No. 15-274

In the Supreme Court of the United States

WHOLE WOMAN'S HEALTH, *et al.*,
Petitioners,
v.
JOHN HELLERSTEDT, M.D., COMMISSIONER OF THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, INC. IN SUPPORT OF RESPONDENTS

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INTRODUCTION AND INTERESTS OF *AMICUS CURIAE*[1]

This case involves a constitutional challenge to medical regulations that enhance the safety of one of the most common outpatient procedures in the United States. Like several other states, Texas requires (1) that outpatient abortion clinics meet safety standards for ambulatory surgical centers, and (2) that physicians performing abortions can admit patients to a hospital in the event of complications. Although lower courts have repeatedly found these kinds of regulations medically reasonable, the theme of petitioners and their *amici* is that they are nothing more than a pretext designed to shut down abortion altogether. That is quite mistaken. From a medical standpoint, it is perfectly reasonable to require outpatient abortion providers to meet the standards at issue here.

Whatever view one takes of abortion, one can hardly deny that it is a common outpatient surgical procedure. Ambulatory surgical center regulations maximize the safety of patients who undergo all kinds of outpatient procedures, including abortion, something that Medicare regulations squarely recognize. And however "safe" one thinks abortion is, one can hardly deny that it carries well-recognized risks that sometimes require admitting women to a hospital. By ensuring providers can do so, states maximize the likelihood that women with potentially life-threatening complications get prompt and effective care. Not long ago, numerous

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[1] Pursuant to Supreme Court Rule 37.6, no counsel for any party authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for petitioners and respondents have consented to the filing of this brief.

medical organizations—including the American Medical Association—agreed that requiring outpatient surgical providers to have admitting privileges was a core principle of sound medicine. While some of those organizations apparently now make an exception for abortion, there is no medical reason to do so.

Amicus curiae Association of American Physicians & Surgeons, Inc. ("AAPS") is a not-for-profit membership organization incorporated under the laws of Indiana and headquartered in Tucson, Arizona. AAPS members include thousands of physicians nationwide in all practices and specialties. AAPS was founded in 1943 to preserve the practice of private medicine, ethical medicine, and the patient-physician relationship. In addition to participating at the legislative and administrative levels in national, state, and local debates on health issues, AAPS also participates in litigation, both as a party,[2] and as an *amicus curiae*.[3] AAPS *amicus* briefs have been cited by this Court. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *District of Columbia v. Heller*, 554 U.S. 570, 703 (2008) (Breyer, Stevens, Souter and Ginsburg, JJ., dissenting).

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[2] *See, e.g., Ass'n of Am. Physicians & Surgeons v. Sebelius*, 113 A.F.T.R.2d (RIA) 1196 (D.C. Cir. 2014); *Ass'n of Am. Physicians & Surgeons v. Clinton*, 997 F.2d 898 (D.C. Cir. 1993).

[3] *See, e.g., Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006) (citing and relying on AAPS argument); *United States v. Rutgard*, 116 F.3d 1270, 1275 (9th Cir. 1997) (noting AAPS as *amicus curiae*).

STATEMENT

In 2013, Texas enacted House Bill 2 ("HB2") to strengthen the safety regulations that apply to outpatient abortion facilities. Two aspects of that law are relevant here. First, HB2 requires that abortion facilities meet standards equivalent to those governing ambulatory surgical centers ("ASCs"). TEX. HEALTH & SAFETY CODE § 245.010(a); 25 TEX. ADMIN. CODE § 139.40, 38 TEX. REG. 9577, 9577-93. Second, HB2 requires that abortion providers have "active admitting privileges" at a hospital within thirty miles from where they provide abortions. TEX. HEALTH & SAFETY CODE § 171.0031(a)(1)(A).

In two separate lawsuits, Texas abortion clinics challenged HB2 as imposing an undue burden under *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). In the first case, the U.S. Fifth Circuit rejected a facial challenge to the privileges requirement. *See Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 748 F.3d 583 (5th Cir. 2014) (*Abbott*). The court found that requirement medically reasonable because the evidence "easily supplied a connection between the . . . rule and the desirable protection of abortion patients' health." *Id.* at 594. In the second case, the Fifth Circuit rejected in large part facial and as-applied challenges to the ASC and privileges requirements. *See Whole Woman's Health v. Cole*, 790 F.3d 563 (5th Cir. 2015), *cert. granted*, 136 S. Ct. 499 (U.S. Nov. 13, 2015) (Mem.). The court affirmed the district court's conclusion that both requirements were "rationally related to a legitimate state interest" and that Texas had "supported the medical basis for both requirements

with evidence at trial." *Id.* at 584. That second decision is now before this Court.

SUMMARY OF ARGUMENT

By requiring outpatient abortion providers to meet ASC and admitting privileges requirements, Texas is on solid medical ground. The Court should defer to the judgment of the Texas legislature that these requirements will protect the health and safety of women who choose to seek an abortion.

1. ASCs are outpatient surgical facilities regulated by state, federal, and private accrediting bodies to improve the quality and safety of patient care. A wide range of outpatient procedures of varying risk and complexity takes place in ASCs. Abortion, which is one of the most common outpatient surgical procedures in the United States, falls squarely within the kinds of procedures that typically occur in ASCs.

Moreover, ASC regulations address precisely the kinds of quality control and patient safety issues presented by abortion. The notion that it is medically unreasonable to require abortion providers to meet ASC standards is unfounded. One need look no further than the federal Medicare system, which approves for reimbursement abortion and other similar gynecological procedures when performed in ASCs.

