

No. 14-1140

IN THE
Supreme Court of the United States

PHILLIP TIBBS, *et al.*,

Petitioners,

v.

KIMBERLY BUNNELL, JUDGE, CIRCUIT COURT OF
KENTUCKY, FAYETTE COUNTY, *et al.*,

Respondents.

**On Petition for a Writ of Certiorari
to the Kentucky Supreme Court**

SUPPLEMENTAL BRIEF OF PETITIONERS

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
SUPPLEMENTAL BRIEF	1
I. THE GOVERNMENT’S NEW INTER- PRETATION CONFLICTS WITH THE STATUTE	1
A. The Privilege Does Not Exclude All Ma- terials Regulated By State Law	1
B. The Government’s Interpretation Rests On Inapposite Provisions.....	2
II. THE GUIDANCE CONTRADICTS THE STATUTE, RULE, AND DECISION BE- LOW	6
III. THIS COURT’S REVIEW IS TIMELY AND ESSENTIAL.....	10
CONCLUSION	13

TABLE OF AUTHORITIES

CASES	Page
<i>CFTC v. Schor</i> , 478 U.S. 833 (1986).....	4
<i>Christopher v. SmithKline Beecham Corp.</i> , 132 S. Ct. 2156 (2012).....	6, 8, 9
<i>FCC v. Fox Television Stations</i> , 556 U.S. 502 (2009).....	9
<i>Gonzales v. Oregon</i> , 546 U.S. 243 (2006).....	8
<i>Lawrence v. Chater</i> , 516 U.S. 163 (1996)	10
<i>Lewis v. Upadhyay</i> , 90 Va. Cir. 81 (2015)....	11
<i>S. Baptist Hosp. of Fla. v. Charles</i> , 178 So. 3d 102 (Fla. Dist. Ct. App. 2015).....	11
<i>Upjohn Co. v. United States</i> , 449 U.S. 383 (1981).....	3
<i>Whitman v. Am. Trucking Ass'ns</i> , 531 U.S. 457 (2001).....	4
STATUTES AND REGULATIONS	
42 U.S.C. § 299b-21	2, 5, 6
§ 299b-22	2, 3, 5, 7
§ 299b-23	5
73 Fed. Reg. 8,112 (Feb. 12, 2008).....	4
70,732 (Nov. 21, 2008)	<i>passim</i>
81 Fed. Reg. 32,655 (May 24, 2016).....	7, 10
LEGISLATIVE HISTORY	
H.R. Rep. No. 109-197 (2005)	3, 4, 5
S. Rep. No. 108-196 (2003).....	5

SUPPLEMENTAL BRIEF

In the guise of “clarifying” the patient-safety work product privilege, the Department of Health and Human Services rewrote it to exclude material protected by the rule HHS purported to interpret.

This made-for-litigation “guidance” deserves no deference, and only heightens the need for this Court’s review. HHS’s about-face misconstrues the statutory text, jeopardizes the medical community’s reliance on the rulemaking, and deters future participation in the patient-safety program. Given the government’s audacious assertion of *Auer* deference, few providers will risk litigation over the protection offered by this *voluntary* government program, depriving this Court of the chance to review the question presented: whether *every* state record requirement *automatically* nullifies the federal privilege.

I. THE GOVERNMENT’S NEW INTERPRETATION CONFLICTS WITH THE STATUTE.

A. The Privilege Does Not Exclude All Materials Regulated By State Law.

According to the government, “[a] record mandated by a state recordkeeping requirement is not patient safety work product [PSWP].” Br. 11. The Patient Safety Act contains no such state-law carveout. Congress defined the privilege to protect:

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 [PSO] ...

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

42 U.S.C. § 299b-21(7)(A).

Congress’s test asks two questions: Are the documents among the types—root cause analyses, memos, reports, etc.—eligible for the privilege? And did the provider assemble or develop them for reporting to a PSO?¹

If both answers are yes, the material is PSWP—and therefore privileged and confidential absent an express statutory exception. § 299b-22(a)-(c). The statute expressly *preempts* state law that would otherwise require discovery. § 299b-22(a)-(b). And it expressly *preserves* providers’ state reporting and recordkeeping obligations. § 299b-21(7)(B)(iii). Thus, the Act does not shield a provider that violates a state requirement, *contra* Br. 15-16—but neither does it allow states to pierce the federal privilege by authorizing disclosure of protected materials.

