a PSO in February 2009, and continues to be listed today. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://pso.ahrq.gov/listed. Baptist executed an agreement with PSOFlorida on January 25, 2010, and has been a member ever since. Tab A 419 ¶ 10. Baptist began to submit information to PSOFlorida in 2011 and has continued to submit information to PSOFlorida on a regular basis. *Id*. ¶ 11.

A central feature of Baptist's PSE System is its "occurrence reports." Occurrence reports record any and all events inconsistent with the routine operation of the hospital or the routine care of a patient. *Id*. ¶ 13. Hospital employees prepare occurrence reports through secure electronic portals to which they have constant

access. *Id*. 420 ¶ 15. Employees are instructed in the operation of the PSE System and enter information with the assurance that information will remain privileged and confidential. *Id*. All occurrence reports are collected and maintained within Baptist's PSE System for submission to PSOFlorida. *Id*. Occurrence reports do not exist in any other place, separate and apart from the PSE System. *Id*. 421 ¶ 16. Occurrence reports are labeled "Patient Safety Work Product" and have not been disclosed to state agencies. *Id*. 420–21 ¶¶ 16–17. Baptist periodically submits its occurrence reports to PSOFlorida. *Id*. ¶ 16. As of May 2013, Baptist had collected approximately 52,000 occurrence reports in its PSE System. *Id*. 420 ¶ 15.

The State does not require Baptist to collect occurrence reports. It requires Baptist to create an "incident reporting system" in which "adverse incidents" are reported to an internal risk manager (or a designee) within three business days after their occurrence. § 395.0197(1)(e), (4), Fla. Stat. (2015). The State does not require hospitals to report adverse incidents to the State—only to their risk managers. *Id*.

Adverse incidents are incidents that result in death or in certain statutorily enumerated injuries, such as brain or spinal damage, permanent disfigurement, or the fracture or dislocation of bones or joints. *Id*. § 395.0197(5). It also includes certain surgical procedures, such as procedures performed on the wrong patient or to remove unplanned foreign objects remaining from an earlier procedure. *Id*. In either case, to be an adverse incident, the event must be one over which health care

personnel could exercise control and which is associated, at least in part, with medical intervention, rather than the condition for which the intervention occurred. *Id*.

The adverse incident reports that the State requires Baptist to create and maintain (but not report to the State) are a subset of Baptist's occurrence reports. Tab A 422 ¶ 20. Baptist collects occurrence reports regardless of whether the reported events might also qualify as "adverse incidents" under Section 395.0197(5), and reports are forwarded to Baptist's risk managers—not state agencies. *Id*. 420–21 ¶¶ 14, 17. Most occurrence reports do not involve "adverse incidents," but relate to a diverse array of unanticipated events, including events that did not result and could not have resulted in death or injury. *Id*. 422 ¶ 20. Thus, while some occurrence reports concern incidents subject to Baptist's state-law obligation to create and maintain an internal incident reporting system, most occurrence reports do not relate to adverse incidents at all. As a matter of course, *all* occurrence reports are collected and maintained in Baptist's PSE System; they do not exist outside of that system. *Id*. 420–22 ¶¶ 16, 20.

Of course, the State does require hospitals to report certain information to state agencies. A hospital must submit an Annual Report that summarizes the adverse incidents that occurred at the hospital during the year. § 395.0197(6), Fla. Stat. (2015). A hospital must also submit reports, known as Code 15 Reports, of specific adverse incidents within 15 days after their occurrence. *Id*. § 395.0197(7).

Because they must be reported to the State, Baptist does not maintain Annual Reports and Code 15 Reports within its confidential PSE System. Tab A 422–23 ¶¶ 23–24. These reports are separate and "additional analyses" of events for which occurrence reports were created and confidentially maintained within the PSE System, *id*. 423 ¶ 24, as the Act expressly permits, *see* 42 U.S.C. § 299b-22(h). Thus, Baptist has not treated its Annual Reports and Code 15 Reports as protected PSWP, and has produced them in discovery. Tab A 423 ¶ 25.

The Trial Court's Orders Compelling Production

Appellants allege that Baptist committed malpractice in its care and treatment of Marie Charles. *Id*. 495. At issue here is Appellants' third request for production, dated July 24, 2013 (the "Third Request"). *Id*. 29.

Appellants served the Third Request pursuant to Article X, Section 25 of the Florida Constitution. Article X, Section 25 provides a right of access to records "made or received in the course of business by a health care facility or provider relating to any adverse medical incident." It defines "adverse medical incident" to mean any "act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient." Art. X, § 25(c)(3), Fla. Const.

A person who requests records under Article X, Section 25 need not establish the relevance of those records to pending litigation, nor are the burdens of

compliance a valid ground of objection to a request for records under Article X, Section 25. *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 240 (Fla. 4th DCA 2009). A provider may, however, charge the requester a fee for the production of records. *W. Fla. Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1, 15 (Fla. 2012).

In general, Appellants requested all documents that (1) relate to adverse medical incidents, as defined in the Florida Constitution; and (2) either relate to any physician who worked for Baptist or arose from care and treatment rendered by Baptist during the three-year period preceding Marie Charles' care and treatment, and through the date of the Third Request. Tab A 32–35. The following limiting language accompanied each category of documents sought by the Third Request:

> This request is limited to adverse incident documents as described above that are created by you, or maintained by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, documents created by you, or maintained by you pursuant to Fla. Stat. §§ 395.0197, 766.010 (*sic*), and 395.0193. This request, as limited, specifically includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

Id.

Baptist produced its Annual Reports and its Code 15 Reports, none of which resides in its PSE System. *Id*. 423 ¶ 25. After preserving its objections under the Act, Baptist produced the *only* two occurrence reports regarding Marie Charles. *Id*.

These reports were pending in the PSE System and had not been submitted to PSOFlorida. *Id*. Baptist removed these reports from the PSE System, divesting them of protection, as federal regulations permit. *Id*.; 42 C.F.R. § 3.20(2)(ii) (definition of PSWP). Baptist thus produced all occurrence reports related to Marie Charles. It declined, however, to produce other occurrence reports within its confidential PSE System—none of which relates to Marie Charles.

Appellants moved to compel production. Tab A 2. Appellants did not dispute that the Act expressly preempts their state constitutional right of access to PSWP. Rather, Appellants argued that information collected for submission to a PSO and maintained within the PSE System is PSWP only if collected "solely" for purposes of submission to a PSO. *Id*. 59–64.

Baptist opposed the motion. It argued that federal law protects information collected for reporting to a PSO unless the information exists separately from the PSE System. *Id*. 381–82 ¶¶ 3, 5. Its occurrence reports were collected for reporting to a PSO and did not exist separately from the PSE System. *Id*. 382–83 ¶ 7, 12. The fact that some occurrence reports can also serve to satisfy Baptist's state-law obligation to create and maintain an internal reporting system did not remove them from the Act's definition of PSWP or otherwise divest them of federal protection. *Id*. 382 ¶ 9.

