No. 14-1140

In the Supreme Court of the United States

PHILLIP TIBBS, ET AL., PETITIONERS

v.

ESTATE OF LUVETTA GOFF, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF KENTUCKY

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

DONALD B. VERRILLI, JR.
Solicitor General
Counsel of Record
BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
BRIAN H. FLETCHER
Assistant to the Solicitor General
MICHAEL S. RAAB
SARAH W. CARROLL
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 *et seq.*, establishes a system for health care providers to report information about medical errors and other patient safety events to certified patient safety organizations, which analyze the information and make recommendations for improving patient safety. To encourage voluntary reporting, the Act creates a privilege protecting "patient safety work product" against disclosure in a variety of contexts, including medical malpractice litigation. 42 U.S.C. 299b-22(a). The Act defines "patient safety work product" to include certain information "assembled or developed by a provider for reporting to a patient safety organization." 42 U.S.C. 299b-21(7)(A)(i)(I). But the definition specifically excludes "original patient or provider record[s]," and the Act specifies that it shall not be construed to limit "the discovery of or admissibility of [such records] in a criminal, civil, or administrative proceeding" or "a provider's recordkeeping obligation with respect to [such records] under Federal, State, or local law." 42 U.S.C. 299b-21(7)(B)(i) and (iii).

The question presented is whether an incident report that a hospital created to comply with a state recordkeeping requirement qualifies as privileged patient safety work product because it was prepared in a computer system used to collect information for reporting to a patient safety organization.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Statutes, regulations and rule:

Statutes, regulations and rule—Continued: Page

Miscellaneous:

Miscellaneous—Continued: Page

In the Supreme Court of the United States

No. 14-1140

PHILLIP TIBBS, ET AL., PETITIONERS

v.

ESTATE OF LUVETTA GOFF, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF KENTUCKY

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. This case involves the privilege created by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act or Act), 42 U.S.C. 299b-21 *et seq.* That privilege is designed to encourage greater sharing of information about medical errors and other patient safety events by assuring health care providers that information they create for the Act's system of voluntary reporting will remain confidential. But Congress carefully limited the scope of the privilege to ensure that it does not prevent patients and regulators from obtaining information required to be preserved or reported under other federal and state laws.

a. In 1999, the Institute of Medicine (IOM) issued a landmark report finding that preventable medical errors were responsible for tens of thousands of deaths each year and proposing a "national agenda for reducing errors in health care." IOM, *To Err Is Human: Building a Safer Health System* 5 (1999); see *id.* at 1-2. The IOM recognized that litigation and mandatory reporting play an important role in deterring and redressing errors. *Id.* at 8-9, 86-88, 110. But it also endorsed voluntary reporting programs that encourage providers to share information about patient safety events so that those events can be analyzed. *Id.* at 9-10, 89-90. And because "fears about the legal discoverability of information" can discourage voluntary reporting, the IOM urged Congress to enact legislation protecting the confidentiality of information collected or shared "solely for purposes of improving safety and quality." *Id.* at 10; see *id.* at 109-131.

b. In 2005, in response to the IOM's report, Congress enacted the Patient Safety Act. See H.R. Rep. No. 197, 109th Cong., 1st Sess. 9 (2005) (House Report). The Act established a system of "patient safety organizations" (PSOs), which are public or private entities certified by the United States Department of Health and Human Services (HHS) to collect patient safety information reported by health care providers. 42 U.S.C. 299b-21(4), 299b-24. PSOs aggregate and analyze those reports and then "disseminate information back to providers in [an] effort to improve quality and patient safety." House Report 9.

To encourage providers to report to PSOs, the Patient Safety Act created a privilege for "patient safety

work product." 42 U.S.C. 299b-22.[1] As relevant here, the Act defines "patient safety work product" to include "any data, reports, records, memoranda, analyses * * * , or written or oral statements" that "are assembled or developed by a provider for reporting to a [PSO] and are reported to a [PSO]," and that "could result in improved patient safety, health care quality, or health care outcomes." 42 U.S.C. 299b-21(7)(A). With narrow exceptions, patient safety work product is confidential and is not subject to discovery in any administrative or judicial proceeding. 42 U.S.C. 299b-22(a), (b), and (c).