2. Admitting privileges refer to a physician's ability to admit patients to a hospital for treatment. If an outpatient surgical provider has privileges, she is in a better position to ensure prompt and effective care for her patients who experience complications. Moreover, a physician privileged to admit patients is thoroughly vetted for competence and ethical integrity. Thus, it

makes medical sense to require any outpatient surgical provider to be able to admit patients at a local hospital.

Numerous medical organizations have endorsed this principle for all forms of outpatient surgery, and there is no medical reason to exempt abortion from that consensus. A woman whose abortion provider has privileges is more likely to receive prompt care in the event she experiences a complication. If that complication is excessive hemorrhaging, or a perforated uterus, or a missed ectopic pregnancy, then ensuring her rapid and effective treatment in a hospital may mean the difference between life and death.

3. As a general matter, this Court's precedents strongly defer to the kind of medical regulations represented by the Texas law at issue here. That principle of deference holds true in the abortion context as well. In numerous cases, the Court has deferred to legislative judgments about the licensing of outpatient abortion facilities, the qualifications of abortion providers, and the ethics and integrity of the abortion procedure. Petitioners' argument in this case would undermine all of those precedents by asking the Court to weigh the medical wisdom of abortion regulations. They would require this Court to put aside its judicial robes and assume the duties of a national medical board. The Court should decline that invitation, which would roll back abortion jurisprudence to the days before *Casey*.

ARGUMENT

I. It is medically reasonable to require outpatient abortion providers to abide by ASC and admitting privileges requirements.

Contrary to the arguments of petitioners and their *amici*, HB2 imposes medically reasonable safety measures that enhance the safety of a common outpatient procedure and reinforce the competence and integrity of the physicians who perform it.

A. ASC Requirements

1. *ASC regulations enhance patient safety for an array of outpatient procedures.*

An ASC refers to a health care facility that provides diagnostic and preventive procedures that do not typically require hospitalization. As the Ambulatory Surgical Center Association explains, ASCs are "modern health care facilities focused on providing same-day surgical care including diagnostic and preventive procedures."[4] The federal government, which certifies ASCs through Medicare, provides a similar definition: an ASC is "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission." 42 C.F.R. § 416.2.[5]

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[4] *What is an ASC?,* AMBULATORY SURGICAL CENTER ASSOCIATION ("ASCA"), http://www.advancingsurgicalcare.com/whatisanasc (last visited Jan. 21, 2016).

[5] See also, *e.g.*, *Ambulatory Surgery in the United States, 2006*, NATIONAL HEALTH STATISTICS REPORTS (Centers for Disease

ASCs began to develop in the 1970s as a more convenient, cost-effective, and safer alternative to hospital-based surgery.[6] Over the past four decades ASCs have grown exponentially: one report estimates that in 2009 there were over 5,000 Medicare-certified ASCs operating around the country, accounting for about 6 million of Medicare's total volume of procedures, employing about 117,700 full-time workers, with an economic impact of some $90 billion.[7] A report from the federal Centers for Disease Control estimates that, in 2006, 14.9 million surgical and nonsurgical procedures took place in ASCs. NHS Report at 1, 5.

A wide range of procedures of varying risk and complexity are provided in ASCs. For instance, a 2010 analysis of federal CMS claims data reported ASC procedures in the fields of gastroenterology (31% of

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Control and Prevention Sept. 4, 2009) ("NHS Report") at 1 (defining "ambulatory surgery" as "surgical and nonsurgical procedures performed on an ambulatory (outpatient) basis" in a variety of settings, including a "freestanding center's general operating rooms, dedicated ambulatory surgery rooms, and other specialized rooms, such as endoscopy units and cardiac catheterization laboratories"), http://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf.

[6] See *Ambulatory Surgical Centers: A Positive Trend in Health Care* at 1, AMBULATORY SURGICAL CENTER ASSOCIATION ("*Positive Trend*"), http://www.ascassociation.org/advancingsurgicalcare/aboutascs/industryoverview/apositivetrendinhealthcare (last visited Jan. 21, 2016); *see also* NHS Report at 2 (noting "[a]mbulatory surgery has been increasing in the United States since the early 1980s").

[7] *Positive Trend* at 1 (citing CENTERS FOR MEDICARE & MEDICAID SERVICES ("CMS"), MEDICARE CLAIMS DATA 2005-2010; OXFORD OUTCOMES ASC IMPACT ANALYSIS 2010).

Medicare case volume), ophthalmology (28%), pain management (22%), orthopedics (8%), and dermatology (4%). *Positive Trend* at 3 (citing CMS Claims Data 2010). A 2006 survey reported a similar variety of ASC procedures, including significant numbers of gastroenterological, orthopedic, urologic, gynecological, ophthalmologic, and diagnostic procedures. *See* NHS Report at 6, 16-17 (Table 6); 18-20 (Table 7).[8] Additionally, CMS publishes a comprehensive list of "covered surgical procedures" certified as reimbursable under Medicare when performed in an ASC. See 42 C.F.R. § 416.65 (standards for covered procedures); 71 Fed. Reg. 68226, 68231-68384 (Addenda) (Nov. 26, 2006) (listing covered ASC procedures). The vast array of covered procedures varies widely in complexity and risk. Compare, *e.g.,* 71 Fed. Reg. at 68249 ("Treat spine fracture"); *id.* at 68259 ("Amputation of foot at ankle"), with *id.* at 68231 ("Smoking Cessation Services"); *id.* at 68235 ("Allergy Tests").

