No. 15-1142

IN THE

# Supreme Court of the United States

WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES,

*Petitioner*,

v.

E.H. ET AL.,

*Respondents*.

On Petition for a Writ of Certiorari to the Supreme Court of Appeals of West Virginia

## BRIEF IN OPPOSITION

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## QUESTION PRESENTED

Whether the Health Insurance Portability and Accountability Act prohibits petitioner from disclosing patient health information to patient advocates at West Virginia's two state psychiatric hospitals under judicially and legislatively approved agreements designed to improve patient care in response to a history of neglect and abuse.

## TABLE OF CONTENTS

# TABLE OF AUTHORITIES

Page(s)

## Cases



## Statutes

**Rules and Regulations**

**Other Authorities**

## STATEMENT OF THE CASE

For over twenty-five years, petitioner West Virginia Department of Health and Human Resources (DHHR) agreed that independent patient advocates needed timely access to patients' medical information to protect the health and civil rights of seriously ill patients at West Virginia's two state psychiatric hospitals. This understanding was codified in state law and enforced by state-court orders. In 2014, DHHR abruptly cut off the advocates' access, maintaining that the federal Health Insurance Portability and Accountability Act (HIPAA) prohibits what state law expressly authorizes. A West Virginia circuit court disagreed and ordered DHHR to reinstate the advocates' access. The Supreme Court of Appeals of West Virginia affirmed, holding that HIPAA does not preempt the state law authorizing the patient advocacy program.

DHHR now seeks this Court's review on the ground that the preemption reasoning in the West Virginia Supreme Court of Appeals' opinion is incorrect. But "this Court reviews judgments, not opinions." *Chevron, U.S.A. Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984). Because the judgment of the Supreme Court of Appeals is plainly correct, albeit principally for reasons different from those given in its opinion, this case does not warrant review.

The West Virginia law at issue here is not preempted for two reasons. First, HIPAA expressly authorizes the kind of disclosure at issue here – release of patient health information to the patient advocates. Second, even if the state law permitting the disclosures were not affirmatively authorized by

HIPAA, the law would not be preempted because it falls within an exception to HIPAA's express preemption clause for "more stringent" state laws.

Moreover, this case is a poor vehicle for considering HIPAA's preemptive scope. West Virginia seeks a ruling here that its own law is invalid. But a state's quarrel with its own law is properly remedied by amending that law, not by a ruling from this Court. That is particularly true in this case, which presents only fact-bound questions unique to the patient advocacy program at West Virginia's two state psychiatric hospitals.

## I. Historical facts

This litigation began in 1981, when patients in West Virginia's state psychiatric hospitals petitioned the Supreme Court of Appeals of West Virginia under state law to remedy what that court called a "Dickensian Squalor of unconscionable magnitudes." *E.H. v. Matin*, 284 S.E.2d 232, 232-33 (W. Va. 1981) (citation omitted).

The court identified a litany of "bleak and squalid" conditions that violated West Virginia laws guaranteeing state psychiatric patients a basic standard of care and humane treatment. *Matin*, 284 S.E.2d at 234-38. Patients would "mill about aimlessly," with "a distinctive odor caused by patient incontinence" in the air. *Id.* Hospital staff, many of whom had no relevant training and displayed "a Kafkaesque lack of coordination," spent most of their shifts at a nurse's station "behind iron bars," generally interacting with patients only when they passed medication through a partitioned door. *Id.* at 234-36.

As a result of these illegalities, DHHR agreed to a plan for reform, part of which required DHHR to establish a patient advocacy program in the state's psychiatric hospitals. Pet. App. 4-5. Originally, the patient advocates were DHHR employees. *Id.* But in the late 1980s, after learning of "improper personal relationships between the patient advocates and the hospital administrators," a court-appointed monitor recommended that DHHR instead contract with external advocates. *Id.* 5. DHHR agreed and immediately contracted with Legal Aid of West Virginia to provide these advocacy services. *Id.* Legal Aid has occupied that role ever since.

The West Virginia legislature recognized the wisdom of this arrangement and codified it by legislative rule in 1995. Pet. App. 5; *see* W. Va. Code R. § 64-59-20.1 ("There shall be persons designated as client (or patient or resident) advocates who are independent of the facility management in every behavioral health facility."). This state law specified that "[n]o written consent is necessary" for the disclosure of patient health information to advocates in state-run mental health facilities. W. Va. Code R. § 64-59-11.5.1.d.

For the next twenty-four years, the patient advocates "assist[ed] with and investigate[d] individual grievances, conducte[d] abuse and neglect investigations, educate[d] staff and patients about patient civil rights," and otherwise strove to ensure that the hospitals were complying with state law. Pet. App. 5. Like the patient advocates DHHR had directly employed, Legal Aid advocates maintained offices inside the hospitals. DHHR also provided advocates with the access to patients and health

records necessary to fulfill their responsibilities. *Id.* 8.

In 2008, DHHR's ombudsman relied on "regular reports of grievances" from patients and their advocates to conclude that the hospitals had again fallen out of compliance, despite the advocates' efforts. *State ex rel. Matin v. Bloom*, 674 S.E.2d 240, 244 (W. Va. 2009). The circuit court that had monitored DHHR's compliance with judicial orders and state law held an evidentiary hearing, which confirmed the ombudsman's and patient advocates' allegations. Pet. App. 6-7.