The trial court agreed with Appellants and held that documents "created, or maintained pursuant to any statutory, regulatory, licensing, or accreditation requirements are not protected from discovery." *Id*. 503. Apart from occurrence reports, this ruling compelled production of root-cause analyses that Baptist had performed in compliance with its accreditation requirements—even though root-cause analyses are specifically enumerated in the definition of PSWP. The court indicated that it would "address the breadth and scope" of the document production in a future order. *Id*.

The court entered its subsequent order on December 9, 2014. *Id*. 727. In that order, the court correctly determined that, before production, Baptist is entitled under Section 381.028(7)(c)1., Florida Statutes, to a fee equal to the reasonable cost of compliance with the request, including the cost of time to locate responsive records and to redact information protected by the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Tab A 730. The court ordered Baptist to produce documents within a reasonable time after payment of the fee. *Id*. 731. On January 8, 2015, Baptist petitioned the First DCA for a writ of certiorari. R1 1.

The Decision of The First DCA Quashing the Discovery Orders

On October 28, 2015, the First DCA concluded that Baptist's records are privileged and confidential and quashed the trial court's discovery orders. R3 464–80. The court explained that the Act is "clear and unambiguous" and that its inter-

pretation requires no recourse to rules of statutory construction. *Id*. 473. The records at issue were collected within Baptist's PSE System for submission to a PSO, were not original patient or provider records, and were not collected, maintained, or developed separately from the PSE System. *Id*. 475. The documents were therefore entitled to protection as PSWP under the plain language of the federal statute.

The court further explained that federal regulations permit a provider to collect information in its PSE System with the expectation of protection and then later remove the information if the provider determines that the information must be reported and disclosed to the State. *Id*. 476–77. The Act does not, therefore, exclude reportable information from protection as PSWP. *Id*. "Rather, the Act gives the provider the flexibility to collect and maintain its information in the manner it chooses with the caution that nothing should be construed to limit any reporting or recordkeeping requirements under state or federal law." *Id*. Nothing in the plain language of the Act denies protection to documents that also satisfy state reporting or recordkeeping requirements. *Id*. 478. The court concluded that Appellants' interpretation of the Act "would render it a 'dead letter' and is contrary to Congress's intent to cultivate a culture of safety to improve and better the healthcare community as a whole." *Id*. 480. The Act preempted state law to the limited extent that records are privileged and confidential under the Act's plain language. *Id*. 478-79.

SUMMARY OF ARGUMENT

The records that Appellants seek are privileged and confidential under the plain language of federal law. The court below correctly concluded that Baptist's records fall comfortably within the straightforward federal definition of PSWP. In doing so, it preserved the federal statute and the important, patient-protection policies that Congress intended to promote, while simultaneously affirming the hospital's duty to report information to state and federal agencies.

In 2005, Congress created a uniform, national system to enable providers to evaluate their mistakes confidentially and improve safety and health care quality for their patients. To encourage providers to share sensitive information about medical errors, and to transform a culture of blame into a culture of safety, Congress created a federal privilege and conferred confidentiality in clear and comprehensive language.

The uncontested facts establish that the documents Appellants seek fall well within the federal definition of PSWP. They were assembled or developed for submission to Baptist's PSO and have been or will be submitted to the PSO. They are not original patient or provider records, they exist within Baptist's PSE System, and they do not exist separately outside of that system. Under the plain language of the Act, Baptist's records are PSWP.

Appellants' reading of the Act departs from its plain and obvious meaning and undermines the purposes of a uniform, nationwide system. Appellants contend that, if *state law* requires providers to maintain a document in a non-confidential manner, then *federal law* yields, and the document is not confidential. This position finds no support in the language of the Act and turns the Supremacy Clause upside down. It elevates state law over federal law and permits state legislation to redefine—in fact, *nullify*—the federal privilege on which the Act's entire system of information exchange depends.

Appellants' atextual position renders the Act a dead letter. State law already purports to authorize state regulators to access *all* hospital records. Thus, according to Appellants, *none* of Baptist's records can ever be protected as PSWP, and the Act has no relevance to any hospital in this State. Appellants present no limiting principle that would preserve the operation of the Act. The intent of Congress to create a uniform, national system of information exchange would perish under a patchwork of conflicting state laws. And in support of such a counterintuitive position, Appellants ignore the statutory text and offer garbled fragments of non-binding administrative commentary and select, post-enactment statements of three United States Senators.

One thing is clear: if providers lose confidence in the security of the protected learning environment that Congress designed—an environment in which errors

are identified, evaluated, and corrected confidentially, without risk of liability and exposure—then Congress's vision of a robust information exchange will never be fulfilled. Providers will not share information, and patient safety will suffer. This Court's decision will inspire trust in Congress's assurance of confidentiality and further its important purposes—or reduce that assurance to an empty promise.

STANDARD OF REVIEW

This Court reviews questions of law, including those of statutory interpretation, de novo. *See*, 79 So. 3d at 8.

ARGUMENT

Appellants seek production of more than 50,000 internal hospital safety records that Baptist created and maintains. None of these records relates to the care provided to Marie Charles. None is required to be reported to the State. In fact, Baptist long ago produced all records that relate to Marie Charles or which Baptist was required to report to the State. What Appellants seek now is tens of thousands of records that have nothing to do with their malpractice action.

The question before this Court is a question of federal law: do the records that Appellants seek meet the federal statutory definition of PSWP? If so, they are privileged and confidential, notwithstanding any other provision of state or federal law. 42 U.S.C. § 299b-22(a); *see also* Art. VI, cl. 2, U.S. Const. ("This Constitu-

tion, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land . . . .").

A straightforward application of the statutory text leads seamlessly to the conclusion that Baptist's records are PSWP. The records were assembled or developed in Baptist's PSE System for submission to a PSO, they are not medical records or other original patient or provider records, and they do not exist and have never existed outside of the PSE System. The plain language of the Act requires nothing more.

I. BAPTIST'S OCCURRENCE REPORTS ARE PRIVILEGED AND CONFIDENTIAL UNDER FEDERAL LAW.

PSWP is privileged and confidential, notwithstanding any other provision of state or federal law. 42 U.S.C. § 299b-22(a), (b). Because Baptist's records are PSWP under the clear and unambiguous terms of the Act, those records are privileged and confidential, notwithstanding state law. The question before the Court is a purely *federal* question.

A. THE FEDERAL DEFINITION OF PSWP EASILY ENCOMPASSES BAPTIST'S OCCURRENCE REPORTS.

To determine whether Baptist's records are PSWP, the Court must begin with the words of the Act. "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Gross v. FBL Fin. Servs., Inc.*,

557 U.S. 167, 175 (2009) (quoting *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004)). If the text is plain and unambiguous, then courts must apply the statute according to its terms. *Carcieri v. Salazar*, 555 U.S. 379, 387 (2009).

The Act defines PSWP in relevant part to mean:

> 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 . . .
>
> and which could result in improved patient safety, health care quality, or health care outcomes . . . .