B. The Government’s Interpretation Rests On Inapposite Provisions.

If Congress had defined PSWP according to state law, the statute surely would have mentioned it. Tellingly, the government’s tortured interpretation rests on two provisions that do not.

¹ The government attacks a caricature of Petitioners’ position: “any document that a provider places in its [PSES] is privileged.” Br. 14. As Petitioners made clear, Pet. 19; Reply 5, 10, the statute considers documents’ content *and* placement. The quoted language responds to the decision below, which largely turned on the second consideration.

1. Section 299b-21(7)(A)(i) defines PSWP in part as material “assembled or developed by a provider for reporting to a [PSO].” Br. 11. The government argues this means material “assembled or developed by a provider [*solely*] for reporting to a PSO,” which would exclude materials also intended to serve “some other purpose,” such as satisfying state recordkeeping rules. *Id.* But the government may not insert this word into the text Congress enacted.

The Act’s other provisions squarely foreclose reading “for” as “solely for.” Its confidentiality exceptions authorize the use of PSWP “for a variety of purposes,” H.R. Rep. No. 109-197, at 14 (2005): for “patient safety activities,” for authorized “research” and “demonstration projects,” “to an accrediting body,” “for business operations,” and to law enforcement, § 299b-22(c)(2)(A)-(G). For example, providers regularly prepare root-cause analyses to share with their PSO *and* their accrediting body. See Joint Commission Br. 6.

Under the statute, material developed for any such authorized purpose in addition to “reporting to a PSO” remains privileged PSWP. § 299b-22(d)(1). Under the government’s position, by contrast, the material was never PSWP in the first place because it was also prepared for “some other purpose.” That approach would render Congress’ list of exceptions pure surplusage. See Pet. App. 57a-61a. And it would necessitate a subjective, amorphous inquiry into a provider’s *true* purpose, “result[ing] in widely varying applications” of the privilege. See *Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981).

2. Section 299b-21(7)(B)(i) clarifies that PSWP “does not include a patient’s medical record, billing and discharge information, or any other original patient or provider record.” The government asserts,

without support, that “original provider record” “encompasses state-mandated reports.” Br. 11.

As above, this interjects state law where the statute never mentions it. If Congress intended the privilege to depend on state law—notwithstanding its goal of a uniform privilege to *overcome* inconsistent state laws, Pet. 6—a “clarification” referring only to “original” records would be a bizarre way to say so. See *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001) (“Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.”). That presumably explains the suspicious novelty of the government’s position: Petitioners are aware of no interpretation of “original provider record” that includes state-regulated reports (aside from Respondents’ unsupported brief, see Reply 5).

“Original provider record” is naturally and commonly understood to mean contemporaneous clinical and administrative materials. Such “traditional health care operations or record keeping” include “medical records, billing records, guidance on procedures, physician notes, hospital policies, logs of operations, records of drug deliveries, [and] primary information *at the time of events*.” H.R. Rep. No. 109-197 at 14 (emphasis added). Quality and safety reports developed *after the fact*, by contrast, are not original records.² They are protected because they in-

² The proposed rule described the “original record[s]” provision as “illustrative of the types of information that providers routinely assemble ... for [non-PSO] purposes.” 73 Fed. Reg. 8,112, 8,123 (Feb. 12, 2008); see Br. 11. This snippet did not define “original record” or mention state law, but merely restated that records maintained “for a purpose other than [PSO] reporting” are not PSWP. 73 Fed. Reg. at 8,123. Regardless, HHS did not include this language in the final Rule as its “considered interpretation.” *CFTC v. Schor*, 478 U.S. 833, 845 (1986).