The hospitals were miserably overcrowded. Tr. 117-121, *E.H. v. Matin*, Civil Action No. 81-MISC-585 (W. Va. Cir. Ct. Apr. 24, 2009). Patients lacked privacy. DHHR was housing three or more patients in rooms designed for two. Some patients were housed in common areas and visitor rooms. Patients suffered injuries as they fell over each others' cots; some lacked access to bathrooms. *Id.* DHHR unlawfully sedated patients with "chemical restraints." Pet. App. 6. Without testimony from the advocates, this information likely would never have come to light.

The parties agreed to a new court order detailing steps for compliance. Pet. App. 7-8. DHHR renewed its contract with the Legal Aid patient advocates and directed them to "create an assessment tool for the hospital audits necessary to enable the DHHR to comply with the [court-ordered] periodic review." *Id.* The advocates began to implement this new compliance regime. *Id.* 8.

Patient advocates thus continue to "serve patient needs in a variety of individual and systemic ways" at West Virginia's two state psychiatric facilities – the William R. Sharpe (Sharpe) and Mildred M. Bateman (Bateman) hospitals. Supreme Court of Appeals Appendix (WVaApp) 795. In addition to investigating individual grievances, patient advocates conduct systemic audits to monitor the hospitals' compliance with state law, ensure proper implementation of patients' treatment plans, and facilitate reports on hospital conditions. *Id.* 229-30, 253; Pet. App. 8. The advocates thus play an important role in helping DHHR comply with state law and court orders.

But in 2014, without notice, patients' access to their advocates changed suddenly. The advocates arrived at work to find their access to the facilities and patient information cut off. Without warning, DHHR had abruptly decided that the quarter-century old patient advocacy program violated the federal Health Insurance Portability and Accountability Act.

## II. The Health Insurance Portability and Accountability Act

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191, 110 Stat. 1936 (1996). Among other things, HIPAA directed the U.S. Department of Health and Human Services (HHS) to establish new requirements governing the use and disclosure of patients' protected health information (PHI).

Pursuant to this directive, HHS issued the HIPAA Privacy Rule, which serves three main purposes: to enhance patients' access to and control over their health information, to improve health care

quality, and to create standards for health privacy protection. 65 Fed. Reg. 82,462, 82,463 (Dec. 28, 2000).

The rule requires "covered entities," such as health care providers and health insurance plans, to follow certain requirements before using or disclosing PHI. 45 C.F.R. §§ 160.103, 164.506-08. It created a two-part regime governing when and how covered entities may use or disclose PHI.

First, patients typically give general consent for some uses and disclosures when they begin a relationship with a covered entity. *See* 45 C.F.R. § 164.506. This consent acknowledges the covered entity's right to use and disclose PHI for a wide variety of purposes broadly related to patient care, such as treatment, payment, and health care operations. *Id.* Patients at Sharpe and Bateman sign consent forms and receive notice of the hospitals' privacy practices during intake. WVaApp 777-88.[1]

Second, if a covered entity wishes to use or disclose PHI for purposes unrelated to patient care, such as for its own marketing and fundraising, it must obtain additional, specific written authorization from patients. 45 C.F.R. § 164.508(a).

Accordingly, whether a covered entity's use and disclosure of PHI complies with HIPAA may depend, as it does in this case, on whether the use or

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[1] HIPAA does not require written consent for use and disclosure of PHI for these purposes, but "a covered entity may obtain consent" from patients, 45 C.F.R. § 164.506(b)(1), as Sharpe and Bateman do.

disclosure falls within the Privacy Rule's provisions allowing use and disclosure related to patient care absent authorization, or whether instead it falls within the provisions requiring a specific authorization. Either way, HIPAA limits the disclosure of information to the "minimum necessary" to accomplish the purpose for which the information is disclosed. 45 C.F.R. § 164.502(b).

The Privacy Rule also expressly preempts any contrary state law unless the state law falls within a specific exception for "more stringent" state laws. 45 C.F.R. § 160.203(b).

## III. The current dispute

### A. Denial of access

Not a single patient or hospital employee has alleged that advocates have ever improperly used or disclosed patient information, and DHHR has found no evidence that advocates have ever done so. Pet. App. 15, 60. But as noted, in 2014, without prior notice and unprompted by any concern raised by either a patient or a patient's guardian, a newly-hired DHHR privacy officer revoked the advocates' access to patient records on the ground that this access violated HIPAA. This new officer had no expertise in HIPAA, did not investigate the advocates' responsibilities at Sharpe and Bateman, did not visit the hospitals, did not review DHHR's agreements with the court and court monitor, and did

not speak to a single advocate before terminating the advocates' access. *Id.* 8 n.11; WVaApp 206.[2]

Although the patients at Sharpe and Bateman had already consented upon admission to the general use and disclosure of their PHI, DHHR began requiring advocates to obtain additional authorizations from each patient. Pet. App. 8-9. The process for satisfying these new authorization requirements was demanding and lengthy. Before advocates could access any PHI they were required to obtain signatures from the patient, the patient's guardian, and (where applicable) the individual with the patient's power of attorney. *Id.* DHHR demanded that these releases state the specific reason for the disclosure and its connection to a particular patient grievance. *Id.*