42 U.S.C. § 299b-21(7)(A). Baptist's records satisfy all elements of this definition. In fact, Appellants do not contend otherwise. Baptist's records (1) are assembled or developed for reporting to a PSO; (2) are reported to a PSO; and (3) could result in improved patient safety or health care quality or outcomes.

The inquiry then proceeds to two exceptions to the definition of PSWP. These exceptions are found in clauses (i) and (ii) of subparagraph (B).

Clause (i) provides that PSWP:

> does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

Id. § 299b-21(7)(B)(i). Baptist's records are not original patient or provider records, and Appellants do not contend otherwise.

Clause (ii) provides that PSWP:

> does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

Id. § 299b-21(7)(B)(ii). This provision asks a simple and objective question of fact: was the record collected, maintained, and developed—and does the record exist—within the provider's PSE System? If so, it is protected. If not, it is not.

The undisputed evidence establishes that all occurrence reports are collected, maintained, and developed within Baptist's PSE System for submission to Baptist's PSO, and that occurrence reports do not exist elsewhere, separately from the PSE System. Tab A 420–21 ¶ 15–16.

"Separate" means "parted, divided, or withdrawn from others; disjoined, disconnected, detached, set or kept apart." OXFORD ENGLISH DICTIONARY ONLINE, http://www.oed.com.[1] No occurrence reports are parted or withdrawn from the PSE System, detached, or set or kept apart. All occurrence reports exist within the PSE System and nowhere else. Thus, clause (ii) does not exclude occurrence reports.

[1] In *Tinal v. Norton Healthcare, Inc.*, No. 3:11-cv-00596 (W.D. Ky. 2014), a provider testified that contested documents were "maintained within" its PSE System for reporting to its PSO. ECF No. 30-1 at 2. The court held that, because the information did not exist separately from the PSE System and was not publicly disclosed or reported, it was privileged. ECF No. 59 at 21-22.

Appellants point to no evidence to suggest that Baptist's occurrence reports were not collected, maintained, or developed within, and do not exist within, Baptist's PSE System. Instead, Appellants contend that clause (ii) requires providers to collect, maintain, and develop certain documents separately from their PSE Systems. Appellants argue that, under clause (ii), documents that *state law* requires providers to collect, maintain, or develop in a non-confidential manner must be separated from the PSE System, and that the collection, maintenance, or development of such documents within a provider's PSE System is "unlawful." Br. 38.

Nothing in the words of the Act supports that contention. Clause (ii) states that PSWP "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." It does not mention state law. It does not impose a legal obligation to collect, maintain, or develop certain documents inside or outside of the PSE System. It does not dictate *where* documents may or may not be collected, maintained, or developed. It does not prohibit the collection, maintenance, or development of particular classes of documents within a PSE System. It states that documents that, as a matter of fact, providers collect, maintain, or develop separately from their PSE Systems are not PSWP. Baptist's occurrence reports *are* collected, maintained, or developed within the PSE System. Clause (ii) is inapplicable to Baptist's occurrence reports.

The second sentence of clause (ii) provides:

> Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered [PSWP].

42 U.S.C. § 299b-21(7)(B)(ii). The meaning of this provision is clear. "Such separate information" refers to the information mentioned in the preceding sentence: "information that is collected, maintained, or developed separately, or exists separately, from" a PSE System. Thus, the second sentence of clause (ii) means that information collected, maintained, or developed separately from the PSE System does not become privileged and confidential even if the non-confidential information (or a copy of it) is reported to a PSO. Stated differently, information outside of the PSE System may be reported to a PSO, but does not acquire protection as a result. Baptist has never contended otherwise.

Here, the evidence is unequivocal that occurrence reports are collected, maintained, and developed within Baptist's PSE System. The second sentence of clause (ii), therefore, does not relate to Baptist's occurrence reports, which are not separate from, but part of, the PSE System.

The operation of clause (ii) is easily illustrated. Baptist maintains the agendas and minutes of meetings of some of its quality-improvement committees outside of its PSE System. The first sentence of clause (ii) makes clear that those documents are not protected. The second sentence clarifies that, even if Baptist were to submit such documents to its PSO, those documents would nevertheless not be-

come PSWP. This is the natural and obvious reading of clause (ii). *See Chandler v. Roudebush*, 425 U.S. 840, 848 (1976) (explaining that "the plain, obvious and rational meaning of a statute is always to be preferred to any curious, narrow, hidden sense that nothing but the exigency of a hard case and the ingenuity and study of an acute and powerful intellect would discover" (quoting *Lynch v. Alworth-Stephens Co.*, 267 U.S. 364, 370 (1925))). In no sense does this untortured reading "drain" clause (ii) of meaning. Br. 42.

Appellants contend that "information in a report is 'separate' under clause (ii) . . . if state law mandates that the information be collected, maintained, or developed separately, or exist separately," from the PSE System. Br. 39–40 (internal marks omitted). But clause (ii) says no such thing. Clause (ii) grants no permission to States to reverse-preempt federal law and repeal the federal privilege or restrict its scope. Nor does it hint that documents that States require providers to collect, maintain, or develop in a non-confidential manner must be excluded from the PSE System and cannot acquire protection under the Act. The statute means what its words say. Preemption must not be avoided through wishful, imaginative interpretations of federal law. *Wos v. E.M.A. ex rel. Johnson*, 133 S. Ct. 1391, 1398 (2013) ("A State may not evade the pre-emptive force of federal law by resorting to creative statutory interpretation or description at odds with the statute's intended opera-

tion and effect."). When federal law declares a record privileged and state law declares the same record public, the record is privileged.

Exceptions to general policies must be read "narrowly in order to preserve the primary operation of the provision," and must not be extended "to the farthest reach of their linguistic possibilities if that result would contravene the statutory design." *Maracich v. Spears*, 133 S. Ct. 2191, 2200 (2013); *accord Comm'r v. Clark*, 489 U.S. 726, 739 (1989); *cf. Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616–17 (1980) ("Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent."). And it is meaningful that Congress entitled subparagraph (B) "clarification," and not "exception." Congress employs the softer word "clarification" when it intends to resolve an imprecision, rather than to effect a substantive change that makes a deep crevasse in the law otherwise adopted. *Henning v. Union Pac. R. Co.*, 530 F.3d 1206, 1216 (10th Cir. 2008). Appellants' atextual reading would devour the general policy that Congress established.

Here the definitional inquiry ends. Appellants agree that "only the first two clauses of subparagraph (B)—clauses (i) and (ii)—define the exceptions to PSWP." Br. 39. Because Baptist's occurrence reports fall within the definition in subparagraph (A) and are not excluded by clauses (i) and (ii) of subparagraph (B), the occurrence reports are PSWP. And as PSWP, the occurrence reports are privi-

leged and confidential, notwithstanding any provision of state or federal law. 42 U.S.C. § 299b-22(a), (b).

The court below correctly held that the language of the Act is plain. If Congress had intended to require providers to separate from their PSE Systems all documents that state law requires them to collect, maintain, or develop in a non-confidential manner, then it would have expressed that intention clearly. It did not. The Act has no hidden meanings or lurking provisions that Congress did not intend to make plain. Its interpretation requires no act of divination. The meaning of the Act finds expression in its words—not in the choice quotations that Appellants select from secondary sources, edit thoroughly, and, without explanation of their context, scatter throughout their brief.