The Patient Safety Act's privilege was intended to encourage the voluntary development and dissemination of new information about patient safety events. House Report 9. But Congress did not want to interfere with federal and state reporting and recordkeeping requirements, and the Act carefully limits the scope of the privilege to ensure that, "[i]n general, information that [wa]s available to the public [before the Act] will continue to be available." *Ibid.* The Act thus specifies that patient safety work product "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." 42 U.S.C. 299b-

[1] A health care provider's participation in a PSO is generally voluntary. In the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119, Congress sought to encourage participation by hospitals with more than 50 beds by providing that an insurance plan offered through one of the ACA's Exchanges may not contract with such a hospital unless it has a relationship with a PSO. 42 U.S.C. 18031(h)(1); see 45 C.F.R. 156.1110(a)(2). The ACA also requires HHS to make available a program to help hospitals with high readmission rates reduce those rates by working with PSOs. 42 U.S.C. 280j-3.

21(7)(B)(ii). And the Act separately provides that patient safety work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." 42 U.S.C. 299b-21(7)(B)(i).

Original records and information maintained separately from a patient safety evaluation system "may be relevant" to patient safety and may be reported to a PSO. House Report 14. But because such materials "are not themselves patient safety work product," they are not privileged even if they are reported. *Ibid.* Congress thus emphasized that nothing in the Act "shall be construed to limit" the "discovery of or admissibility of" original records or separate information "in a criminal, civil, or administrative proceeding"; the reporting of such records or information "to a Federal, State, or local governmental agency"; or "a provider's recordkeeping obligation" with respect to such records or information "under Federal, state, or local law." 42 U.S.C. 299b-21(7)(b)(iii); see 42 U.S.C. 299b-22(g)(2) and (5).

c. In 2008, after notice and public comment, HHS promulgated regulations implementing the Patient Safety Act. 73 Fed. Reg. 70,732 (Nov. 21, 2008); see 42 C.F.R. Pt. 3. Three aspects of those regulations and the accompanying preamble are relevant here.

First, HHS clarified the role of a "patient safety evaluation system." The Act and the regulations define such a system as "the collection, management, or analysis of information for reporting to or by a [PSO]." 42 U.S.C. 299b-21(6); 42 C.F.R. 3.20. Under that definition, a patient safety evaluation system exists whenever a provider collects information for reporting to a PSO, "regardless of whether the pro-

vider * * * has formally identified a 'patient safety evaluation system.'" 73 Fed. Reg. 8119 (Feb. 12, 2008). But HHS urged providers to designate separate systems to collect patient safety work product for reporting to PSOs. HHS observed that such separate systems ensure that privileged material is segregated "from information collected, maintained, or developed for other purposes," and therefore allow providers "to provide supportive evidence to a court when claiming privilege protections" by establishing that the information at issue was prepared for reporting to a PSO and not for some other purpose. *Id.* at 8120; see 73 Fed. Reg. at 70,738-70,739.

Second, HHS clarified the point in time at which information becomes patient safety work product. The regulations provide that the privilege extends to qualifying information "that is documented as within a patient safety evaluation system for reporting to a PSO," even if it has not yet been reported. 42 C.F.R. 3.20; see 73 Fed. Reg. at 70,741-70,742.

Third, HHS addressed the interaction between the Patient Safety Act and federal and state reporting and recordkeeping requirements. HHS emphasized that "[i]nformation is not patient safety work product if it is collected to comply with external obligations" such as "state incident reporting requirements." 73 Fed. Reg. at 70,742. But HHS explained that if providers prepare information for reporting to a PSO and are uncertain whether similar information is required to comply with their external obligations, they can "protect this information as patient safety work product within their patient safety evaluation system while they consider whether the information is needed to meet external reporting obligations." *Ibid.* If a pro-

vider decides instead to use that information to satisfy its external obligations, the information can then be "removed from the patient safety evaluation system before it is reported to a PSO." *Ibid.*; see 42 C.F.R. 3.20 (paragraph (2)(ii) of the definition of patient safety work product).