DHHR also required the patients to complete a new authorization form – with an additional signature from a guardian and, where applicable, an individual with power of attorney – for each request for information, even if the request was filed one day after submission of the previous authorization, and even if the information request pertained to an ongoing investigation for which an authorization had already been completed. Pet. App. 8-9, 69. The trial

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[2] Though DHHR claimed that HIPAA required it to revoke the advocates' access, DHHR never notified either HHS or its own patients of its supposed years-long breach of federal law, as HIPAA would require. WVaApp 185; Pet. App. 71-72; *see also* 42 U.S.C. § 1320d-5(a)(1), (3) (ongoing failure of covered entity to report HIPAA violation exposes covered entity to state and federal enforcement actions with monetary liability).

court found that, in light of these new restrictions, "[a]buse and neglect allegations [were] not being properly or timely reported to the advocates." *Id.* 72-73.

DHHR also restricted the advocates' ability to work with patients and fulfill their mandate to ensure the hospitals' compliance with state law. WVaApp 256-57. DHHR prohibited the advocates from speaking with patients unless the patient specifically requested a meeting and signed the additional authorization form. Pet. App. 71; WVApp 190. This requirement created a Catch-22 for patients unable to fill out the necessary form themselves: advocates could not speak with patients until the paperwork was completed, but patients could not complete the paperwork without the advocates' help. This effectively suspended severely ill patients' right to file grievances. WVApp 180-81, 255; Pet. App. 73-74.

Even when patients were able to complete the new authorization process, DHHR still refused to provide advocates with timely access to patient records, instead forcing advocates to "wait up to 30 days to get the medical records" they needed. WVaApp 256. This imposed "a hardship on the [hospital] staff" and worsened existing staff shortages by "t[ying] up staff because they [had] to get the medical records . . . [and] get the releases." *Id.* 255-56.

Although patient advocates sign confidentiality agreements and receive the same formal HIPAA training as hospital staff, DHHR refused to allow the advocates to enter the patient wards unsupervised. WVaApp 180-82, 261. This new constraint alerted

DHHR to the content of ongoing investigations and prevented patients from speaking to their advocates confidentially. *Id.* 257, 259. The requirement of a staff escort made it nearly impossible for advocates to help patients because, in the words of one advocate, "patients trust us as advocates, they need us, they look up to us to help them, to protect them. And when we go on the unit with staff members, suddenly their trust starts to dissolve." *Id.* 254-55. In sum, as the trial court found, under the new restrictions, "advocates [could] no longer investigate whether a patient is being provided appropriate, quality care." Pet. App. 74.

DHHR also denied advocates access to records for court-mandated audits. WVaApp 236-37; Pet. App. 72-73. Without access to patient records, physical access to patients, and the ability to speak with patients in confidence, advocates could not do their jobs. WVApp 237-39.

No patient, relative, or guardian has expressed any support for these new rules. To the contrary, an entire ward of patients protested DHHR's actions. Pet. App. 74; WVaApp 262, 852. They demanded that DHHR restore the advocates' access to their records. WVApp 852. The patients "all agree[d] that [advocates] cannot perform their advocacy duties without the privilege to compare what is written pertaining to any and all formal complaints and issues." *Id.* They protested that "[a]dvocates are being hendered [sic] needlessly and the grievance process is not being completed quickly enough to protect patients from rights violations." *Id.* 853.

### B. This litigation

In response to respondents' emergency motion to restore advocate access, the circuit court held that HIPAA expressly authorizes the release of the relevant patient records to patient advocates. In a lengthy opinion, the court agreed with respondents that several provisions of the HIPPA Privacy Rule – concerning use of PHI by business associates and for health care operations and health care oversight – affirmatively and independently allow the disclosures at issue here. Pet. App. 77-83. It ordered DHHR to restore access. *Id.* 86.

The Supreme Court of Appeals of West Virginia affirmed. It first rejected DHHR's argument that the disclosures to the patient advocates violate patients' constitutional rights to privacy. Pet. App. 16. Turning to HIPAA and citing a state agency's preemption analysis, the court held that the West Virginia law establishing the patient advocate program is not preempted by HIPAA because its provisions are "more stringent than those required by federal law." *Id.* 28. The court rejected respondents' other arguments regarding the patient advocate program's consistency with HIPAA.

## REASONS FOR DENYING THE WRIT

Petitioner seeks this Court's intervention solely on the basis of error correction, going so far as to suggest the "rare and exceptional disposition" of summary reversal, Stephen M. Shapiro et al., *Supreme Court Practice* 351 (10th ed. 2013) (citation omitted). Far from meeting this Court's "clearly erroneous" standard for summary reversal, *id.* at 352,

the Supreme Court of Appeals' judgment is plainly correct. Review should be denied.

## I. The disclosure of protected health information to West Virginia's patient advocates complies with HIPAA.

The Privacy Rule does not preempt West Virginia's state law authorizing the disclosures for two reasons. First, as the West Virginia circuit court held, the disclosures do not conflict with HIPAA because the Privacy Rule itself expressly authorizes the types of disclosures at issue here. As with any preemption analysis, this ends the inquiry because there is no preemption when state law "do[es] not conflict with federal law." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 289 (1995). Second, even if HIPAA did not authorize the disclosures, the relevant state law is more stringent than the Privacy Rule's requirements and thus exempt from preemption under HIPAA itself.