B. BAPTIST'S OCCURRENCE REPORTS ARE NOT STRIPPED OF FEDERAL PROTECTION MERELY BECAUSE THEY SIMULTANEOUSLY SATISFY STATE-LAW REQUIREMENTS TO CREATE AND MAINTAIN RECORDS.

While admitting that clause (iii) of subparagraph (B) is not an exception to the definition of PSWP, *see* Br. 39, Appellants suggest that clause (iii) requires providers to exclude from their PSE Systems documents that state law directs providers to collect, maintain, or develop in a non-confidential manner. Once again, Appellants strain to find provisions they wish Congress had enacted.

Clause (iii) states in relevant part:

Nothing in [the Act] shall be construed to limit . . .

> (II) the reporting of information described in this subparagraph to a Federal, State, or local government 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 the subparagraph under Federal, State or local law.

The plain meaning of these provisions is that the Act does not relieve providers of their obligation to report information or maintain records. Baptist does not claim that it does. Baptist continues to report all required information and to maintain all required records. There is no credible contention that Baptist has failed to report or maintain records that state law required it to report or maintain. Clause (iii) is satisfied.

Clause (iii) is a commonsense disclaimer that the Act does not excuse noncompliance with any state-law obligation to report or maintain information. Baptist has never sought to be relieved of its obligations to report or maintain information. If Baptist had argued that the Act erases its duty under state law to report or maintain information, then clause (iii) would have been pertinent. It made no such contention.

Notably, clause (iii) does not define PSWP. Unlike clauses (i) and (ii), it does not provide that PSWP "does not include" certain information. Thus, clause (iii) is not an exclusion from the definition of PSWP, but rather a rule of statutory construction. It performs a straightforward, cautionary function. It guards against

any suggestion that the Act supplants the obligation of providers to report and maintain records. The Court need not go beyond the unambiguous text.[2] No secret, sweeping meaning hides behind the simple words and obvious sense of clause (iii).

Appellants misread the Act because they blend clause (ii) and clause (iii). Appellants presume that, because clause (iii) recognizes the obligation of providers to report and maintain information that state law requires them to report and maintain, clause (ii) in turn requires providers to collect, maintain, and develop that information outside of their PSE Systems. But clause (ii) and clause (iii) are not so connected. Appellants' fusion of the two distinct clauses in order to force certain documents out of the confidential PSE System finds no support in the text of the Act or in the natural, commonsense reading of its provisions.

The regulations that implement the Act further refute Appellants' theory. First, the regulations state that nothing in the Act "shall be construed to limit information that is not [PSWP] from being . . . [m]aintained as *part* of a provider's recordkeeping obligation." 42 C.F.R. § 3.20(2)(iii) (definition of PSWP) (emphasis

[2] The Act clearly states that PSWP is not discoverable. 42 U.S.C. § 299b-22(a)(2). Even the provision stating that the Act does not limit discovery of original records, such as medical records, or information outside the PSE System, confirms that discovery of records *within* the PSE System is proscribed. *Id*. § 299b-21(7)(B)(iii)(I). And the statement that the Act does not "limit, alter, or affect" state law pertaining to "information that is not privileged" proves that the Act *does* control state law as it relates to information that *is* privileged. *Id*. § 299b-22(g)(2).

added). Clearly, the regulations do not provide that all records that a State requires a provider to maintain are excluded from protection.

Second, the regulations permit providers to collect records within their PSE Systems and, before information is reported to a PSO, to remove records from their PSE Systems. 42 C.F.R. § 3.20(2)(ii) (definition of PSWP). A record acquires protection upon its collection within the PSE System and remains privileged and confidential *until* the provider removes it from the PSE System. *Id*. (providing that, upon removal from the PSE System, information is "no longer" protected as PSWP).

Appellants admit that this regulation avoids the need to create duplicate data-collection systems, and that even documents that must be *reported* to the State may be protected within a PSE System until removed. Br. 6. But Appellants insist on the inconsistent position that a unified data-collection system is "unlawful." *Id*. at 38. If Appellants are correct, then providers would be required to create separate reports and separate systems, reviving the very concerns regarding the burdens of duplication that federal regulations sought to remove. Far from being "unlawful," a single, streamlined data-collection system is just what Congress contemplated.

Of course, if documents that must be *created and reported* to the State are protected until removed from the PSE System, then documents that need only be *created*—such as the documents at issue here—fare no worse. Nowhere does the

Act state that a document that must be created or maintained, but not reported, cannot be protected as PSWP. Neither law nor reason supports the position that reportable documents are protected until removed from the PSE System, while documents that providers must create but not report receive no protection at all.

C. APPELLANTS' INTERPRETATION OF THE ACT PERMITS STATES TO DECLARE NON-CONFIDENTIAL WHAT CONGRESS DECLARED CONFIDENTIAL, AND THUS AUTHORIZES STATE NULLIFICATION OF FEDERAL LAW.

Appellants' contention would render the Act a dead letter and authorize state nullification of federal law. If the Act does not encompass records that *state law* requires hospitals to maintain in a non-confidential manner, then, at least in this State, no hospital records are protectable.

Florida law purports to allow state agencies to access *all* hospital records. *See* §§ 395.0197(13), 395.1046(1), 408.811(3), Fla. Stat. (2015). For example, state statutes authorize the State to access "all licensed facility records necessary to carry out" Section 395.0197. *Id.* § 395.0197(13). That section empowers the State to (1) investigate any incident that warrants discipline or triggers a Code 15 Report; (2) require hospitals to adopt plans of correction; and (3) review hospital risk-management programs. *Id.* § 395.0197(6)(b), (7), (12), (15). *All* hospital records are relevant to those functions and therefore liable to disclosure under state law. Thus, according to Appellants, no hospital records qualify for federal protection.

Congress is presumed to be aware of state law, *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 184–85 (1988), and could not have intended to enact a dead letter.

The broad, unwritten exception for which Appellants contend would allow States to nullify federal law. Each State might adopt laws that, like Florida law, purport to authorize its regulatory agencies to access all hospital safety records. That right of access would (according to Appellants) extinguish the federal privilege, despite the Act's express language of preemption.

A reading that allows state legislatures to overrule Congress and define the scope of a federal privilege turns preemption on its head and offends the supremacy of federal law. State laws that confer a right of access yield to federal laws that confer confidentiality—not the other way around. *See, e.g.*, *Fla. Dep't of Educ. v. NYT Mgmt. Servs., Inc.*, 895 So. 2d 1151, 1154 (Fla. 1st DCA 2005) (concluding that federal confidentiality provisions supplanted the disclosure requirements of the Public Records Act, Art. I, § 24, Fla. Const.; Ch. 119, Fla. Stat. (2015)). The Act's express preemption of state law dictates precisely that result. Indeed, the Act was a direct response to state laws that compelled the disclosure of information about health care errors, enabled a culture of blame, and frustrated voluntary and systematic self-evaluation. If States could enact laws that authorize access to provider records, and thus abrogate federal confidentiality, then the scope and operation of federal law would reside in the discretion of the States, and the privilege that Con-

gress created might be extinguished. "States would then be free to nullify for their own people the legislative decisions that Congress has made on behalf of all of the People." *Howlett ex rel. Howlett v. Rose*, 496 U.S. 356, 383 (1990).