2. This case involves a discovery dispute arising out of a medical malpractice suit. Pet. App. 2a. Luvetta Goff died as a result of complications during a surgery performed at the University of Kentucky Hospital (the Hospital). *Ibid.* Her estate sued petitioners, the three doctors who performed the surgery, in Kentucky state court. During discovery, the estate sought production of any "incident reports" describing Ms. Goff's surgery. *Id.* at 2a-3a. Under Kentucky law, hospitals must "maintain[]" certain reports about their operations, including "[i]ncident investigation reports." 902 Ky. Admin. Regs. 20:016, at 3(3)(a) (2015); see Pet. App. 14a-15a. Those reports are "to be used by employees in the ordinary course of business when significant events occur to document their experience and observations." Pet. App. 14a n.10 (quoting *University Med. Ctr., Inc.* v. *Beglin*, 375 S.W.3d 783, 787 (Ky. 2011)). "Under Kentucky law, these types of reports are required in the regular course of the hospital's business, are hospital records, and, thus, are generally discoverable" in civil litigation. *Id.* at 15a (citing *Saleba* v. *Schrand*, 300 S.W.3d 177, 184 (Ky. 2009)).

In this case, petitioners acknowledged that a nurse created such an incident report on the day of Ms. Goff's surgery. Pet. App. 3a. But petitioners asserted that the report was patient safety work product and therefore immune from discovery under the Patient

Safety Act. To support that assertion, petitioners submitted an affidavit stating that the incident report was created using "Patient Safety Net®," an internet-based system that serves as the Hospital's patient safety evaluation system. *Id.* at 16a-17a. The affidavit represented that "all incident reports" at the Hospital are "generated exclusively through [the] Patient Safety Net® system" and that Hospital employees "must input data through" that system to create a report. *Id.* at 18a. The affidavit added that "incident reports * * * are automatically transmitted to [the Hospital's PSO] every 45 days." *Ibid.*

The trial court rejected the claim of privilege, holding that the incident report describing Ms. Goff's surgery is discoverable so long as it was prepared by a person with actual knowledge about her care. Pet. App. 49a-51a.

3. Petitioners sought a writ of prohibition from the Kentucky Court of Appeals. Pet. App. 42a-48a. A divided panel held that the incident report is privileged only to the extent it contains "self-examining analysis." *Id.* at 48a.

4. The Supreme Court of Kentucky reversed. Pet. App. 1a-41a.

a. The court first held that, as a general matter, a report mandated by a state recordkeeping requirement does not qualify as patient safety work product. Pet. App. 14a-15a. The court emphasized that its conclusion was consistent with HHS's view that "[i]nformation is not patient safety work product if it is collected to comply with external obligations," including "state incident reporting requirements." *Id.* at 15a (quoting 73 Fed. Reg. at 70,742).

The court then rejected petitioners' contention that the report on Ms. Goff's surgery nevertheless must be treated as privileged because it was created in the Hospital's patient safety evaluation system. Pet. App. 18a-26a. The court reviewed prior decisions applying the Patient Safety Act and concluded that "no opinion ha[d] directly addressed" such a circumstance. *Id.* at 21a. But based on the Act's text and history, the court held that "Congress did not intend for separately-mandated incident information sources to be able to acquire a federal privilege" solely because a provider places them in a patient safety evaluation system. *Id.* at 25a.

Finally, the court addressed the possibility that the report on Ms. Goff's surgery might contain "other material properly privileged" in addition to "the information normally contained in * * * state-mandated incident reports." Pet. App. 26a. The court directed the trial court to review the report in camera and to exclude any such material before ordering disclosure. *Ibid.*

b. Justice Noble concurred in the result only. Pet. App. 26a.

c. Justice Abramson dissented, joined by Chief Justice Minton. Pet. App. 26a-41a. Justice Abramson agreed with the court that "Kentucky clearly requires hospitals to maintain incident investigation reports," and she also agreed that patients should "continue to have access to those records." *Id.* at 27a. But she interpreted the Act and the preamble to HHS's implementing regulations to mean that all information in a provider's patient safety evaluation system is privileged, even if that information consists of records required to be maintained by state law. *Id.* at 34a-37a.

Accordingly, she concluded that the proper course in a case like this one is not to require the provider to divulge documents from its patient safety evaluation system, but instead to compel it to create a new incident report outside that system. *Id.* at 40a.