### A. Four provisions of HIPAA's Privacy Rule each independently authorize the disclosure of health information to the patient advocates.

HIPAA expressly authorizes covered entities to disclose PHI without individualized patient authorization for any of several dozen, overlapping reasons aimed at enhancing the quality of patient care. Four of these reasons apply here. HIPAA authorizes disclosures to the advocates because advocates (1) use PHI for health care operations, (2) are business associates of the hospitals, (3) use PHI for health care oversight, and (4) receive PHI in the course of a judicial proceeding.

DHHR's petition ignores all of this. It asks this Court to grant certiorari and reverse without so much as considering the predicate preemption question whether state law conflicts with HIPAA in the first place. Eliding this predicate question would be improper. "Respondent[s] may, of course, defend the judgment below on any ground which the law and the record permit," *Smith v. Phillips*, 455 U.S. 209, 215 n.6 (1982) (citations omitted), including on reasoning accepted only by the trial court. *Id.* at 215.

### 1. Health care operations

The Privacy Rule recognizes that, to deliver the best care as efficiently as possible, modern health providers rely on networks of practitioners, specialists, administrators, and consultants – all of whom may need regular access to patient records to do their jobs. *See* 67 Fed. Reg. 14,776, 14,778 (Mar. 27, 2002). "[S]o as not to interfere with an individual's access to quality health care or efficient payment for such health care," the Privacy Rule "permit[s] these activities to occur with little or no restriction." *Id.*

HIPAA thus allows covered entities to disclose PHI as necessary to "carry out . . . health care operations" without individualized authorizations. 45 C.F.R. § 164.506(b)(1). Health care operations include all activities "compatible with and directly related to treatment and payment." 65 Fed. Reg. 82,462, 82,490 (Dec. 28, 2000) (internal quotation omitted). They exclude, in contrast, only activities unrelated to patient care, such as the covered entity's marketing and fundraising. *Id.* As long as an activity is among those enumerated in the regulatory definition of

"health care operations," *see* 45 C.F.R. § 164.501, a covered entity may disclose PHI as needed without any patient authorization.

Although many participants in health care operations are employees of a covered entity, some are not. Consistent with the Privacy Rule's broader purpose of promoting both quality care and patient privacy, "[d]isclosures for health care operations may be made to an entity that is neither a covered entity nor a business associate of the covered entity." 65 Fed. Reg. at 82,491.

Before it invoked HIPAA to cut off advocate access, DHHR agreed with the common-sense conclusion that patient advocates could receive PHI because they were involved in the hospitals' health care operations. WVaApp 785. That initial conclusion was correct.

**a. The patient advocates use PHI for four types of health care operations specifically enumerated in the Privacy Rule.**

Patient advocates perform four different types of health care operations for Sharpe and Bateman, each of which is separately identified in the Privacy Rule: quality assessment and improvement activities, resolution of internal grievances, patient safety activities, and auditing. 45 C.F.R. § 164.501.

*Quality assessment and improvement activities*. Quality assessment is a "process for ensuring compliance with specifications, requirements or standards and identifying indicators for performance monitoring and compliance with standards." Centers for Medicare and Medicaid Services, *Quality*

*Assessment and Performance Improvement Programs* 6 (Sept. 8, 2010), http://snip.li/Af9Ne. In psychiatric facilities, quality assessment activities monitor an organization's treatment of its patients, measured against accepted standards of care. West Virginia enshrines those standards in state regulations, which govern everything from the frequency of physical examinations to limits on the use of medications and chemical restraints to the size of hospital rooms. *See* W. Va. Code R. §§ 64-59-5 – 20. Through their resolution of patient grievances and use of systemic audits, patient advocates monitor the hospitals' compliance with these state-law standards. Pet. App. 6-8.

Improvement activities naturally refer to a covered entity's efforts to improve its patients' health outcomes, including in response to any deficiencies revealed by quality assessment. In working with DHHR to resolve patient grievances and improve hospital conditions based on the results of system-wide audits, patient advocates help Sharpe and Bateman improve patient health and safety.

*Resolution of internal grievances*. HIPAA authorizes disclosure to entities that participate in the "resolution of disputes from patients . . . regarding the quality of care and similar matters," 65 Fed. Reg. at 82,491; *see* 45 C.F.R. § 164.501. Authorizing disclosure to resolve grievances – one of the advocates' most important duties – comports with the regulatory approach of permitting disclosure to improve patient care. Addressing a patient's allegation of abuse or inadequate care can materially improve treatment quality in a way that marketing

or fundraising – the type of activities expressly excluded from "health care operations" – cannot.

The Supreme Court of Appeals did not recognize that patient advocates are part of internal grievance resolution, concluding instead that "internal grievances" means only grievances initiated within the walls of the covered entity. Pet. App. 24. This misreads the regulation. Given that the health care operations provision is principally concerned with promoting a high standard of patient care, "internal" must refer to a grievance's subject matter, not to its origin. Here, the patient advocates help resolve grievances about conditions of care within the state hospitals, making them entirely internal.