Appellants offer no reasoned, limiting principle that would preserve the Act from obsolescence. They assure the Court that, under their interpretation, only those records that state law requires hospitals to maintain in a non-confidential manner are denied federal protection. Br. 35. But, in Florida, that describes *all* hospital records. And if States could guarantee access to documents, require those documents to be maintained separately from the PSE System, and strip them of federal protection, then States could eviscerate the Act and undo Congress's effort to create a protected environment within which providers can confidently share information in order to improve the quality of their services. This is hardly the usual relationship between state and federal laws, and only the most explicit language in federal law should suffice to overcome the strong presumption against such reverse preemption. Congress, which well understood the barriers to robust information exchange, could not have intended to enact a statute so flimsy that state law could nullify its protections.

Congress enacted a clear, objective, and understandable definition of PSWP. It provided clarity and certainty in order to encourage providers to disclose their errors without fear of exposure. Under Appellants' theory, a provider could never

know with confidence whether federal law protects its records or whether state law removes those records from the sphere of federal protection. Rational providers will not choose to make sensitive disclosures, the confidentiality of which depends on such imponderables as the reach of a State's access and recordkeeping laws. In the face of uncertainty, providers will not participate, and Congress's intent to build an essential data-collection system on voluntary, broad-based participation will not be fulfilled.[3] As the United States Supreme Court wrote of the attorney-client privilege, "if the purpose of the . . . privilege is to be served, the attorney and client must be able to predict with some degree of certainty whether particular discussions will be protected. An uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all." *Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981).

Last month, the United States Supreme Court concluded that the Employee Retirement Income Security Act of 1974 ("ERISA") preempted a state statute to the extent the state statute required the third-party administrators of health plans established by employers under ERISA to report information regarding health care

[3] Hospitals with more than 50 beds must create a PSE System or meet other stringent criteria in order to contract with qualified health plans under the Patient Protection and Affordable Care Act. 42 U.S.C. § 18031(h)(1)(A)(i); Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12,203, 12,351 (Mar. 8, 2016) (to be codified at 45 C.F.R. § 156.1110(a)(2)(i)(A)). If Appellants are correct, then, although the participation of such hospitals is mandatory, none of their records would be protected. The federal policy to replace a culture of blame with a culture of safety would be upended.

services to the State. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936 (2016). The Court concluded that the state statute "imposes [reporting] duties that are inconsistent with the central design of ERISA, which is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States even when those laws, to a large extent, impose parallel requirements." *Id*. at 947. Here, the requirements of state law are not "parallel" with those of federal law, but antithetical to them. If a state-law obligation to collect, maintain, or develop records in a non-confidential manner were to control and prevail over a federal law that confers confidentiality, then state law would impose duties that are "inconsistent with the central design" of the Act, "which is to provide a single uniform national scheme" for the collection, evaluation, and dissemination of sensitive information concerning medical errors. The Supremacy Clause bars that result.

D. THE DISCRETION OF PROVIDERS TO COLLECT INFORMATION IN THEIR PSE SYSTEMS IS NEITHER UNILATERAL NOR UNREVIEWABLE, AND CERTAINLY DOES NOT JUSTIFY THE CREATION OF UNWRITTEN, STATE-LAW EXCEPTIONS TO THE ACT'S PROTECTIONS.

Providers do not have "unilateral, unreviewable" discretion to store records in their confidential PSE Systems. Br. 1. For example, a provider can never protect original patient or provider records, such as medical and billing records, 42 U.S.C. § 299b-21(7)(B)(i), or refuse to report to the State information that must be report-

ed, *id*. § 299b-21(7)(B)(iii)(II). The court below did not hold otherwise; the language that Appellants quote five times in their brief is not the court's holding, but rather its restatement and rejection of Appellants' exaggerated argument.

While not without limits, the federal definition of PSWP is broad. The words of the Act are comprehensive and evidence a congressional design to be inclusive. *See id*. § 299b-21(7)(A). It is not the province of the States to second-guess that policy and create unwritten exceptions to the definition of PSWP. The boundaries of the federal privilege are to be found in the language of the Act. The Act protects the documents to which its terms extend—no more and no less.

Courts have ample means to prevent gamesmanship by providers who might store in their PSE Systems information ineligible for protection as PSWP. A court may exercise its inherent authority to conduct an in-camera review to determine whether documents qualify for protection under the federal definition of PSWP. While a court may not, as Appellants urge this Court to do, create exceptions to the definition of PSWP, it can ensure that providers have complied with the Act as written.

Moreover, while the Act protects PSWP from disclosure, it does not shield facts. Thus, a plaintiff may take depositions or propound interrogatories regarding every aspect of a patient's care. And, of course, original patient and provider records, such as patient charts, nursing notes, and discharge and billing documents,

are not protected and remain discoverable. *Id*. § 299b-21(7)(B)(i). What are not discoverable are documents or statements that satisfy the definition of PSWP.

The fact that some documents will not be discoverable is an inherent feature of any privilege. To some extent, every privilege, including the attorney-client privilege and the work-product doctrine, opens a door to gamesmanship. Courts, however, have ample tools—such as in-camera review, litigation sanctions, and professional discipline—to police such gamesmanship by parties or their counsel. Where Congress has weighed these interests and granted federal protection, States may not reweigh those interests and abrogate that protection. When Congress says "privileged," a State may not require production—regardless of the earnestness of its disagreement with federal policy.

E. THE ACT DOES NOT OBSTRUCT STATE OVERSIGHT OF HEALTH CARE PROVIDERS.

Appellants suggest that, as written, the Act denies state regulators access to information essential to the performance of their oversight functions. No such conflict exists, however, and no state agencies have sought to appear in support of Appellants, either in this Court or below. And if a state agency were ever to demand access to records protected as PSWP, still it would not entitle Appellants or other third parties to access those records. Such a dispute would concern the provider, the State, and federal regulators. Appellants would neither benefit from nor have

standing to assert any right of a state agency to access federally privileged hospital records.

If a state agency were to demand access to confidential records, then the provider would have several options to satisfy its obligations short of a disclosure that would violate federal law. The provider might (as Baptist did in this case) remove from its PSE System a record that has not yet been transmitted to a PSO, in which case the record would "no longer" be protected and might be disclosed. *See* 42 C.F.R. § 3.20(2)(ii) (definition of PSWP). It might obtain the consent of each provider identified in the record and then disclose the record to the State. *See* 42 U.S.C. § 299b-22(c)(1)(C). It might create a new record for the State from original patient and provider records, such as medical and billing records, which the Act does not protect. *Id*. §§ 299b-21(7)(B)(i), 299b-22(h). It might produce other records that satisfy the state agency and demonstrate the provider's compliance, without disclosure of a protected record. Or the provider might accept whatever sanction the State claimed a right to impose, and even challenge the sanction on federal preemption grounds. By whatever means the provider complies with state law, the record remains privileged until removed from the PSE System.