volve precisely the sort of “feedback and assistance to effectively minimize patient risk” that Congress intended to protect. § 299b-21(5)(D). If incident reports were unprivileged “original” records simply because providers “routinely” prepare them, Br. 12, the exception would swallow the rule, preventing the robust exchange Congress intended to create, §§ 299b-21(5)(D), 299b-23.³

3. The provisions that actually mention state law do not aid the government. Treating certain state-regulated records as *privileged* is fully consistent with Congress’s instruction that the Act should not “limit, alter, or affect the requirements of ... State ... law pertaining to information that is *not privileged*.” § 299b-22(g)(2) (emphasis added); contra Br. 16. And treating such records as privileged does not “limit, alter, or affect” state requirements anyway: providers must still comply, notwithstanding their participation in the patient-safety program. Any state-law violations may be “remedied ... in ‘the same manner as’” before the Act. Pet. App. 38a (Abramson, J., dissenting) (quoting 73 Fed. Reg. at 70,742); Pet. 20.

The Act was created to preempt a patchwork of inconsistent state protections with a uniform federal privilege. § 299b-22(a); Pet. 6. The government’s position eviscerates this purpose by allowing states to control the privilege’s scope. It defends this upside-down result by asserting state-regulated records were never privileged to begin with—but this just begs the

³ Nor did Congress protect only “*additional* information created” for PSO reporting. Br. 10–11, 15. Congress also intended to foster the “dissemination,” “reporting,” and “sharing” of existing medical-error information among PSOs and participating providers to improve patient safety. § 299b-22(c)(2)(A); H.R. Rep. 109-197 at 9; S. Rep. No. 108-196, at 3-5 (2003). *Accord* § 299b-21(5)(C); 73 Fed. Reg. 70,32, 70,732 (Nov. 21, 2008).

question. Br. 16-17. In the government’s view, nothing stops a state from requiring providers to maintain and disclose all root cause analyses, though Congress expressly identified them as privileged. § 299b-21(a)(7)(A). But the statute does not preempt only what states declined to regulate.

“Assurances” from two legislators that facts remain discoverable, Br. 12, cannot overcome the statutory text. Regardless, even under Petitioners’ reading, no *fact* about a plaintiff’s treatment—whether recorded in a chart or recalled by a witness—is shielded from discovery, because that information is not “developed ... for reporting to a [PSO].” § 299b-21(7)(A)(i)(I). The Act protects not “what’ happened,” but the provider’s candid analysis of “how’ and ‘why.” See AQIPS Br. 9.

II. THE GUIDANCE CONTRADICTS THE STATUTE, RULE, AND DECISION BELOW.

The government tried to manufacture support for its preferred outcome by promulgating agency “Guidance.” On the same day the Justice Department filed its brief, HHS issued Guidance “clarifying” the 2008 Final Rule. That Rule, unlike the Guidance, underwent public notice and comment. And it interpreted the PSWP privilege to apply regardless of whether a state recordkeeping requirement applied. Despite years of provider reliance on that Rule, the Guidance now retroactively rejects its interpretation in favor of one that undermines Congress’s core purpose of “encourag[ing] providers to share [PSWP] without fear of liability.” 73 Fed. Reg. at 70,732.

No deference is due an agency’s “post hoc rationalization,” mere “litigating position,” or “inconsistent” interpretation. *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2166 (2012) (collecting cases).

The Guidance ticks all these boxes. HHS’s 2008 notice-and-comment rulemaking, not its 2016 made-for-litigation “clarification,” answers the question presented.

1. HHS’s Guidance purportedly “clarifies that documents created to comply with a provider’s external obligations are ‘original ... provider record[s]’ that ‘do not qualify as [PSWP].’” Br. 13-14 (citing 81 Fed. Reg. 32,655, 32,658 (May 24, 2016)). The government thus contends this revisionist but “controlling” Guidance renders certiorari unnecessary by “eliminat[ing] any confusion or divergent results in the future.” Br. 13 (citing *Auer*), 23.