To enhance patient safety, ASCs are licensed by states, certified by the federal government, and accredited by private accrediting bodies.[9] *See, e.g.,* 42

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[8] Specialists who commonly utilize ASC facilities include ENTs, general surgeons, OB/GYNs, oral surgeons, plastic surgeons and podiatrists. See *Establishing and Ambulatory Surgery Center: A Primer from A to Z*, BECKERSASC.COM, http://www.beckersasc.com /news-analysis/establishing-an-ambulatory-surgery-center-a-primer-from-a-to-z.html (last visited Jan. 27, 2016).

[9] See, *e.g., Positive Trend* at 4 (noting "[t]he safety and quality of [ASC] care" evaluated by "state licensure, Medicare certification and voluntary accreditation"). The principal accrediting bodies are the Joint Commission, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for

C.F.R. § 416.1(b)(1) (listing "[t]he conditions that an ASC must meet in order to participate in the Medicare program"). Regulatory requirements generally address topics such as governance,[10] quality assessment,[11] physical environment,[12] staff privileges,[13] personnel records,[14] nursing,[15] recordkeeping,[16] pharmaceutical

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the Accreditation of Ambulatory Surgical Facilities (AAAASF), and the American Osteopathic Association (AOA). *Id.*

[10] See, *e.g.,* 42 C.F.R. § 416.41 (requiring ASC to "have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies"); WASH. ADMIN. CODE § 246-330-115 (same).

[11] See, *e.g.,* 42 C.F.R. § 416.43 (requiring ASC to implement "an ongoing, data-driven quality assessment and performance improvement . . . program"); ALA. ADMIN. CODE REG. 420-5-2-.02(2)(d) (requiring ASC to "seek consultation . . . for the improvement of efficiency of operation and the quality of patient care").

[12] See, *e.g.,* 42 C.F.R. § 416.44(a)(1) (requiring operating rooms to be "designed and equipped" so that surgery can be performed "in a manner that protects the lives and assures the physical safety of all individuals in the area"); *id.* § 416.44(a)(2) (requiring "a separate recovery room and waiting area") UTAH ADMIN. CODE REG. 432-500-18(4)(c) (listing required equipment for "operating suite").

[13] See, *e.g.,* 42 C.F.R. § 416.45(a) (requiring "legally and professionally qualified" staff and privileges "in accordance with recommendations from qualified medical personnel"); ch. 5 WYO GOV'T REG. HEALTH HQ § 6(a)(x) (requiring "[m]edical and nursing staff [to] be licensed, certified, or registered").

[14] See, *e.g.,* NEV. ADMIN. CODE § 449.9855 (ASC must "maintain employee health records"); ch. 5 WYO GOV'T REG. HEALTH HQ § 4(e) (ASC governing body controls personnel policy).

[15] See, *e.g.,* 42 C.F.R. § 416.46 (registered nurse must be "available for emergency treatment"); ALA. ADMIN. CODE REG. 420-5-2-

and laboratory services,[17] radiology services,[18] patient rights,[19] infection control,[20] and patient assessment.[21]

The Texas ASC regulations at issue in this case cover the same range of topics.[22] These kinds of

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.02(3)(e)(1)(i) (operating room personnel must include "at least one . . . registered professional nurse").

[16] See, *e.g.,* 42 C.F.R. § 416.47 (requiring "a system for the proper collection, storage, and use of patient records"); ALA. ADMIN. CODE REG. 420-5-2-.02(6)(a) (requiring ASCs to "keep adequate records").

[17] See, *e.g.,* 42 C.F.R. § 416.48(a) (requiring that "[d]rugs must be prepared and administered according to established policies and acceptable standards of practice"); UTAH ADMIN. CODE REG. 432-500-19 (regulating pharmacy service).

[18] See, *e.g.,* UTAH ADMIN. CODE REG. 432-500-21 (listing requirements for radiation services); 42 25 MISS. CODE REG. § 1 (requiring a radiology technician be employed if services offered).

[19] See, *e.g.,* 42 C.F.R. § 416.50(a)-(g) (requiring notice to patient concerning physician's financial interests, advance directives, grievance procedures, anti-discrimination rights, informed consent, privacy, and safety); 42 17 MISS. CODE REG. § 5 (requiring record of patient consent).

[20] See, *e.g.,* 42 C.F.R. § 416.51(b) (requiring "an ongoing program designed to prevent, control, and investigate infections and communicable diseases"); 42 18 MISS. CODE REG. § 8 (requiring written policy on infection control).

[21] See, *e.g.,* 42 C.F.R. § 416.52 (requiring standards for "appropriate pre-surgical and post-surgical assessments"); ALA. ADMIN. CODE REG. 420-5-2-.04(4)(d), (e) (requiring recovery rooms and, if patients admitted for more than twelve hours, observation rooms).

[22] See 25 TEX. ADMIN. CODE §§ 135.1-.29 (addressing operating requirements, such as patient rights, personnel, medical records, physical environment, anesthesia, radiology, drug and laboratory

regulations seek to "ensure that the facility is operated in a manner that assures the safety of patients and the quality of services." *Positive Trend* at 5.

2. *It is medically reasonable to require outpatient abortion clinics to meet ASC standards.*

In insisting that outpatient abortion facilities met ASC standards, states are on solid medical ground.