5. The Supreme Court of Kentucky denied rehearing by an equally divided vote. Pet. App. 52a.[2]

6. In May 2016, HHS issued guidance to "clarify what information that a provider creates or assembles can become patient safety work product," and in particular to address the relationship between the Patient Safety Act's privilege and a provider's external recordkeeping and reporting obligations. 81 Fed. Reg. 32,655 (May 24, 2016). That guidance was prompted by HHS's examination of this case, as well as by its experience working with providers, PSOs, and state and federal regulators to administer and enforce the Patient Safety Act. As relevant here, the guidance reiterates HHS's view that "any information that is prepared to meet any Federal, state, or local health oversight agency requirements is not [patient safety work product]." *Id.* at 32,657. Instead, HHS explained, a document required by such an external obligation is an "original * * * provider record" expressly excluded from the privilege by 42 U.S.C. 299b-21(7)(B)(i). See 81 Fed. Reg. at 32,658. The guidance disapproves the practice of using a patient safety evaluation system as the exclusive repository for records required to be maintained under federal or state law, and it confirms that such a practice does not

[2] Justice Noble voted with the dissenters to grant rehearing. Pet. App. 52a. The court's seventh member did not participate in the original decision or the petition for rehearing. *Id.* at 26a, 52a.

confer privileged status on the mandated records. *Ibid.*

DISCUSSION

Petitioners contend (Pet. 15-33) that any record a provider prepares in a patient safety evaluation system is privileged under the Patient Safety Act—even where, as here, the provider was required to prepare and maintain that record under state law. The Supreme Court of Kentucky correctly rejected that contention, holding that the incident report concerning Ms. Goff's surgery is not patient safety work product because it was mandated by Kentucky law. That decision does not conflict with any decision of another state court of last resort or a federal court of appeals. To the contrary, it appears that no prior decision by such a court has even considered the question presented here, and only a handful of reported decisions at any level have addressed the Patient Safety Act at all. This Court's review is therefore unwarranted. And that is particularly true now that HHS has issued guidance specifically addressing the application of the Act to circumstances like those present here and adopting an interpretation consistent with the one applied in the decision below.

A. The Supreme Court of Kentucky Correctly Held That The Incident Report At Issue In This Case Is Not Privileged Because It Was Mandated By A State Record-keeping Requirement

The Patient Safety Act "was intended to spur the development of *additional* information created through voluntary patient safety activities." 81 Fed. Reg. at 32,657; see House Report 9. That purpose is served by affording a robust privilege to information

that providers voluntarily create for reporting to a PSO. But Congress's purpose would not have been furthered by extending the same protection to records that providers are independently *required* to create or maintain under other laws. The text and history of the Act, as well as HHS's consistent interpretation, confirm that Congress did not authorize providers to immunize such information from disclosure merely by placing it in a patient safety evaluation system.

1. A record mandated by a state recordkeeping requirement is not patient safety work product

a. The relevant portion of the statutory definition of "patient safety work product" specifies that to qualify for the privilege, information must be "assembled or developed by a provider *for reporting to a [PSO]*." 42 U.S.C. 299b-21(7)(A)(i) (emphasis added). That phrase is most naturally read to describe information that a provider assembles or develops for the purpose of reporting to a PSO—not records that must be created for some other purpose, but that a provider also chooses to place in its patient safety evaluation system. And that natural reading is reinforced by the separate provision clarifying that patient safety work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." 42 U.S.C. 299b-21(7)(B)(i). That provision describes "the types of information that providers routinely assemble, develop, or maintain for purposes and obligations other than those of the Patient Safety Act." 73 Fed. Reg. at 8123. In particular, the phrase "original * * * provider record" encompasses state-mandated reports like the one at issue here because those reports are "hospital records" that are "required in the regular

course of [a] hospital's business" and that are routinely prepared and maintained by hospital employees. Pet. App. 14a-15a (citation omitted).

b. The legislative history of the Patient Safety Act confirms that reports mandated by state recordkeeping requirements are not privileged. The House Committee noted that the Act's definition of patient safety work product does not include "documents or communications that are part of traditional health care operations or record keeping," including "primary information at the time of events." House Report 14. The Committee explained that such documents are "original provider records" and thus do not qualify as privileged even if they are "relevant to a patient safety evaluation system" or "sent to a [PSO]." *Ibid.*