Insofar as the Guidance clarifies anything, it does so only through ipse dixit. HHS identifies no particular ambiguity in the relevant regulatory language. It confronts none of the interpretive difficulties identified above. It repeatedly conflates disclosure of PSWP to satisfy reporting requirements—which the statute bars absent a specific exception, § 299b-22(c)-(d)—with the use of non-disclosed PSWP to satisfy record-keeping requirements—which the statute does not prohibit, 81 Fed. Reg. at 32,655-56. The “sole-purpose” interpretation discussed above rests on an entirely different statutory provision in the Guidance, see *id.* (citing § 299b-21(7)(B)(ii)), than in the brief, Br. 11 (§ 299b-21(7)(A)(i)). And the Guidance’s “original record” interpretation cites no authority for vastly broadening this exclusion to cover documents required “to meet any Federal, state, or local public health or health oversight requirement.” 81 Fed. Reg. at 32,658.⁴ This is hardly the sort of “thoroughness”

⁴ Nor is deference due this “interpretation” of the Rule, which merely paraphrases the statute’s “original records” language. 73

or “consistency” that gives the agency the “power to persuade”—much less “contro[l]”—this Court’s interpretation. *Christopher*, 132 S. Ct. at 2166-69.

2. The Guidance also contradicts the regulation it supposedly interprets. The entire 2008 Final Rule presupposes that PSWP may overlap with state-regulated records. Although the Act does not preempt state-law obligations, disclosure of PSWP “*even to a State entity, ... must have an applicable disclosure permission,*” and “*a State may not require that patient safety work product be disclosed.*” 73 Fed. Reg. at 70,743-44 (emphases added). The Rule plainly contemplates the privilege’s application to state-regulated documents; it never hints they are by definition not PSWP.

Even more glaring is HHS’s about-face that providers must maintain PSWP separately from other state-regulated information. The Rule directly addressed this question, which was among the “most significant areas of comment”: “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 70,740-42 (emphasis added); *id.* at 70,794 (rejecting proposal to segregate PSWP from “routine data collection activities” through “dual information systems”). Yet the government, in Orwellian fashion, now says HHS has “*reiterated* that a provider ‘*should* maintain at least two systems or spaces: a [PSES] for [PSWP] and a separate place where it maintains records for external obligations.” Br. 19 n.6 (citing 81 Fed. Reg. at 32,659) (emphases added). It states Petitioners’ error was to “maintain the incident reports

Fed. Reg. at 70,742, 70,797 (§ 3.20). See *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006).

required by Kentucky law in its [PSES].” Br. 19. But Petitioner’s decision simply followed HHS’s rulemaking, which indicated providers should leverage “existing infrastructure for reporting and examination of patient safety events to minimize duplication of resources.” 73 Fed. Reg. at 70,744.⁵

Post hoc guidance that contradicts a Rule is entitled to no weight, particularly where the regulation “has engendered serious reliance interests.” *FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009); *Christopher*, 132 S. Ct. at 2166. Petitioners—like many other providers—declined to maintain separate recordkeeping systems based on HHS’s Rule, and *voluntarily* joined the government’s patient-safety program on this basis. See AQIPS Br. 8-9 (because the Rule “does not require providers to maintain duplicate systems ... it is common practice among hospitals to combine their incident reporting system and their [PSES], consistent with this federal regulation”).

3. The decision below disregarded the Act’s text to hold that any information “normally contained in” a state-regulated report is not PSWP. Pet. 16-18.⁶ The government purports to embrace this decision, Br. 10, but in fact interprets the statute much differently.

⁵ Worse still, the brief (at 5) relies on the *proposed* rule in suggesting HHS supported a separate PSWP system. The quoted text refers to identification, not segregation, of PSWP—and the Final Rule rejected duplicate systems.

⁶ The government agrees that *Tibbs’s in camera* review is “inconsistent with the [statute].” Br. 17. But this error jeopardizes, rather than protects, provider participation and confidentiality, *contra id.* at 17-18, by applying a subjective, ad hoc disclosure standard to any number of documents that could contain information “normally contained in” state-regulated records. Pet. 25-31.