1. For decades, induced abortion has been a common outpatient surgical procedure in the United States. The Guttmacher Institute reports that, in 2011 alone, 1.06 million abortions were performed in the United States, and that from 1973 through 2011, "nearly 53 million legal abortions occurred." GUTTMACHER INSTITUTE, FACT SHEET (July 2014) (citing Jones RK and Jerman J, "Abortion incidence and service availability in the United States, 2011," *Perspectives on Sexual and Reproductive Health*, 2014, 46(1):3-14) ("Jones"). The overwhelming majority of those abortions occurred in outpatient settings. See, *e.g.,* Jones, at 8, Table 3 (reporting that 94% of abortions in 2011 occurred either in abortion clinics or "other clinics"). And despite the availability of medication abortions (which, as noted below, carry their own risks), over 75% of abortions involve a surgical procedure. See, *e.g.,* Jones, at 8 (reporting that "early medication abortion" accounted for 23% of all nonhospital abortions in 2011).

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protocols, and inspections); *id.* at §§ 135.31-.43 (addressing fire prevention and safety requirements); *id.* at §§ 135.51-.56 (addressing physical plant, ventilation, and construction).

Abortion involves well-recognized patient risks, which are described by the National Abortion Federation's 2015 Clinical Policy Guidelines. See NATIONAL ABORTION FEDERATION, 2015 CLINICAL POLICY GUIDELINES ("NAF Guidelines"), http://prochoice.org/wp-content/uploads/2015_NAF_CPGs.pdf. Risks include:

- infection (NAF Guidelines 4-8)
- missed ectopic pregnancy (*id.* at 20-22)
- risks and side-effects of anesthesia (*id.* at 31-37)
- incomplete abortion (*id.* at 40)
- excessive bleeding (*id.* at 43)
- uterine perforation (*id.* at 45-46).

The NAF Guidelines also advise that early medical abortion involves the risk of "excessive bleeding and infection," and the possibility of an incomplete abortion requiring uterine aspiration. *Id.* at 13 (6.2, 6.4). Finally, the Guidelines require abortion providers to inform patients of these risks and to provide emergency protocols for addressing them—protocols that may involve a patient's transfer and admission to a hospital. *Id.* at 21, 24, 28, 42, 45 (noting various concerns to be taken into account during a transfer).

ASC regulations target precisely the kinds of potential complications involved in outpatient abortion. As described above, ASC regulations commonly address matters such as infection control, quality assessment, anesthesia and laboratory protocols, informed consent, and patient monitoring, discharge, and follow-up. ASC regulations also require specific emergency protocols to respond to potential complications. See*, e.g.,* 42 C.F.R.

§ 416.41 (requiring ASC to "have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC"). More broadly, ASC regulations ensure that physicians performing surgical procedures are credentialed and qualified, are properly supervising facility employees, and are appropriately monitoring patients. See generally *supra* I.A.1.

It should thus be beyond dispute that it is reasonable to require outpatient abortion facilities to abide by ASC regulations. After all, it is common ground that abortion in most cases involves a surgical procedure, that abortions occur in large numbers in outpatient settings, and that abortion (including medication abortion) presents medical risks that ASC regulations seek to prevent, mitigate, or remedy.

2. The objections of petitioners and their *amici* to requiring outpatient abortion providers to meet ASC requirements cannot withstand scrutiny.

For instance, petitioners object that requiring a sterile surgical environment cannot enhance abortion safety because, unlike other surgeries, abortion does not involve "cutting into sterile body tissue." Pet. Br. at 18; see also Br. for *Amici Curiae* American College of Obstetricians and Gynecologists *et al.* in support of Petitioners ("ACOG Br.") at 11-13. That argument is misguided for many reasons.

First, other procedures often take place in ASCs that do not involve "cutting into sterile body tissue," such as any number of the gastroenterological, orthopedic, urologic, gynecological, ophthalmologic, and diagnostic procedures that widely occur in ASC

settings. See *supra* I.A.1 (discussing NHS Report at 6, 16-17 (Table 6); 18-20 (Table 7)).

Second, as petitioners themselves admit, sterility *is* extremely important to abortion safety because "abortion providers must ensure that instruments that enter the uterus are sterile." Pet. Br. at 19; see also *Cole*, 790 F.3d at 579 (finding that "the State offered expert testimony that the sterile environment of an ASC was medically beneficial because surgical abortion involves invasive entry into the uterus, which is sterile").

Third, ASC regulations require more than just a sterile surgical environment. They broadly address any number of additional safety issues—such as infection control, patient supervision, anesthesia standards, and emergency protocols—that are directly relevant to the well-being of abortion patients. See *supra* I.A.1. Petitioners and their *amici* say nothing about whether these additional aspects of ASC regulation would enhance abortion patients' safety. Yet it is common sense that they would.

Instead, petitioners suggest only that ASC regulations are reserved for surgeries more "complex" than abortion. Pet. Br. at 39. But this ignores that the surgical and nonsurgical procedures that occur in ASCs vary widely in terms of complexity. See *supra* I.A.1. Contrary to petitioners' shortsighted view, abortion need not present the complexity or risk of heart, brain, or bowel surgery for abortion patients to benefit from—or need—the protections afforded by ASC regulations.

Finally, petitioners note that Medicare discourages the performance in an ASC of procedures "safely and commonly performed in an office-based setting"—and from this they suggest it is unreasonable to require abortions to be performed in an ASC. See Pet. Br. at 17 (citing 71 Fed. Reg. 49506, 49639 (Aug. 23, 2006); 42 C.F.R. § 416.171(d)). Petitioners are quite mistaken. It is true that Medicare does not reimburse ASC procedures that "[a]re not of a type that are commonly performed, or that may be safely performed, in physicians' offices." 42 C.F.R. § 416.65(a)(2). But this does not imply that Medicare discourages performing abortions in an ASC. To the contrary, the official list of ASC procedures that Medicare reimburses plainly includes "abortion" (71 Fed. Reg. at 68277), as well as other gynecological procedures analogous to abortion. See *id.* at 68233, 68277 (covering "Dilation and Curettage" and "Treatment of Miscarriage"). Thus, contrary to petitioners' suggestion, the federal Medicare system squarely recognizes that abortion and similar procedures are properly performed in a setting subject to ASC regulations.