None of these eventualities would authorize Appellants to inspect Baptist's records. If the mere possibility that a state agency might assert a state-law right of access to records that are privileged and confidential under federal law warrants

disclosure of those records, then the Act would protect no records at all. Given the unlimited nature of the right of access that state law purports to confer on state agencies, Appellants can devise no limiting principle that would preserve the Act.

Department of Financial and Professional Regulation v. Walgreen Co., 970 N.E.2d 552 (Ill. App. Ct. 2012), is instructive. In *Walgreen*, a state agency subpoenaed a pharmacy's reports of medication error, which were generated in the pharmacy's PSE System for submission to its PSO. *Id*. at 555. The court concluded that the reports were confidential. It noted that the responsive documents were collected within the PSE System and transmitted to the PSO. *Id*. at 558. Because the reports resided in the PSE System, clause (ii) did not strip them of federal protection.

In *Walgreen*, state law authorized regulators to "subpoena and compel the production of documents, papers, files, books, and records in connection with any hearing or investigation" concerning potential violations by pharmacies. *See* Br. of Pet'r-Appellant at 6, *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. Ct. 2012) (No. 2-11-0452) (citing 225 Ill. Comp. Stat. 85/35.5 (2010)), *available at* http://tinyurl.com/q9cqfdy. Nevertheless, the court held that the Act protected the records. That state law purported to grant regulators access to all of the pharmacy's records did not deprive the pharmacy's records of protection.

F. FINDING NO SUPPORT IN THE PLAIN LANGUAGE OF THE ACT, APPELLANTS IMPROPERLY RELY ON SECONDARY SOURCES.

Besides the words of the Act, the surest evidence of Appellants' error is their inordinate reliance on secondary sources. Unable to identify any provision of the Act that permits States to make non-confidential what federal law makes confidential, Appellants scoured the Federal Register and the Congressional Record. Appellants then sorted, edited, and combined picked quotations to paint a picture that cannot be discerned from a fair reading of the Act. This is not statutory interpretation, but statutory revisionism.

Floor Statements. When a statute is unambiguous, reliance on legislative history is improper. *United States v. Woods*, 134 S. Ct. 557, 567 n.5 (2013); *Mohamad v. Palestinian Auth.*, 132 S. Ct. 1702, 1709 (2012). Appellants identify no ambiguities in the Act. They point to no words or provisions of the Act that they contend are ambiguous. There is no ambiguity that legislative history might clarify.

For additional reasons, the floor statements with which Appellants interlard their brief are entitled to no weight. First, Appellants quote only three members of Congress. Their remarks do not reveal the intent of the other 532 members. *Zuber v. Allen*, 396 U.S. 168, 186 (1969) ("Floor debates reflect at best the understanding of individual Congressmen."). Courts are loath to rely on statements made by small and perhaps unrepresentative samples. *See Barnhart v. Sigmon Coal Co., Inc.*, 534

U.S. 438, 457 (2002) ("We see no reason to give greater weight to the views of two Senators than to the collective votes of both Houses . . . .").

Second, most of the remarks on which Appellants rely were delivered in the United States Senate on July 22, 2005—one day *after* the Senate passed the bill. Post-enactment statements could not have affected the vote and are not an accepted means of interpretation. *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1081 (2011); *Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 132 (1974). This is true even where, as here, the bill was still pending in the other chamber. *See Barnhart*, 534 U.S. at 457 n.15; *United States v. McKesson & Robbins, Inc.*, 351 U.S. 305, 313–15 (1956). Remarks made in the Senate after passage did not affect the vote in the Senate and cannot be presumed to have affected the vote in the other chamber.

Third, legislative history is usually "murky, ambiguous, and contradictory," and floor statements in particular are inherently prone to manipulation. *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568–69 (2005). This is true here. For example, days *before* the Senate passed the bill, Senator Enzi made such remarks as these:

> Healthcare providers will be much more likely to share information about honest mistakes and how to prevent them if they have some assurance that the analysis of their information won't result in a tidy package of information that a personal injury lawyer could use against them in court. . . .

> Litigation does nothing to improve quality or safety. The constant threat of litigation instead stifles honest analysis of why health errors happen.

Tab A 440. The legislative record, therefore, furnishes imprecise and inconsistent statements (sometimes by the same person) that appear alternatively to favor either a broader or a narrower construction of the Act. Where, as here, the statutory text is unambiguous, principles of statutory interpretation do not authorize a hunt for competing statements in the legislative record.

To make matters worse, Appellants' account of the Act's passage is wishful revisionism. To be sure, the Act passed after Congress made important "compromises," but those compromises did not (as Appellants imply) weaken the federal privilege or authorize access to the secure environment that Congress established. Br. 10. Senator Enzi gave two examples of these "compromises." First, the compromise bill provided that PSWP was not only privileged, but also *confidential*. Tab A 457. Second, the compromise bill ensured that the definition of PSWP:

> was drawn broadly enough to assure that providers will feel safe and secure in participating in a patient safety system—and that they not be chilled from participating by the fear that their efforts to assemble, analyze, deliberate on, or report patient safety information to patient safety organizations would somehow fall outside of a too-narrow statutory definition of patient safety work product.

Id. The compromises did not weaken—but strengthened—the Act's protections.

Senator Kennedy's remark that the Act does not "accidentally shield persons who have negligently or intentionally caused harm to patients" is an example of the

inexactitude and unhelpfulness of legislative history. Br. 11. This imprecise statement suggests that the Act does not protect from discovery any records of medical errors, but of course it does. Senator Enzi's post-enactment statement that records formerly available to plaintiffs will remain available relates to original patient and provider records, *see* Br. 11 n.8, which are not protected, 42 U.S.C. § 299b-21(7)(B)(i), especially as nothing in the Act prohibits providers from discontinuing elements of preexisting data-collection systems or incorporating them into their PSE Systems. The will of Congress is gleaned from the unambiguous and authoritative text of the Act—not from imprecise or overbroad floor statements, or a psychoanalysis of three United States Senators.

Regulatory Preamble. Appellants offer an arrangement of short quotations culled from the non-binding regulatory preamble published in the Federal Register. Amazingly, Appellants do not even discuss the regulations in the Code of Federal Regulations, *see* 42 C.F.R. pt. 3—only the preamble, as though the preamble were law.

A preamble is but a commentary on regulations. Unlike the final regulations, a preamble "does not create law; that is what the regulation's text is for." *Tex. Children's Hosp. v. Burwell*, 76 F Supp. 3d 224, 237 (D.D.C. 2014).