Even if the Supreme Court of Appeals were correct that health care operations cannot include resolution of "a grievance [initiated] by Legal Aid," Pet. App. 24, the health care operations provision would still permit disclosures because patient advocates do not initiate grievances for their own purposes. Instead, they act solely as the patients' agents. As DHHR acknowledges, the advocates "bring *patients'* grievances to the hospitals' attention upon *patient* request." Pet. 20 (emphases added). This confirms that patient advocates simply help the hospitals perform their overall function of providing patient care.

*Patient safety activities*. HIPAA permits disclosure for "[e]fforts to improve patient safety and the quality of health care delivery" carried out on behalf of the health provider. 42 C.F.R. § 3.20.

The patient advocates play a central role in protecting patient safety. Many patients are unable

to advocate for themselves or voice their concerns regarding threats to their safety. WVaApp 255. Advocates use PHI to uncover dangerous and negligent practices by investigating patient grievances and conducting system-wide audits.

*Auditing functions*. Health care operations cover "auditing functions, including fraud and abuse detection, and compliance programs." 45 C.F.R. § 164.501. As the original court order required, WVaApp 357, and as the circuit court's 2009 agreed order continues to require, *id.* 405, patient advocates use patient information to audit DHHR's compliance with state law and court orders regarding patient health and rights. For this reason as well, patient advocates are part of the hospitals' health care operations. Pet. App. 82.

**b. The Supreme Court of Appeals mistakenly concluded that the patient advocates can never conduct health care operations for DHHR.**

The Supreme Court of Appeals maintained that the health care operations provision does not encompass the disclosure of PHI to patient advocates on the ground that the advocates are "external to the facility" and not acting "on behalf of the facility." Pet. App. 24-25.

This understanding is mistaken. The health care operations provision authorizes disclosures to a host of contracted third parties who are "external to the facility." Even parties adverse to the covered entity's own interests may receive PHI to conduct health care operations, so these activities need not be "on behalf of the facility." These activities include:

*"Conducting or arranging for . . . legal services."* 45 C.F.R. § 164.501. Although some large covered entities employ in-house counsel, many rely on outside attorneys. And "arranging," defined as to "organize" or "ensure that (something) is done or provided," often refers to work done by others, and so does not refer only to work done by the covered entity itself. *Arrange*, *New Oxford American Dictionary* (1st ed. 2001). That is especially true here because the regulation offers "arranging for" legal services as an alternative to the more self-regarding "[c]onducting" legal services, connoting a difference between the two words.

*"Conducting . . . auditing functions."* 45 C.F.R. § 164.501. An audit is "an official inspection of an individual's or organization's accounts, typically by an *independent* body." *Audit*, *New Oxford American Dictionary* (1st ed. 2001) (emphasis added). The Supreme Court of Appeal's conclusion that "external audits . . . fall outside the scope of the facility's operations and thus the applicability of the exemption," Pet. App. 25, would bar any covered entity from conducting an independent audit using PHI – an illogical result given that much of an audit's credibility stems from its independence.[3]

*Disclosures "to an employee and/or employee representative" in resolving grievances.* 65 Fed. Reg. at 82,491. This type of disclosure occurs, "for

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[3] A range of other federal laws confirm this understanding by requiring independent outside audits of various entities. *See, e.g.*, 15 U.S.C. § 78m(a) (publically-held companies); 31 U.S.C. § 7502(c) (recipients of federal grants).

example[,] when the employee needs protected health information to demonstrate that the employer's allegations of improper conduct are untrue." *Id.* An employee's representative, who may have no relationship with the covered entity at all, does not act "at the direction of or on behalf of" the covered entity when she disputes charges made by the covered entity itself.

*"[A]ccreditation, certification, licensing, or credentialing."* 45 C.F.R. § 164.501. Every state requires medical providers to be accredited by an external board or licensing authority. *See* Am. Med. Ass'n, *State Medical Licensure Requirements and Statistics 2014* 162-65 (2014) (listing licensing authorities).[4]

The Supreme Court of Appeals did not consider the regulations' many examples of third parties who access PHI as part of health care operations. It relied instead on language in the regulatory comments – but nowhere in the regulation itself – stating that "health care operations are the listed activities *undertaken by*" the covered entity. Pet. App. 24 (quoting 65 Fed. Reg. at 82,490) (emphasis in original).

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[4] Sharpe and Bateman, for instance, both hold accreditations from the independent Joint Commission on Accreditation of Healthcare Organizations. Mildred Mitchell-Bateman Hospital, http://www.batemanhospital.org (last accessed June 27, 2016); William R. Sharpe, Jr. Hospital, http://www.dhhr.wv.gov/bhhf/facilities/WilliamRSharpeJrHospital/Pages/Sharpe.aspx (last accessed June 27, 2016).

This language does not help DHHR. "To undertake" reaches broadly to include "commit[ing] oneself to" something or "promis[ing] to do a particular thing." *Undertake*, *New Oxford American Dictionary* (1st ed. 2001). Accordingly, nothing prohibits DHHR from undertaking, or "committing to," various activities that qualify as health care operations by working with the patient advocates – just as when DHHR commits itself to certain objectives by disclosing PHI to an auditor, employee representative, or accreditor.