B. Admitting Privileges Requirement

1. *Physician admitting privileges enhance patient safety and reinforce physician competence.*

In addition to the broad requirement that abortion clinics meet ASC standards, Texas has also imposed the specific requirement that physicians at those clinics have "admitting privileges" at a hospital within thirty miles of the clinic. TEX. HEALTH & SAFETY CODE § 171.0031(a)(1)(A). Hospitals generally determine whether to grant physicians privileges to admit and

treat patients through a process known as "credentialing" and "privileging."[23] A hospital credentials physicians by assessing their qualifications to become a member of the medical staff.[24] Based on that assessment, physicians are "privileged" to provide delineated care to patients at the hospital. *Id.* at GL-33. "Admitting" privileges refers to a physician's ability to admit patients for treatment by virtue of his membership on the hospital's medical staff. See, *e.g.*, J.C. SEGEN, THE DICTIONARY OF MODERN MEDICINE 691 (1992). "Clinical" privileges refers to specific care a physician may provide to patients at the hospital. See *JC Standards* at MS-9 (noting that "[e]ach member of the medical staff is to have specific clinical privileges to provide care, treatment, and services authorized through the [credentialing and privileging] processes").

By granting privileges to a physician, a hospital seeks to improve patient care in several ways—all of which are promoted by Texas' admitting privileges requirement.

First, at the most basic level, a physician with admitting privileges can continue to care for a patient admitted to the hospital. After all, this is the physician

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[23] See JOINT COMMISSION RESOURCES, 2016 HOSPITAL ACCREDITATION STANDARDS ("*JC Standards*"), Medical Staff ("MS") at MS-1-MS-2 (Overview). Criteria for credentialing and privileging are found in hospital bylaws, *id.* at MS-9, but most hospitals follow standards set by The Joint Commission, "[a]n independent, not-for-profit organization" that "accredits and certifies more than 20,000 health care organization and programs in the United States." *Id.* at GL-41.

[24] *JC Standards* at GL-9 (defining "credentialing"); GL-23 (noting different kinds of medical staff).

who originally treated the patient, and it typically benefits the patient to have that physician continue to be personally involved in his care.

Second and relatedly, by having privileges, that physician is better able to communicate with other physicians at the hospital and coordinate patient care. See *JC Standards* at MS-18 (explaining "[t]he management and coordination of each patient's care … is the responsibility of a practitioner with appropriate privileges").

Third, the closer connection between physician and hospital created by privileging helps ensure that all physicians involved in the patient's care have the best information about the patient's health status and ready access to medical records. See *JC Standards* at MS-17 (requiring that a practitioner "who has been granted privileges . . . to do so performs a patient's medical history . . . and required updates"); *id.* MS-18 (explaining that "[c]ommunication among all practitioners and staff involved in a patient's care . . . is vital to ensuring coordinated, high-quality care"). Improved information flow improves patient diagnosis and reduces miscommunication. See *id.* MS-19 (noting importance of "coordination of the care, treatment, and services among the practitioners involved in a patient's care").

Fourth, at the level of medical ethics, this closer connection between the physician and the hospital where a patient is admitted reinforces the physician's

ethical obligation never to abandon care of his patient.[25]

Fifth, the credentialing and privileging process is also an effective means of ensuring physician competence and integrity. See *JC Standards* at MS-23 (noting the process "involves a series of activities designed to collect, verify, and evaluate data relevant to a practitioner's professional performance."). In credentialing a physician, a hospital verifies items such as her licensure, education, and training. *Id.* at MS-25-MS-26. This allows a hospital to assess basic matters such as whether the applicant is who she claims to be, whether her medical license is current, and whether she has maintained competence to performed the requested privileges. *Id.* at MS-27-MS-28. Similarly, in deciding which privileges to grant, a hospital engages in a "clearly defined procedure" that considers sources such as the National Practitioner Data Bank, a physician's own health records, any clinical data bearing on the physician's performance record, and peer recommendations. See *id.* at MS-29-MS-32.

In sum, credentialing and privileging enhance both the safety of patients and the integrity of the medical profession. The process ensures that "[p]ractitioners have privileges that correspond to the care, treatment

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[25] See, *e.g.,* CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION, OPINION 8.115 (2014-2015 ed.) ("Physicians have an obligation to support continuity of care for their patients."); *id.*, OPINION 10.01(5) (providing that "[t]he physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care").

and services needed by individual patients." *Id.* at MS-18. It maximizes a physician's ability to communicate with other physicians and coordinate all necessary care for the benefit of the patient. At the same time, the process allows "an overview of each applicant's licensure, education, training, current competence, and physical ability to discharge patient care responsibilities." *Id.* at MS-23. Put simply, an outpatient surgical provider with the ability to admit his patients to a hospital is more likely to be a physician with the experience, integrity and ability to provide his patients with the care they need, especially in the event of unforeseen emergencies.

2. *It is medically reasonable and responsible to require outpatient abortion providers to have admitting privileges at local hospitals.*

By requiring outpatient abortion providers to have admitting privileges at local hospitals, states like Texas have adopted a reasonable means of safeguarding patient safety and reinforcing physician competence and integrity.