Courts do not consider preambles in the interpretation of statutes. *Saunders v. City of New York*, 594 F. Supp. 2d 346, 355 (S.D.N.Y. 2008). A preamble may

assist in the interpretation of regulations, but only if the regulations are ambiguous. *El Comité Para El Bienestar de Earlimart v. Warmerdam*, 539 F.3d 1062, 1070 (9th Cir. 2008); *Albemarle Corp. v. Herman*, 221 F.3d 782, 786 (5th Cir. 2000).

The case that Appellants cite to excuse their reliance on the preamble is directly contrary to their position. *See Ramos v. Baldor Specialty Foods, Inc.*, 687 F.3d 554, 560 (2d Cir. 2012) ("We consider and defer to the Department of Labor's interpretation of a regulation—including the regulatory preamble included in the Federal Register—only if the regulation is ambiguous. If the text of the regulation presents no ambiguity, then we are simply tasked with an application of an unambiguous regulation to the particular facts of a case." (citations and internal marks omitted)).

Appellants do not argue that the regulations are ambiguous. Their brief contains not a single quotation from the regulations. *A fortiori*, Appellants have not identified a single ambiguity in those regulations, and have not justified their reliance on the preamble as a means of interpretation. Indeed, the regulations are crisp and unambiguous, and compel no recourse to interpretive aids.

Under no circumstances is a preamble entitled to deference under *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Agency pronouncements without the force of law are not accorded *Chevron* deference. *Wos*, 133 S. Ct. at 1402. A preamble—which is neither codified nor itself subject

to notice and comment—is not a pronouncement with the force of law. *A & E Coal Co. v. Adams*, 694 F.3d 798, 801 (6th Cir. 2012). Appellants cite no case that extended *Chevron* deference to a preamble and thus illogically gave the same weight to the preamble as to the regulation.

"The preamble to a rule is not more binding than a preamble to a statute." *Nat'l Wildlife Fed. v. EPA*, 286 F.3d 554, 569–70 (D.C. Cir. 2002). Like a statutory preamble, a regulatory preamble is not an operative part of the regulations and cannot control their plain meaning. *Warmerdam*, 539 F.3d at 1070; *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999). The preamble "does not prescribe rights and duties and otherwise declare the legislative will." *Warmerdam*, 539 F.3d at 1070 (quoting *Wyo. Outdoor Council*, 165 F.3d at 53).

When examined in context, even the passages that Appellants quote do not advance their cause. The passage quoted on Page 7 concerns state laws that "require the *reporting* of information" and, like the Act, states that "[t]hese external obligations"—*i.e.*, *reporting* obligations—are not preempted. Indeed, the preamble repeatedly discusses "external *reporting* obligations," Patient Safety and Quality Improvement, 73 Fed. Reg. 70732, 70739, 70740, 70742, 70744 (Nov. 21, 2008) (emphasis added). There is no colorable assertion here that Baptist failed to report information, or that Baptist has not produced all responsive documents that it reported to the State.

The highly edited quotation on Page 7 that suggests that "oversight entities" continue to have "access to this original information" is incomplete. In context, the phrase "original information" refers to the previous sentence, which discusses "information that is not patient safety work product." *Id*. at 70742. Thus, the quotation supports the proposition that oversight entities continue to have access to information that is not PSWP—true enough—and not that oversight entities have access to all documents to which state law purports to grant access, whether PSWP or not.

Likewise, the quotation on Page 7 that providers have "flexibility" to protect information as PSWP "while they consider whether the information is needed to meet external reporting obligations" does not avail Appellants. Of course, providers must continue to report information that States require them to report, *see* 42 U.S.C. § 299b-21(7)(B)(iii)(II) (providing that the Act does not limit "the reporting of information described in this subparagraph"), and, before a document may be reported, it must be removed from the PSE System. Otherwise, the disclosure would violate the Act's confidentiality mandate. *See id*. § 299b-22(b). It does not follow that state laws can authorize access to—and destroy the confidentiality of—documents that are confidential under federal law and not reportable under state law.

The statement on Page 7 that the PSE System exists alongside other collection activities presents an incomplete picture. The regulations and even the pream-

ble recognize that all documents may be collected within the PSE System and remain protected *until* the provider removes them. 42 C.F.R. § 3.20(2)(ii) (definition of PSWP); 73 Fed. Reg. at 70740–42. Thus, the very preamble on which Appellants rely states that "providers 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 70742, and that a PSE System "must of necessity be flexible and scalable to meet the needs of specific providers," *id*. at 70739. The privilege attaches "in a manner that is as administratively flexible as permitted" to accommodate varied systems and processes, *id*. at 70741, and the regulations allow "providers the flexibility to collect and review information within [the PSE System] to determine if the information is needed to fulfill external reporting obligations," *id*. at 70744. The preamble itself refutes Appellants' claim that the Act mandates separate systems, and that a unified system is "unlawful."

The passages on Page 8 merely state that information not collected for submission to a PSO is not PSWP. *See* 42 U.S.C. § 299b-21(7)(B)(ii). Baptist has recognized that the agendas and minutes of some quality-improvement committees, for example, were not collected for submission to a PSO and are therefore not PSWP. But the undisputed evidence shows that Baptist's occurrence reports are routinely reported to PSOs and are collected for that purpose. Tab A 420–21.

Like floor statements, the preamble contains passages that refute Appellants' position. The very passage that Appellants quote on Page 8 also states: "While the [Act] does not preempt state laws that require providers to report information that is not [PSWP], a State may not require that [PSWP] be disclosed." 73 Fed. Reg. at 70743–44. This passage recognizes that the existence of a state law that mandates disclosure does not (as Appellants contend) strip the record of protection as PSWP.

Baptist relies on a straightforward application of the statute and regulations. It does not rely on the secondary sources from which Appellants are constrained to construct their argument. Baptist quotes from these sources to demonstrate the fallibility of Appellants' atextual, pick-and-choose method of statutory construction. Rather than seek the natural and genuine meaning of the statute, Appellants seek to interpolate their own notions into the statute.

Committee Reports. Appellants quote the report of a Senate committee, Br. 12, 42, even though Appellants previously argued *against* reliance on that report. Below, Appellants dismissed the Senate committee report on the ground that the report "discussed a prior, materially different version of the [the Act] rejected by the Senate." R2 213. Nor is reliance on any committee report appropriate where the statute is clear. *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 808 n.3 (1989). Regardless, the quotations express no more than the uncontested propositions that the Act does not (1) shield from discovery the facts that underlie PSWP; or (2) lim-

it the reporting and recordkeeping obligations of providers. *See* Br. 12. Neither proposition resolves this case, as Baptist does not claim that facts are immune from discovery, or that the Act relieves it of the obligation to report or maintain records.

The *Tibbs* Plurality Opinion. Appellants' reliance on *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014) (plurality opinion), is equally misplaced. Br. 46–47. In *Tibbs*, only three of seven Justices joined the lead opinion. An opinion of the Kentucky Supreme Court that commands "less than a majority" has "no stare decisis effect" and "no binding precedential value" in Kentucky, *J.A.S. v. Buchanan*, 342 S.W.3d 850, 853 (Ky. 2011), and of course none in this State. A plurality opinion is therefore not "an authoritative platform upon which to build a solid legal argument." *Id*.