### 2. Business associate

"A covered entity may disclose protected health information to a business associate" without specific patient authorization. 45 C.F.R. § 164.502(e)(1). The "business associate" provision acknowledges that hospitals and other covered entities may need to disclose patient information to certain outside entities to run their businesses efficiently while caring for patients.

A "business associate" is a person or organization who, "[o]n behalf of [a] covered entity[,] . . . creates, receives, maintains, or transmits protected health information" for any number of purposes, including, as relevant here, "quality assurance [and] patient safety." 45 C.F.R. § 160.103. As DHHR expressly recognized for nearly a decade in its contract with Legal Aid, WVaApp 47-52, and as the trial court held, Pet. App. 78-80, patient advocates are the hospitals' business associates, as they receive and use health information for quality assurance and patient safety on behalf of West Virginia's state psychiatric hospitals.

Quality assurance refers to "the maintenance of a desired level of quality in a service or product, esp[ecially] by means of attention to every stage of the process." *Quality Assurance*, *New Oxford American Dictionary* (1st ed. 2001). Patient advocates' resolution of internal grievances and systemic audits are quality assurance activities. Through their work with hospital staff to resolve patient grievances, advocates act as a bridge between patients and hospital staff. *See* WVaApp 255. For example, advocates help staff resolve problems with patients' treatment plans or meet basic patient needs. *Id.* 253, 255. Patient advocates, using a process to which DHHR had agreed for years, conduct systemic audits to monitor the quality of the hospitals' patient care and respect for patient rights. WVaApp 47-52. These audits in turn shape both DHHR's and the court monitor's efforts to ensure that patients' care complies with West Virginia law. Pet. App. 6-7.

Patient advocates are also DHHR's business associates because they strive "to improve patient safety and the quality of health care delivery." 42 C.F.R. § 3.20. Patients in wheelchairs, for example, sought the advocates' help because they had fallen as a result of hospital overcrowding. Tr. 120, *E.H. v. Matin*, Civil Action No. 81-MISC-585 (W. Va. Cir. Ct. April 24, 2009). Advocates worked with hospital management to resolve the safety concerns revealed during these grievance investigations. Systemic audits conducted by advocates have similarly revealed patient safety concerns regarding the use of chemical restraints. Pet. App. 6, 67.

Business associates generally must use PHI "on behalf of" the covered entity that discloses it. 45 C.F.R. § 160.103. This limitation makes sense because the business associate provision was not meant to allow outside entities to use patient information for their *own* interests but rather "in the interests of" the covered entity. *See New Oxford American Dictionary* (1st ed. 2001) (defining "on behalf of" as meaning "in the interests of a person, group, or principle").

Patient advocates advance Sharpe's and Bateman's interests, and thus act on behalf of the hospitals, by helping hospital staff implement treatment plans for patients. WVaApp 253. Advocates act as a bridge between treatment staff and patients, who often "can't speak for themselves." *Id.* 255. They help staff communicate to patients details of their treatment plans and help patients communicate with staff when they are concerned about their care. *See id.* 253-56.

Patient advocates likewise advance the hospitals' interests (and thus act on the hospitals' behalf) simply by acting in patients' interests. That is because, in the circumstances here, the interest of the hospitals and the interest of their patients are identical: the hospitals' sole overarching mission as state psychiatric hospitals is to serve the needs of vulnerable West Virginia psychiatric patients.

In this regard, recall that the hospitals themselves conducted these same activities with internal patient advocates until 1990, when DHHR agreed that it was essential to contract with an outside entity. Pet. App. 4-5. No one could sensibly dispute that by acting in the patients' interests, the

pre-1990 internal advocates also acted in the hospitals' interests. So, too, with the patient advocates today.

The Supreme Court of Appeals believed that advocates had an adverse relationship with the hospitals and thus could not be business associates. Pet. App. 20. This misperceives the relationship between advocates and the hospitals. Advocates and hospitals are not adverse to each other because, as noted, patient advocates help hospital staff communicate with and more effectively treat patients. WVaApp 255. Indeed, patient advocates now – just as they did when they were DHHR employees prior to 1990 – help DHHR comply with state law and protect patient rights, core interests of state hospitals.[5]

### 3. Health care oversight

"A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law" without specific patient authorization. 45 C.F.R. § 164.512(d). A "health oversight agency" is a public "agency or authority . . . *or a person or entity acting under grant of authority*

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[5] A business associate may have some measure of temporary adversity with a covered entity so long as it acts in the long run to further the covered entity's interests. That is why external auditors, who often have some temporary adversity with the audited entity, may nevertheless be business associates. *See* 67 Fed. Reg. 53,182, 53,203 (Aug. 14, 2002); *see also* 65 Fed. Reg. at 82,490. The same is true of patient advocates who act in the state hospitals' interests under a business associate contract.

*from or contract with such public agency* . . . that is authorized by law to oversee the health care system." 45 C.F.R. § 164.501 (emphasis added).

Legal Aid, which provides the patient advocacy services here, is an "entity acting under . . . contract" with DHHR, a public agency. Pet. App. 30. As the Supreme Court of Appeals held, Legal Aid operates in Sharpe and Bateman based on a written contract with DHHR "that specifies the legal obligations of the parties, including the manner of payment and the duties associated with the provision of patient advocacy services." *Id.*; *see also* WVaApp 8-54 (contract between DHHR and Legal Aid).