1. As already discussed, abortion is a procedure that occurs in large numbers in outpatient settings and carries specific risks to patients. See *supra* I.A.2. Inevitably, some patients who experience complications from abortion will be admitted to a hospital for care. Indeed, the clinical guidelines of one of the nation's leading abortion groups require emergency protocols for transferring women to hospitals in the event of complications. *See* NAF Guidelines at 42. The evidence in this case indicates that over 200 women per year in Texas are hospitalized as a result of complications from

abortion. See *Abbott*, 748 F.3d at 595 (noting that "Planned Parenthood conceded that at least 210 women in Texas annually must be hospitalized after seeking an abortion"). Regardless of the numbers, however, it is perfectly reasonable to conclude that any woman who requires hospital treatment because of an abortion complication will benefit if her abortion provider has the ability to admit her to a local hospital.

That woman, for example, will be assured that her physician, who originally provided the abortion, can continue to be personally involved in her care at the hospital. Her provider will be in a better position to communicate with the hospital about the details of her complications and to transfer her medical records. This improved information flow will enable her to receive a more timely and accurate diagnosis, which will in turn help her receive the targeted care she needs to resolve the complication. That may literally mean the difference between life and death since certain abortion complications can require rapid surgical intervention. See, *e.g.,* NAF Guidelines at 20 (warning against undiagnosed ectopic pregnancy).

Furthermore, because the woman's abortion provider will have undergone the credentialing and privileging process at a local hospital, she is more likely to have a physician who can perform the procedure in a safe and ethical manner. She can be more assured that her provider is currently licensed to practice medicine, has the requisite training and experience, and has been recommended by his peers in the medical profession.

Most importantly, she can be assured that her provider has a professional relationship with a local

hospital that enables him to personally admit her in the event that she has a complication requiring the resources of a hospital. Anyone undergoing an outpatient surgical procedure like abortion would want such an assurance, no matter the frequency of serious complications. This explains why a federal circuit court observed in 2002 that requiring abortion providers to have admitting privileges at local hospitals is "obviously beneficial to patients." *Greenville Women's Clinic v. Comm'r*, 317 F.3d 357, 363 (4th Cir. 2002).

2. Indeed, long before the current controversy, numerous medical organizations strongly recommended that outpatient surgical providers have admitting privileges to ensure complication care and provider competency. In 2004, the American Medical Association ("AMA") and American College of Surgeons ("ACS") coordinated a "consensus meeting" that produced a set of "Core Principles" on patient safety for office-based surgery.[26] Core Principle #4 provided:

> Physicians performing office-based surgery must have *admitting privileges at a nearby hospital*, a transfer agreement with another physician who has admitting privileges at a nearby hospital, or maintain an emergency transfer agreement with a nearby hospital.

ACS Statement at 33 (emphasis added). Similarly, Core Principle #8 provided:

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[26] See *Statement on patient safety principles for office-based surgery utilizing moderate sedation / analgesia, deep sedation / analgesia, or general anesthesia*, BULLETIN OF THE AMERICAN COLLEGE OF SURGEONS, Vol. 89, No. 4, at 32-24 (Apr. 2004) ("*ACS Statement*"), https://www.facs.org/~/media/files/publications/bulletin/2004/2004%20april%20bulletin.ashx.

> Physicians performing office-based surgery may show competency by *maintaining core privileges at an accredited or licensed hospital or ambulatory surgical center*, for the procedures they perform in the office setting.

ACS Statement at 34 (emphasis added). These principles were meant to encourage development of "model state legislation for use by state regulatory authorities to assure quality of office based procedures." *Id.* at 32.

To be sure, admitting privileges were not the only means identified to address complications and competency. But these medical organizations plainly considered privileges one effective means of achieving those goals.

The depth of the consensus was likewise remarkable. *Thirty-two* medical organizations, ranging across a variety of specializations, agreed to the Core Principles, including:

- Accreditation Association for Ambulatory Health Care
- American Academy of Ophthalmology
- American Academy of Orthopedic Surgeons
- American Academy of Otolaryngology-Head and Neck Surgery
- American Academy of Pediatrics
- American Association for Accreditation of Ambulatory Surgery Facilities

- American College of Obstetricians and Gynecologists
- American College of Surgeons
- American Medical Association
- American Osteopathic Association
- American Society for Reproductive Medicine
- American Society of Anesthesiologists
- American Society of General Surgeons
- American Society of Plastic Surgeons
- American Urological Association
- Federation of State Medical Boards
- Joint Commission on Accreditation of Healthcare Organizations
- National Committee for Quality Assurance

ACS Statement at 33.[27]

Four of those groups now say they no longer recommend requiring privileges for abortion providers,

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[27] Additional signatures included: American Academy of Cosmetic Surgery; American Academy of Dermatology; American Academy of Facial Plastic and Reconstructive Surgery; American Society for Dermatologic Surgery; American Society of Cataract and Refractive Surgery; Indiana State Medical Society; Institute for Medical Quality-California Medical Association; Kansas Medical Society; Massachusetts Medical Society; Medical Association of the State of Alabama; Medical Society of the State of New York; Missouri State Medical Association; Pennsylvania Medical Society; and the Society of Interventional Radiology. *Id.*

see ACOG Br. at 17 (claiming privileges are "inconsistent with prevailing medical practices"), but their apparent repudiation of the 2004 ACS Statement is unpersuasive. In a footnote, their brief points out that the 2004 statement identified *both* privileges *and* transfer agreements as "core principles" for safe outpatient surgery. *Id.* at 21 n. 50. But this merely confirms that, in 2004, numerous medical organizations thought privileges were one critical means of ensuring prompt care for patient complications. The same footnote also tries to justify the revised view by referring vaguely to "advances in accepted medical practices," *id.*, but never says what those "advances" are. In any event, these four groups make no attempt to explain why admitting privileges—identified as a "core" safety principle for all outpatient surgery in 2004—have over the past few years somehow become medically unreasonable for one particular kind of outpatient procedure.