Unlike the government, the court below did not rely on the “original provider record” exception. Nor did it impose a “sole-purpose” requirement. To the extent *Tibbs* relied on the statute at all, it pointed to § 299b-21(7)(B)(ii)’s “clarification” that PSWP “does not include information ... collected, maintained, or developed separately” from a PSES, Pet. App. 24a-25a, which is not part of the government’s argument, Br. 14. And of course the court could not rely on the subsequent Guidance that underlies the government’s position.

At the very least, the Court should grant, vacate, and remand for reconsideration in light of HHS’s new guidance. See *Lawrence v. Chater*, 516 U.S. 163, 166-67 (1996) (“We have GVR’d in light of ... administrative reinterpretations of federal statutes”). The Guidance’s ostensibly “controlling” analysis, Br. 13, turns on the provider’s “purpose” in preparing a document, 81 Fed. Reg. at 32,656. *Tibbs*, however, did not even consider this “critical factor.” *Id.*; compare Pet. App. 25a (asking whether regulations “separatel[y] mandated” the record), with 81 Fed. Reg. at 32,656 (asking why provider “originally prepare[d]” a “written report”). Petitioners are due at least a remand under this new landscape. See *Lawrence*, 516 U.S. at 167-68.

III. THIS COURT’S REVIEW IS TIMELY AND ESSENTIAL.

Notwithstanding the government’s extraordinary effort to evade this Court’s review, certiorari remains appropriate and necessary. The government’s brief, like Respondent’s, identified no vehicle problems (aside from that manufactured by HHS). And the government recognizes that disagreement among the lower courts has only increased since this petition was filed. *Southern Baptist Hospital of Florida v.*

Charles squarely rejected *Tibbs* and the view that documents cannot be privileged if they “may also be required under” a state rule. 178 So. 3d 102, 109 (Fla. Dist. Ct. App. 2015). The government’s position only deepens the divergence of interpretations between *Charles* and *Tibbs*, as the Guidance squarely conflicts with *Charles*’s interpretation of “original” records, “dual purpose” reporting, and the overlap between PSWP and state-regulated documents. *Id.* at 108-09.⁷ That “only a handful of reported decisions ... have addressed the Patient Safety Act,” Br. 19, simply confirms that opportunities to resolve this disagreement are rare; the issue is almost always litigated in discovery disputes in state trial courts, Pet. 32, where the theoretical possibility of “postjudgment appeals,” Br. 22, does not make the prospect of well-presented vehicles any more likely.

Likewise, the government hardly resists the notion that providers’ *voluntary* participation will be chilled by the enhanced risk of disclosure. Br. 18-19 (addressing *in camera* review, but not the drastically narrowed scope of the privilege). There is every reason to think *Tibbs*’s vague and cramped privilege inquiry will choke off providers’ willingness to share data that any state regulator or judge could decide is discoverable because it is “normally contained in” records required to be “maintained” under state law. Pet. 28-29, 31.

The Guidance merely amplifies this chilling effect. It does not “clarify” how to participate in the pro-

⁷ Contrary to the government’s position (at 20 n.8), *Lewis v. Upadhyay* likewise rejected the argument that the privilege does not apply to “information [used] to fulfill other reporting obligations,” relying (like *Charles*) on the *Tibbs* dissent and the Final Rule. 90 Va. Cir. 81, at *4 (2015).

gram—only the circumstances in which the privilege offers no protection. There can be no realistic expectation that providers will continue to participate, much less litigate against the government’s ostensibly “controlling” interpretation. As the *amicus* briefs demonstrate, healthcare providers relied on HHS’s Rule to protect their patient-safety activities. *E.g.*, AQIPS Br. 9. But if *Tibbs* and the Guidance stand, “providers will stop voluntarily submitting incident reports to patient safety evaluation systems and PSOs.” *Id.* at 18; see University HealthSystem PSO & American Medical Association Br. 15; American Hospital Association Br. 14-20. Unless the program is to die a quick, atextual death at the hands of Guidance promulgated without notice or comment, the time to grant is now—when the diametrically opposed interpretations of the government and the provider community are squarely presented.

CONCLUSION

The Court should grant plenary review or, at a minimum, summarily vacate and remand.

Respectfully submitted,

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