More broadly, the Committee stated that notwithstanding the Act's protections for patient safety work product, "[i]n general, information that [wa]s available to the public [before the Act] will continue to be available." House Report 9. The Act's supporters repeatedly echoed that point, emphasizing that "information which is currently available to plaintiffs' attorneys or others will remain available just as it is today." 151 Cong. Rec. 17,120 (2005) (Sen. Enzi); see, *e.g.*, *id.* at 17,780 (Rep. Dingell) ("[The Act] continues to allow public access to information that is available today."). Those assurances were part of the careful balance Congress struck in crafting the Act, and they are predicated on the understanding that the Act's privilege does not extend to records that providers are already required to maintain under other laws.

c. That conclusion is further reinforced by HHS's interpretation of the Patient Safety Act. HHS is responsible for administering and enforcing the Act, and

it has promulgated regulations implementing the Act's provisions. 42 C.F.R. Pt. 3. Those regulations, issued after notice and public comment, are entitled to deference under *Chevron U.S.A. Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842-843 (1984). HHS's interpretation of its regulations is, in turn, "controlling" unless it is "plainly erroneous or inconsistent with the regulation[s]." *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997) (citations and internal quotation marks omitted). And even with respect to matters not addressed by the regulations, HHS's interpretation of the Act based on its experience and expertise warrants a measure of deference under *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944).

In promulgating the 2008 regulations, HHS emphasized that "[i]nformation is not patient safety work product if it is collected to comply with external obligations, such as * * * state incident reporting requirements." 73 Fed. Reg. at 70,742; see, *e.g.*, *id.* at 8121 (similar). HHS thus cautioned that a provider should not maintain information required to satisfy its external obligations in its patient safety evaluation system. *Id.* at 70,742-70,743.

The preamble to the 2008 regulations did not expressly discuss the application of the Patient Safety Act to the circumstances presented here—*i.e.*, to a provider that maintains reports or other records required to comply with its external obligations exclusively within its patient safety evaluation system. But HHS has now issued guidance directly addressing such practices. The guidance clarifies that documents created to comply with a provider's external obligations are "original * * * provider record[s]," 42 U.S.C. 299b-21(7)(B)(i), and that such documents

consequently do not qualify as patient safety work product even if "[t]he provider only maintains the [documents] in the [patient safety evaluation system]." 81 Fed. Reg. at 32,658.[3]

2. Petitioners' contrary arguments lack merit

On petitioners' view (Pet. 19), the privileged status of a record turns solely on "whether it exists inside the PSO program. If so, it is protected; if not, it is not." In other words, petitioners maintain that any document that a provider places in its patient safety evaluation system is privileged, without regard to the document's content or the reasons for its creation. That interpretation contradicts the Act's text, purpose, and history.

a. Petitioners are of course correct that whether a document is located in a patient safety evaluation system is relevant to its status under the Patient Safety Act. The Act specifies that patient safety work product "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." 42 U.S.C. 299b-21(7)(B)(ii). The fact that information was collected in a patient safety evaluation system is thus a *necessary* condition for the privilege. But it is not a *sufficient* condition, because the Act also provides that patient safety work product "does not include a patient's medical record, billing and discharge information, or any other original patient or provider

[3] The guidance explains that this interpretation is consistent with the views HHS expressed in the preamble to the 2008 regulations. 81 Fed. Reg. at 32,658 n.32; see *ibid.* (acknowledging a change in HHS's interpretation with respect to a separate issue not presented in this case).

record." 42 U.S.C. 299b-21(7)(B)(i). Such original records thus do not qualify as patient safety work product even when—as here—they are developed or maintained in a provider's designated patient safety evaluation system. In asserting that a document's status depends solely on its placement in a patient safety evaluation system, petitioners violate a "cardinal principle of statutory construction" by denying effect to the separate provision governing original records. *Williams* v. *Taylor*, 529 U.S. 362, 404 (2000).

b. Petitioners' interpretation would also undermine the Patient Safety Act's purpose. Petitioners identify no reason why a Congress seeking to encourage the voluntary development of new information would have conferred privileged status on records that providers are already *required* to create and maintain. And, as this case illustrates, petitioners' reading would allow providers to use the Act to circumvent their legal obligations. Kentucky law—as authoritatively construed by the State's highest court—requires hospitals to maintain incident reports like the one at issue here. Pet. App. 14a-15a. But the Hospital has structured its operations so that "all incident reports" must be "generated exclusively through" its patient safety evaluation system. *Id.* at 18a. If petitioners' interpretation were correct, all of those reports would be privileged, effectively thwarting Kentucky's independent recordkeeping requirement.