3. Petitioners' objections to the privileges requirement cannot withstand scrutiny. For example, they claim privileges are unnecessary because, if complications arise at the clinic, patients can be transported to a hospital by ambulance and the abortion provider can simply inform the emergency room about the patient's condition by telephone. Pet. Br. at 19. That entirely misses the point. States like Texas have determined that privileges are a *more effective* way of ensuring prompt complication care than other arrangements, such as telephoning ahead to the ER.

That judgment is perfectly reasonable. For instance, none of the regulations governing ambulatory surgical

centers—including Medicare rules—would allow complications to be addressed by sending a patient to the ER by ambulance and transmitting her medical condition by telephone. They would instead require either the provider to have privileges or the clinic to have a transfer agreement, as would the 2004 ACS Statement discussed above. See*, e.g.,* 42 C.F.R. § 416.41; ACS Statement at 33.[28] The fact that a state like Texas requires privileges instead of a transfer agreement does not mean Texas is unreasonable. It means that Texas has chosen the more patient-protective alternative.[29]

Furthermore, petitioners (and some of their *amici*) claim that privileges do not adequately ensure physician competence because privileges are sometimes denied based on considerations other than competence.

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[28] See also, *e.g.,* AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES, REGULAR STANDARDS AND CHECKLIST FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES § 400.012.010 (2014) (requiring that the facility have "a written transfer agreement" or that "the operating surgeon has privileges to admit patients" to a hospital within 30 minutes of the facility), http://www.aaaasf.org/Surveyor/asf_web/PDF%20FILES/Standards%20and%20Checklist%20Manual%20V14.pdf.

[29] Petitioners also argue that, if complications arise when the patient returns home, the patient would "be instructed to seek care at an emergency room near [her] home." Pet. Br. at 19. That also misses the point. The fact that a privileges requirement may not directly assist a patient in *every* scenario does not mean that it is unreasonable. The same thing could be said for any outpatient surgical procedure performed in an ASC, where complications could arise either in the surgical center or after the patient returns home. Furthermore, the competency-ensuring function of the privileging process benefits *all* patients by raising the standard of care and reducing the likelihood of complications to begin with.

See Pet. Br. at 22; ACOG Br. at 16-17. But this objection ignores that the widely-accepted standards for credentialing and privileging are overwhelmingly focused on ensuring physician competence. See *supra* I.B.1 (discussing Joint Commission standards). As the Joint Commission explains, one of the key goals of credentialing and privileging is to "[d]etermin[e] the competency of practitioners to provide high quality, safe patient care." *JC Standards* at MS-23. To that end, the Joint Commission standards establish an "objective, evidence-based" process for assessing a physician's "licensure, education, training, current competence, and physical ability to discharge patient care responsibilities." *Id.;* see also *id.* at MS-25-MS-33 (setting out credentialing and privileging standards). Moreover, those standards discourage the use of privileging criteria unrelated to the quality of patient care or physician competence: if a hospital uses such criteria, it must provide evidence evaluating "the impact of resulting decisions on the quality of care, treatment, and services." *Id.* at MS-32.

One of petitioners' *amici* goes so far as to claim it is impossible for abortion providers to obtain privileges under the Joint Commission standards. See Br. of *Amici Curiae* Medical Staff Professionals in support of Petitioners ("MSP Br."), at 13 (referring to Joint Commission standards). The *amicus* misreads the standards. Principally, they claim that the Joint Commission inflexibly requires clinical data from inpatient procedures to verify an applicant's competence, which outpatient abortion providers cannot provide because they rarely perform inpatient procedures. MSP Br. at 19-22. But the Joint Commission standards do not limit assessment of

physician competence to inpatient clinical data. To the contrary, they require consideration of peer recommendations, including "written peer evaluation of practitioner-specific data collected from various sources for the purpose of validating current competence." See *JC Standards*, MS.06.01.03 (Introduction) at MS-26; *id.*, MS-06.01.05 (EP8), at MS-31.[30]

The same *amici* also suggest that an abortion provider could not *maintain* privileges because the Joint Commission standards demand "ongoing" professional evaluation that requires repeated hospital contacts. MSP Br. at 32-33. They again read the standards too rigidly. The ongoing evaluation required by the standards—known as the "Ongoing Professional Practice Evaluation"—allows assessment of physicians through a variety of materials, including periodic chart review, direct observation, monitoring, and discussion of provider competence with others involved in patient care. See *JC Standards*, MS.08.01.01 (Introduction), at MS-40. *Amici* do not explain why these kinds of evaluation methods make maintaining privileges impossible for outpatient abortion providers. Nor do the

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[30] Furthermore, the standards envision a separate process designed to evaluate applicants who lack "documented evidence" of performing requested procedures at the hospital. See *id.*, MS.08.01.01 (Introduction), at MS-37 (discussing "Focused Professional Practice Evaluation"). That process is likewise not limited to inpatient clinical data; rather, it considers various indicators of current competence readily available to outpatient abortion providers. See *id.* at MS-38 (allowing consideration of "chart review, monitoring clinical practice patterns, simulation, proctoring, external peer review, and discussion with other individuals involved in the care of each patient").

Joint Commission standards anywhere require physicians to have some required minimum of hospital admissions to maintain privileges. *Cf.* MSP Br. at 33 (claiming minimum admission requirements prevent abortion providers from maintaining privileges). Indeed, the AMA strongly discourages minimum admissions requirements as a prerequisite to granting or maintaining privileges. See CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION OPINION 4:07 – Staff Privileges (2014-2015 ed.) ("Privileges should not be based on numbers of patients admitted to the facility or the economic or insurance status of the patient.").