Oversight activities include "oversight of health care providers," "oversight of health care and health care delivery," and "oversight activities that involve resolution of consumer complaints." 65 Fed. Reg. at 82,492. The patient advocates provide system-wide oversight of West Virginia's psychiatric care system. DHHR contracted with Legal Aid to "[p]rovide advocacy, including legal representation to achieve *system* improvement, outreach, training, and direct individual assistance *statewide*." WVaApp 27 (emphases added). The contract thus envisions a role for Legal Aid in providing statewide, systemic oversight of psychiatric care. *Id.* And this has been its role in practice. Legal Aid's 2008 audits of West Virginia's only two state psychiatric hospitals revealed deplorable conditions, resulting in the reopening of this litigation. *See* Pet. App. 5.

Legal Aid's patient advocates also fall within the health care oversight provision because they investigate and work toward the "resolution of consumer complaints," 65 Fed. Reg. at 82,492.

DHHR's contract with Legal Aid itself requires that advocates "[i]nvestigate *complaints*, including allegations of abuse or neglect, made by *consumers* of behavioral health services." WVaApp 27 (emphases added).

These oversight activities are "authorized by law," as the regulation requires. *See* 45 C.F.R. § 164.501. Court orders require the advocates to conduct various types of health oversight activities, including investigating grievances and conducting audits. The West Virginia legislature has also authorized the advocates to carry out these activities. State law requires that independent advocates be placed in state psychiatric facilities to protect patient rights and health. W. Va. Code R. § 64-59-20.1. And when the state legislature passed these regulations, Legal Aid was the independent organization responsible for patient advocacy. The legislature thus intended that these patient advocates would conduct the patient advocacy and oversight activities required by West Virginia law.

The Supreme Court of Appeals concluded that Legal Aid's patient advocates are not authorized to conduct health oversight activities in part because Legal Aid does not resemble a government organization like HHS's Office of Civil Rights. Pet. App. 22. As the trial court understood in holding that the patient advocates conduct health care oversight, Pet. App. 81, this misreads the Privacy Rule. Because Legal Aid is an "entity acting under . . . contract with such public agency [DHHR]," 45 C.F.R. § 164.501, it can be a health oversight agency.

### 4. Judicial proceedings

"A covered entity may disclose protected health information in the course of any judicial or administrative proceeding . . . [i]n response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order." 45 C.F.R. § 164.512(e)(1)(i). This section applies to a "broad spectrum of judicial and administrative procedures." 64 Fed. Reg. 59,918, 59,959 (Nov. 3, 1999).

A court order "expressly authorized" DHHR to provide PHI to patient advocates. The 2009 West Virginia circuit court order required DHHR to comply with state law governing treatment of psychiatric patients and provided for periodic review. WVaApp 405. As the circuit court then held, part of the relevant state law expressly authorizes disclosure of patient PHI to patient advocates. Pet. App. 75-76, 86; *see* W. Va. Code R. 64-59-11.5.1.d. The court order therefore incorporates the legislative authorization for PHI disclosure.

And the 2009 court order was issued "in the course of a judicial proceeding." Orders issued in the course of a judicial proceeding include all orders issued "while a case is pending in a judicial forum." *State ex rel. Proctor v. Messina*, 320 S.W.3d 145, 156 (Mo. 2010) (en banc) (discussing HIPAA's "judicial proceeding" provision). The 2009 circuit court order satisfies this definition because it was issued as part of ongoing litigation involving DHHR's compliance with its state-law obligations to provide adequate care to West Virginia's psychiatric patients.

The Supreme Court of Appeals disagreed on the ground that "a ruling that seeks to broadly sanction disclosure not expressly linked to a specific judicial or administrative matter falls outside the framework of the HIPAA exemption which permits disclosure pursuant to judicial authorization." This is incorrect. Pet. App. 26-27. The court-ordered disclosures here *were* "expressly linked" to the 2009 judicial proceedings, as noted above. And the breadth of disclosure is not relevant – no such limitation appears in the regulation's text. So long as a disclosure is made in response to a court order in a judicial proceeding, and otherwise complies with HIPAA's requirement that only the minimum necessary PHI be disclosed, 45 C.F.R. § 164.502(b), the judicial proceedings provision authorizes a covered entity to disclose the PHI.

### B. West Virginia state law is more stringent than HIPAA in protecting state hospital patients' rights of control over their own health information.

Even if HIPAA did not expressly allow the disclosures at issue here – and, as explained above, it does – HIPAA would not preempt the relevant West Virginia state law. HIPAA exempts from preemption any state law that is "more stringent" than HIPAA. 45 C.F.R. § 160.203. Often, "more stringent" state laws are those that prohibit a disclosure that HIPAA allows. But given the circumstances here, disclosing less information would not constitute a "more stringent" regime. To the contrary, the preexisting West Virginia law providing for disclosure of PHI to patient advocates provides more stringent protection because it provides patients with greater access to

their own health information and better enables patients to protect their rights.