The *Tibbs* plurality erred for the reasons articulated in the thoughtful dissenting opinion of Judge Abramson, who correctly concluded the plurality's approach "undercut the Act's effectiveness in advancing patient safety." 448 S.W.3d at 809.

The *Tibbs* defendants, moreover, have petitioned the United States Supreme Court for a writ of certiorari. *See* 83 U.S.L.W. 3772 (U.S. Mar. 18, 2015) (No. 14-1140). The Court has both requested a response, R2 314, and invited the Solicitor General to file a brief expressing the views of the United States, *Tibbs v. Bunnell*, 136 S. Ct. 290 (2015).

II. BAPTIST'S ROOT-CAUSE ANALYSES ARE PRIVILEGED AND CONFIDENTIAL UNDER FEDERAL LAW.

In addition to occurrence reports, Appellants seek to compel production of Baptist's root-cause analyses, which, according to Appellants, state law requires Baptist to create. Br. 16 (citing § 395.0197(1)(a), Fla. Stat.). For the reasons stated above, root-cause analyses that Baptist has assembled or developed within its PSE System for reporting to its PSO are protected as PSWP.

Contrary to Appellants' assertions, state law does not require Baptist to perform root-cause analyses. Section 395.0197(1)(a) does not even mention root-cause analyses. It requires the "investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients," but not every analysis of the causes of adverse incidents is a root-cause analysis. "Root-cause analysis" is a term of art with a specialized meaning for providers and accrediting bodies.

The Joint Commission, which accredits thousands of providers, requires hospitals to respond appropriately to "sentinel events." Tab A 546. Sentinel events are unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof. *Id.* 545. One element of an appropriate response is the performance of a root-cause analysis, which attempts to identify the causes of variation in performance, with a particular focus on systems and processes. *Id*. 546. The product of a root-cause analysis is an action plan that identifies strategies that

the provider intends to implement to reduce the risk that such events will reoccur. *Id*. 547. A root-cause analysis, therefore, is a highly formalized analysis required by Baptist's accrediting body. No provider would confuse a root-cause analysis with the analysis that Section 395.0197(1)(a) requires.

Appellants' demand for root-cause analyses underscores the error of their interpretation of the Act. The Act includes root-cause analyses *by name* in the definition of PSWP. 42 U.S.C. § 299b-21(7)(A) (defining PSWP to include "any data, reports, records, memoranda, analyses (*such as root cause analyses*), or written or oral statements" that satisfy certain criteria). Congress understood that The Joint Commission requires providers to create root-cause analyses—in fact, it received testimony from The Joint Commission regarding root-cause analyses while the Act was under consideration, Tab A 800-01—and took care to define PSWP to include root-cause analyses. The express inclusion of root-cause analyses in the definition of PSWP establishes that Congress was aware of The Joint Commission's requirements and intended to protect root-cause analyses.

Courts construe statutes to give operative effect to every word. *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 167 (2004). Appellants' interpretation of the Act erases the term "root cause analyses" from the definition of PSWP and empties it of all meaning. It denies protection to a class of documents that Congress expressly and deliberately mentioned by name in the definition of PSWP.

The words of the Act cannot more clearly communicate congressional intent. Congress treated root-cause analyses as PSWP. Its choice of words is presumed to be deliberate and must be given effect. *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013). Congress, moreover, authorized providers to share PSWP with their accrediting entities without waiver of the Act's protections, and thus authorized providers to share root-cause analyses with The Joint Commission. 42 U.S.C. § 299b-22(c)(2)(E), (d)(1). This disclosure permission would have been unnecessary if root-cause analyses were not privileged and confidential, and Appellants' position nullifies both the express reference to root-cause analyses in the definition of PSWP and the related disclosure permission, contrary to sound principles of interpretation. *See United States v. Tohono O'Odham Nation*, 563 U.S. 307, 315 (2011) ("Courts should not render statutes nugatory through construction.").

III. APPELLANTS' RECOURSE TO INNUENDO BETRAYS THE WEAKNESS OF THEIR ARGUMENT ON THE MERITS.

Appellants' contentions regarding spoliation reveal their desperation. Never before have Appellants argued that Baptist spoliated evidence, and there is no basis for such an argument now. If, after exhaustion of its appellate options, Baptist is ordered to produce records, it will produce them. Nor is it appropriate to raise the argument for the first time in this Court. *Sunset Harbour Condo. Ass'n v. Robbins*, 914 So. 2d 925, 928 (Fla. 2005) (concluding that argument not raised in trial court

or intermediate appellate court cannot be raised in this Court). Appellants' attempt to bias this Court against Baptist and to insinuate—without record support—that records have been spoliated should be ignored.

Appellants manufacture other allegations of "gamesmanship" as well—none of which was raised below. R2 202–65; R3 477–78. With a weak argument on the merits, Appellants descend to attacks.

Thus, Appellants claim that Baptist has not disclosed whether its possesses additional occurrence reports that relate to Marie Charles. Br. 23, 43. This is untrue and contradicted by the only sworn testimony on the matter. Tab A 423 ¶ 25. In fact, Baptist has repeatedly informed Appellants that it has produced all occurrence reports that relate to Marie Charles. For example, at a hearing on September 26, 2014, Baptist's counsel stated *again* that Baptist had produced all records regarding Marie Charles:

> Your Honor, this is like the person who can't take yes for an answer. We have been saying for a long time now that we have produced the only two Amendment 7 documents related to Marie Charles. . . . They were produced and they were told this is what we have. These are the only two adverse medical incident records concerning Marie Charles and they were produced. . . . So we have produced all Amendment 7 documents, all adverse medical incident records relating to Marie Charles.

Id. 513–14.

No more comprehensible is Appellants' assertion that Baptist engaged in "gamesmanship" when it estimated the substantial cost of collecting, redacting,

and producing more than 50,000 records. *Id*. This Court has expressly validated the statute that authorizes providers to recover the costs of production. *See*, 79 So. 3d at 15 (citing *Fla. Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478, 493 (Fla. 2008)).

Finally, the claim that Baptist failed to create certain adverse incident reports and thus violated state law relies on mistaken inferences from Code 15 Reports. Br. 43 & n.18. There are case-specific reasons that an adverse incident report might not be created before a Code 15 Report is created. For example, it might be apparent at the time of the death or injury that an adverse incident caused or contributed to the death or injury, that the death was unexpected, or that the injury was not the expected complication of a medical procedure. In no way do the Code 15 Reports, which were reported to the State, indicate any violation of a duty to report to the State. In fact, they prove the contrary.

CONCLUSION

Consistent with the expressed intent of Congress to establish a uniform, national system to improve patient safety and patient outcomes, the court below correctly concluded that the records sought by Appellants are privileged and confidential under the plain and unambiguous words of the Act. This Court should affirm.

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

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I certify that the foregoing brief was served by electronic transmission this twenty-first day of April, 2016, on the individuals identified on the Service List that follows.

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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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