Petitioners do not dispute this consequence of their interpretation. Indeed, they assert (Pet. 20) that a provider in the Hospital's situation may insist on the privilege and "simply accept a state penalty, if any, for failing to comply with state law" if a state regulator were to demand production of a document that state

law requires the provider to maintain.[4] But that result would undermine Congress's repeated instruction that the Act shall not be construed "to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information" that is not patient safety work product. 42 U.S.C. 299b-22(g)(2); see 42 U.S.C. 299b-21(7)(B)(iii), 299b-22(g)(5). It would also contradict the legislative history emphasizing that the Act would not deprive regulators or the public of information that was previously available. See p. 12, *supra*. Those assurances would be hollow if, as petitioners maintain, providers could transform any document into patient safety work product simply by placing it in a patient safety evaluation system.

c. Petitioners err in asserting that the decision below "effectively authorizes state nullification of federal law." Pet. 20-21 (citation omitted). The Patient Safety Act provides that "[n]otwithstanding any other provision of Federal, State, or local law," patient safety work product is privileged and confidential. 42 U.S.C. 299b-22(a) and (b). The Act thus preempts any state law that would compel the disclosure of patient safety work product. But the Supreme Court of Kentucky correctly held that the records a provider must create to satisfy its external obligations—including incident reports required by state recordkeeping

---

[4] Petitioners also note (Pet. 20) that, under their reading, a provider could forgo the privilege by "remov[ing] the document" from the patient safety evaluation system. But as petitioners acknowledge (*ibid.*), even where that option is otherwise available, it does not apply once the document is transmitted to a PSO. See 42 C.F.R. 3.20 (paragraph (2)(ii) of the definition of patient safety work product); see also Pet. App. 18a (noting that the Hospital's system is configured so that "[a]ll incident reports * * * are automatically transmitted [to the Hospital's PSO] every 45 days").

laws—do not qualify as patient safety work product in the first place because they are "original * * * provider record[s]." 42 U.S.C. 299b-21(7)(B)(i); see Pet. App. 14a-15a. That holding does not allow state law to "nullify" a federal privilege; it simply recognizes that federal law defines the scope of the privilege so that records created to comply with a provider's external obligations are not privileged to begin with.

d. Petitioners also err in asserting that the Supreme Court of Kentucky held that courts may compel the disclosure of *any* information contained in a patient safety evaluation system (or held by a PSO) if that information "is the sort 'normally contained in' documents subject to a state reporting or recordkeeping obligation." Pet. 25 (quoting Pet. App. 25a-26a). Petitioners are correct that such a holding would be inconsistent with the Patient Safety Act. But the decision below should not be read as adopting such a rule—and petitioners' concerns about wide-ranging discovery certainly are not implicated here.

This case involves a single document—an incident report that was required by Kentucky law, and that petitioners appear to concede was prepared to comply with that state-law requirement. Pet. App. 3a, 14a-15a, 17a-18a; see Pet. 18. Because state law required the Hospital to create and maintain the report, the report is an "original * * * provider record." 42 U.S.C. 299b-21(7)(B)(i). And because such original records are not privileged, nothing in the Patient Safety Act would have prevented the courts below from ordering the disclosure of the entire report. In the portion of the decision petitioners quote, however, the Supreme Court of Kentucky allowed for the possibility that the report might contain not just "the in-

formation normally contained in such state-mandated incident reports," but also "other material" that the court believed might be "properly privileged under the Act." Pet. App. 26a. To allow for that possibility, the court directed the trial court to conduct an in camera review to separate such material before ordering disclosure. *Ibid.*[5]

The Supreme Court of Kentucky's direction for in camera review thus may have afforded petitioners greater protection than what the Patient Safety Act requires by limiting disclosure to information "normally contained" in incident reports. But that portion of the court's opinion should not be read to suggest that a trial court could examine records created solely for reporting to a PSO to determine whether those records happen to include information that would also normally be contained in records a provider is required to maintain under state or federal law. The court's decision rested on its holding that Kentucky law required the Hospital to create the document at issue here, and the court's order directing in camera review and disclosure was limited to that particular document. Pet. App. 14a-15a, 24a-25a.