This is so because "more stringent" is a comparative term that must be construed in light of the Privacy Rule's central purposes: to "protect and enhance the rights of consumers by providing them access to their health information" and to prevent inappropriate use of that information. 65 Fed. Reg. 82,462, 82,463 (Dec. 28, 2000).

To determine whether a state law is more stringent, HIPAA demands a comparison between the two statutes' context-specific, relevant provisions of federal and state law. *See*, 64 Fed. Reg. 59,918, 59,997 (Nov. 3, 1999); *see generally* Beverly Cohen, *Reconciling the HIPAA Privacy Rule with State Laws Regulating Ex Parte Interviews of Plaintiffs' Treating Physicians: A Guide to Performing HIPAA Preemption Analysis*, 43 Hous. L. Rev. 1091, 1133-34 (2006). "[E]very [] court to consider HIPAA preemption has held that 'more stringent' means 'laws that afford patients more control over their medical records." Pet. 40 (collecting cases). Consistent with this view, West Virginia state law is more stringent because it "permits [individuals] greater rights of access," 45 C.F.R. § 160.202, to their own protected health information (PHI), thereby "protect[ing] and enhanc[ing] the rights of consumers," 65 Fed. Reg. at 82,463.[6]

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[6] The cases cited by petitioner regarding HIPAA's preemption of state law are inapposite because they concern the meaning of "more stringent" in other contexts, not with respect to psychiatric patients' access to their own PHI. *See* Pet. 40.

Given the circumstances of severely mentally ill patients at Sharpe and Bateman, patients can achieve "more control" over their health information only with the assistance of advocates, who effectively act as their agents. Patients with difficulty reading or comprehending medical records require advocates' support in interpreting and making decisions regarding their health information.

That the advocates help patients control their own health care is driven home by the patients' own actions. When DHHR denied advocates access to patients' medical records, patients at Sharpe and Bateman formally demanded that the advocates' access be restored. WVaApp 262; *see supra* at 10.

On the other hand, the holding that DHHR seeks here – that HIPAA prevents the disclosure of PHI to patient advocates – would result in DHHR denying patients control over their own care by entirely cutting off the advocacy services patients need, which, as the trial court found, is exactly what happened when DHHR abruptly curtailed advocates' access to PHI. Pet. App. 72-74. That would give DHHR, not patients, access to the "greater amount of [health] information" – undermining patients' access to their own PHI and HIPAA's purposes. 45 C.F.R. § 160.202.

## II. This case is a poor vehicle for examining the scope of the HIPAA Privacy Rule or general preemption principles.

### A. This Court should not intervene to resolve an intra-state policy dispute.

One would expect that if a covered entity had violated the Privacy Rule the victims of the violation,

and not the covered entity itself, would be the ones complaining. But not one of the three hundred or so psychiatric patients under DHHR's care has ever objected to the patient advocates' access to PHI. Pet. App. 15, 60. On the contrary, patients oppose DHHR's actions in restricting that access. *See supra* at 10.

DHHR thus seeks to evade the general principle that "a litigant must assert his or her own legal rights and interests, and cannot rest a claim to relief on the legal rights or interests of third parties," *Powers v. Ohio*, 499 U.S. 400, 410 (1991). This attempt at "adjudication of rights which those not before the Court may not wish to assert" cannot provide "assurance that the most effective advocate of the rights at issue is present to champion them." *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 16 n.7 (2004) (quoting *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 80 (1978)). That HIPAA is designed to protect patients, not covered entities, underscores the unsuitability of this case's adversarial posture for this Court's review.

Stranger yet, West Virginia itself cannot agree on the proper role of patient advocates. West Virginia's legislature and judiciary both authorize the patient advocates' access to PHI. One state agency, the West Virginia Health Care Authority, concurs with the legislature and the judiciary. Pet. 21-22. Another, DHHR, suddenly does not. It is hardly appropriate after state court review to deploy the authority of this Court to resolve an internecine policy dispute among the branches of a single state's government. And it is less appropriate still where the state (and no one else) is seeking protection from itself by asserting

that its own state law – which presumably West Virginia could amend – is federally preempted.

### B. If this Court wishes to consider the meaning of the Privacy Rule, it should wait for a case that presents generally applicable legal issues, unencumbered by complex and case-specific concerns.

To consider in this case whether HIPAA preempts disclosures to the patient advocates, this Court would first have to confront a range of complicated factual issues to answer the predicate question whether HIPAA authorizes the disclosures. *See supra* at 12-27. To reach the result petitioner seeks – reversal of the Supreme Court of Appeals' judgment in this case – this Court would have to evaluate the degree to which the patient advocates access PHI for *every* type of advocacy they perform – filing of individual grievances, abuse investigations, systemic auditing, ongoing compliance monitoring, and so on – with regard to *each* of the Privacy Rule's complex provisions discussed above. In short, review should be denied because this case does not present the clean, cut-and-dried preemption question that DHHR posits.

* * *

DHHR seeks from this Court a holding that the rights of patients at West Virginia's state hospitals are being violated by the patients' own advocates. The Supreme Court of Appeals of West Virginia disagrees. The West Virginia state legislature disagrees. The West Virginia Health Care Authority disagrees. The advocates disagree. And, most importantly of all, the patients disagree. This Court

should reject DHHR's effort to inject this Court into this lopsided intra-state dispute.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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