In short, requiring admitting privileges for outpatient abortion providers is a commonsense measure designed to maximize the prompt and competent care of patients who experience complications. This is true of any outpatient surgical procedure, as scores of medical organizations have recognized in the past decade. There is no medical reason to think it is any less true of abortion, one of the most common outpatient surgical procedures in the United States.

II. This Court's precedents require deference to state medical regulations such as those in HB2.

Petitioners urge the Court to weigh Texas's interests in the medical regulations at issue against any reduction in abortion access they may cause. Pet. Br. at 33, 38-40. But that analysis has no basis in the Court's jurisprudence. Longstanding principles both inside and outside the abortion context require strong deference to state regulation of medical practice. And

accepting petitioners' suggestion to balance medical interests against abortion access would call into question numerous abortion decisions over the past three decades.

1. The Constitution's federal structure requires deference to the states in many areas of law, especially the regulation of medicine. "It is established that a state may regulate the practice of medicine," *McNaughton v. Johnson*, 242 U.S. 344, 348-49 (1917), because states "exercise[] their police powers to protect the health and safety of their citizens." *Medtronic, Inc. v. Lohr* 518 U.S. 470, 475 (1996); see also, *e.g., Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) ("*Gonzales I*") (the "structures and limitations of federalism" give states "'great latitude … to legislate as to the protection of lives, limbs, health, comfort, and quiet of all persons'") (quoting *Medtronic*, 518 U.S. at 475). Among other benefits, this deference affords state legislatures the necessary latitude to make judgments based on conflicting medical evidence. See*, e.g., Kansas v. Hendricks*, 521 U.S. 346, 360 n.3 (1997).

2. This principle of deference fully applies to this Court's abortion jurisprudence.

For instance, it is settled that state legislatures may legitimately take sides in medical debates about abortion given their "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 127, 163 (2007) ("*Gonzales II*"); see also *Stenberg*, 530 U.S. at 970-72 (Kennedy, J., dissenting) (collecting cases). Indeed, deference to state medical regulation was a key reason why the Court abandoned the *Roe* trimester framework. That framework had inappropriately made

the Court "'the country's *ex officio* medical board with powers to approve or disapprove medical and operative practices and standards throughout the United States.'" *Gonzales II*, 550 U.S. at 163-64 (quoting *Webster v. Reproductive Health Services*, 492 U.S. 490, 518-19 (plurality op.)).

Several of this Court's abortion decisions illustrate the deference principle in operation. In *Simopoulos v. Virginia*, the Court held that, given its "considerable discretion in determining standards for the licensing of medical facilities," Virginia could require all second-trimester abortions to be performed in facilities licensed as "outpatient surgical hospitals." 462 U.S. 506, 516, 519 (1983). (Indeed, Justice O'Connor would have upheld the regulation regardless of the trimester. *Id.* at 520 (O'Connor, J., concurring)). Likewise, in *Mazurek v. Armstrong*, the Court upheld a Montana law allowing abortions to be performed only by physicians and not physicians' assistants. See 520 U.S. 968, 969-71 (1997). Responding to the claim that the law's distinction was undermined by all available medical evidence, the Court simply observed that "the Constitution gives the States broad latitude to decide that particular functions may be performed only by licensed professionals." *Id.* at 973 (quoting *Casey*, 505 U.S. at 885). Finally, in *Gonzales v. Carhart*, the Court upheld a ban on one second-trimester abortion technique, despite medical disagreement about the technique's health benefits. See 550 U.S. at 163. The Court noted that "[m]edical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts." *Id.* at 164 (citing *Hendricks*, 521 U.S. at 360 n.3).

3. Petitioners' suggested balancing test is a stark departure from this Court's previous approach, and it would effectively overrule numerous precedents.

Indeed, the standard urged by petitioners is the polar opposite of deference to state legislative judgments in the medical realm. In petitioners' view, this Court has an obligation to "confirm" the legislature's medical judgments, to review "[t]he great weight of the [medical] evidence," and to "strike a careful balance" between abortion safety and access. Pet. Br. 31, 39, 44. This standard is unheard of, either inside or outside the abortion context. It would reinstitute, with a vengeance, the discredited regime that transformed the Court into "the country's *ex officio* medical board." *Gonzales II*, 550 U.S. at 163-64 (internal quotation marks omitted).

Petitioners' novel standard would also provoke immediate reconsideration of many of this Court's abortion decisions, before and after *Casey*. Most obviously, it would overturn *Simopoulos* by requiring the Court to adjudge the wisdom and efficacy of ambulatory surgical center regulations. See Resp. Br. at 28, 37-38, 45 (discussing *Simopoulos*). It would require, contrary to *Mazurek*, that the Court assess whether abortions provided by physicians are medically safer than those provided by non-physicians. And it would call *Gonzales v. Carhart* into question by requiring the Court to take sides in contested issues of medical ethics. See *Gonzales II*, 550 U.S. at 158 (deferring to Congress's judgment that the abortion procedure at issue "requires specific regulation because it implicates additional ethical and moral concerns").

The Court should decline petitioners' invitation to begin writing this new and unpredictable chapter in its abortion jurisprudence. Instead, the Court should continue to apply settled law, which requires deference to state judgments about the best means of protecting the health and safety of their citizens.

CONCLUSION

The Court should affirm the judgment of U.S. Fifth Circuit.

Respectfully submitted,

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