Petitioners thus err in asserting (Pet. 25-31) that the decision below will discourage providers from reporting information to PSOs by allowing wide-ranging discovery or in camera review of materials

---

[5] Petitioners do not suggest that the report actually contains any information beyond that ordinarily included in incident reports required by Kentucky law. Cf. Pet. App. 18a (noting that the Hospital's incident-reporting system collects basic facts such as "the date of the submission, any person harmed or affected by the incident, the location where the event occurred, and a description of the event").

contained in a patient safety evaluation system. As HHS has explained, moreover, providers can avoid that risk by satisfying their external obligations using separate recordkeeping systems, and by reserving their designated patient safety evaluation systems for privileged information created specifically for reporting to a PSO. 81 Fed. Reg. at 32,658-32,659. The issue in this case arose only because the Hospital chose to maintain the incident reports required by Kentucky law in its patient safety evaluation system.[6]

B. The Decision Below Does Not Conflict With Any Decision Of A Federal Court Of Appeals Or Another State Court Of Last Resort

Petitioners do not contend that the decision below conflicts with any decision of a federal court of appeals or another state court of last resort. Indeed, only a handful of reported decisions at any level have addressed the Patient Safety Act at all, and it appears that no federal court of appeals and no other state supreme court has considered the application of the

---

[6] Petitioners erroneously assert (Pet. 9-10) that the preamble to the 2008 regulations endorsed such an approach. The preamble explained that providers may place information in a patient safety evaluation system while they "consider whether the information is needed to meet external reporting obligations." 73 Fed. Reg. at 70,742. But HHS did not did not state that it is appropriate for providers to maintain records exclusively in their patient safety evaluation systems where, as here, it is clear that the records are required by state law. To the contrary, HHS emphasized that a patient safety evaluation system "does not replace other information collection activities mandated by law[]." *Ibid.* And HHS has now reiterated that a provider "should maintain at least two systems or spaces: a [patient safety evaluation system] for [patient safety work product] and a separate place where it maintains records for external obligations." 81 Fed. Reg. at 32,659.

Act to circumstances comparable to those present here. See Pet. App. 21a (stating that "no opinion ha[d] directly addressed" the question presented).[7] This case thus does not implicate the sort of conflict among the lower courts that warrants this Court's intervention. See Sup. Ct. R. 10.

Petitioners nonetheless maintain (Pet. 15) that the Court should grant review to resolve "substantial divergence among the lower courts," which is purportedly reflected in a number of trial and intermediate state-court decisions. With a single exception, however, none of those decisions addressed the question presented here because none of them involved documents subject to external reporting or recordkeeping requirements.[8]

---

[7] Petitioners quote (Pet. 22) the Supreme Court of Tennessee's decision in *Lee Medical, Inc.* v. *Beecher*, 312 S.W.3d 515, 535 (2010). But that case involved a claim of privilege under state law, not the Patient Safety Act. *Id.* at 518-519.

[8] In the two decisions on which petitioners principally rely (Pet. 22-23), there was no suggestion that the documents at issue were subject to reporting or recordkeeping requirements. See *Department of Fin. & Prof'l Regulation* v. *Walgreen Co.*, 970 N.E.2d 552, 555 (Ill. App. Ct. 2012); *Tinal* v. *Norton Healthcare, Inc.*, No. 11-cv-596, at 21-22 (W.D. Ky. July 15, 2014); see also Pet. App. 19a-20a (distinguishing *Walgreen* on this ground). Petitioners also cite (Cert. Reply Br. 2) a third decision upholding a claim of privilege over emails despite the plaintiff's assertion that the provider would need to use the information in the emails "to fulfill other reporting obligations." *Lewis* v. *Upadhyay*, No. CL14-3682, 2015 WL 1417874, at *4 (Va. Cir. Ct. Mar. 3, 2015). But the plaintiff did not suggest that the emails themselves were subject to any reporting requirement. *Ibid.* Petitioners' remaining decisions are even further afield, either because they addressed unrelated questions about the Patient Safety Act, see *Brink* v. *Mallick*, No. 13-cv-1314, 2015 WL 1387936, at *10 (Pa. Ct. Com. Pl. Mar. 27, 2015); Pet.

The one exception is *Southern Baptist Hospital of Florida, Inc.* v. *Charles*, 178 So. 3d 102 (Fla. Dist. Ct. App. 2015) (*Charles*).[9] In that case, a Florida district court of appeals endorsed petitioners' view, citing Justice Abramson's dissent and stating that records maintained in a patient safety evaluation system are privileged even if they are prepared to comply with a "state statute, rule, licensing provision, or accreditation requirement." *Id.* at 109. But the disagreement between that intermediate appellate decision and the decision below does not warrant this Court's review, and the Supreme Court of Florida may well reverse the decision in *Charles*. See *Charles* v. *Southern Baptist Hosp. of Fla., Inc.*, No. SC15-2180 (Fla. filed Nov. 25, 2015).

C. The Question Presented Does Not Otherwise Warrant This Court's Review

Despite the absence of a genuine conflict and the paucity of reported decisions addressing the question presented, petitioners assert that this Court's review is warranted because vehicles for considering the question presented will be rare and because providers need greater clarity on the scope of the Patient Safety Act's privilege. Neither consideration warrants this Court's intervention.

1. Petitioners assert (Pet. 32) that because disputes over the scope of the Patient Safety Act's privilege typically arise during discovery, the issue will

---

App. 94a-97a (describing three Virginia decisions), or because they concerned the existence and scope of a common law privilege rather than the one created by the Act, see Pet. 22, 24 & n.7.

[9] Petitioners cited (Pet. 23-24) the trial-court decision in *Charles*; the court of appeals issued its decision after the petition was filed.

rarely be presented in a reviewable final judgment. But as this Court has recognized, privilege rulings can be reviewed in "postjudgment appeals" in the same manner as "a host of other erroneous evidentiary rulings." *Mohawk Indus., Inc.* v. *Carpenter*, 558 U.S. 100, 109 (2009). When the issue arises in federal court, moreover, litigants have "several potential avenues" for securing interlocutory review, including "an interlocutory appeal" or a petition "for a writ of mandamus." *Id.* at 110-111. And even when the issue arises in state court, a party may be able to secure this Court's review before final judgment if state law provides a mechanism for addressing the issue through a separate action, such as the writ of prohibition used in this case. See Pet. 1-2. This Court should therefore have ample opportunities to take up the question presented if and when a genuine dispute develops in the lower courts.

2. Petitioners also contend (Pet. 15-25) that providers and lower courts need immediate guidance on the scope of the Patient Safety Act's privilege. That assertion rests on an exaggerated characterization of the disagreement in the lower courts. See pp. 19-21, *supra*. But even if petitioners' statements about the need for clarification were correct when the petition was filed, that need has now been met by the detailed guidance issued by HHS, the agency charged by Congress with administering and enforcing the Act. That guidance addresses the proper application of the Act and its implementing regulations to circumstances like those present here. See 81 Fed. Reg. at 32,656-32,659. All of the opinions that have addressed the application of the Act to records required by state law have relied heavily on the guidance HHS previously provided in

the preamble to the 2008 regulations. See Pet. App. 15a-16a (majority opinion); *id.* at 34a-37a (dissent); *Charles*, 178 So. 3d. at 108. Indeed, the disagreement between those opinions rested in substantial part on their differing interpretations of HHS's views. There is thus good reason to think that the additional guidance issued by HHS will eliminate any confusion or divergent results in the future. At a minimum, this Court should not take up the question presented until lower courts have had the opportunity to consider the issue with the benefit of HHS's views.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

DONALD B. VERRILLI, JR.
Solicitor General
BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
EDWIN S. KNEEDLER
Deputy Solicitor General
BRIAN H. FLETCHER
Assistant to the Solicitor General
MICHAEL S. RAAB
SARAH W. CARROLL
Attorneys

MAY 2016