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COMMONWEALTH OF KENTUCKY
SUPREME COURT
NO. 2016-SC-000181-D

LAKE CUMBERLAND REGIONAL HOSPITAL, LLC — APPELLANT

On Review from the Kentucky Court of Appeals
v. Action No. 2013-CA-000983

HELEN ADAMS — APPELLEE

BRIEF OF *AMICUS CURIAE* KENTUCKY HOSPITAL ASSOCIATION

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that copies of this brief have been served via First Class U.S. Mail on this 21st day of December, 2016 to the following: Hon. Stephen M. O'Brien III, Hon. Harold L, Kirtley II, Hon. Adam J. Stigall, 271 West Short Street, Suite 200, Lexington, Kentucky 40507; Hon. B. Todd Thompson, Hon. Millicent A. Tanner, Hon. Eleanor M.B. Davis, Hon. Chad O. Propst, Hon. Joey A. Wright, Thompson Miller & Simpson PLC, 734 W. Main Street, Suite 400, Louisville, Kentucky 40202; Hon. David A. Tapp, Pulaski Circuit Court, 50 Public Square, P.O. Box 1324, Somerset, Kentucky 42502; and Samuel P. Givens, Jr., Clerk of the Kentucky Court of Appeals, 360 Democrat Drive, Frankfort, Kentucky 40601.

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PURPOSE AND ISSUES

On behalf of its members, the Kentucky Hospital Association ("KHA") supports the call of Appellant, Lake Cumberland Regional Hospital, LLC ("Appellant") to reject the tort of negligent credentialing because the tort will compound the numerous challenges already facing Kentucky's rural hospitals to provide access to health care. Existing remedies at law are adequate to redress any harms that may befall a claimant. KHA's interest is public in nature, as *amicus* has no interest in the underlying claims between the litigants.

Instead, KHA's interest focuses on the concern that recognizing negligent credentialing claims would result in unwarranted and disproportionate liability upon hospitals for conduct that is otherwise acceptable under all applicable federal and state laws, regulatory provisions, and standards. The end result would be an immeasurably negative impact on Kentuckians' access to quality, cost-efficient health care. KHA offers the following arguments to supplement and support those raised by Appellant, and as a means of assisting the Court in evaluating the critical implications of these issues on the Kentucky health care system.

ARGUMENT

I. Negligent credentialing claims invite inappropriate comparisons of hospital credentialing standards.

Hospitals use credentialing as an initial mechanism to evaluate whether health care professionals possess qualifications appropriate to

perform health care services at the hospital. Although the credentialing processes for various hospitals may look similar, the patchwork of federal and state laws, regulations, and accreditation guidelines grant hospitals significant autonomy and discretion in choosing the credentialing standards appropriate to the hospital's circumstances. Hospitals select the standards to credential professionals based upon a variety of factors, including population health needs and patient volumes. This flexibility in credentialing standards is intentional and necessary given the wide-ranging influences impacting the delivery of health care.

The tort of negligent credentialing takes the intended benefit of flexible credentialing standards and contorts it into a burden. Negligent credentialing necessarily presumes that all hospitals credential physicians under comparable standards. This presumption is false, impractical and unwanted. Applicable laws, regulations, and guidelines provide hospitals substantial flexibility in credentialing standards so that a hospital in rural western Kentucky is not expected to utilize credentialing standards that may be appropriate for a hospital in Louisville. This fact should not be misconstrued as suggesting that quality health care is subject to a sliding scale. Instead, this approach recognizes that varying credentialing standards are a reflection of the patient population and health care needs of the communities a hospital serves.

The tort of negligent credentialing turns this flexible standard on its head by permitting a 25-bed critical access hospital to be liable for not adhering to the credentialing standards of a 500-bed academic medical center. Although this inequity will affect all hospitals, the practical reality is that rural, non-profit hospitals—which comprise the majority of Kentucky hospitals—will feel the disproportionate brunt of negligent credentialing claims because the tort invites liability based upon apple-to-orange comparisons.

Credentialing is a multistep process wherein a hospital evaluates whether a practitioner has the requisite licensure, education and training qualifications to provide patient care in the hospital. The credentialing process progresses to a determination of specific health care services the practitioner may be privileged to perform at the hospital. "While the credentialing process allows a practitioner to work in a hospital, the privileging process determines in what areas he or she can work and what duties he or she can perform."[1] Thus, credentialing and privileging are "interrelated and concurrent functions" performed by the hospital's self-governed, organized medical staff with collaboration and approval of the hospital's governing body.[2] Credentialing standards are hospital-specific and based upon practical considerations, including the needs of the communities the hospital serves. Evaluating a hospital's credentialing standards is

[1] THE JOINT COMMISSION, *Medical Staff Handbook: A Guide to Joint Commission Standards* (3d ed. 2011), at 63.
[2] *See id.* at 27.

necessarily much broader than simply checking off a list of prescribed rules or requirements, as there are none.

The credentialing standards established in hospital bylaws, rules, and regulations can look drastically different from hospital to hospital. As The Joint Commission has noted, "[t]he organized medical staff of a hospital has a great deal of latitude when developing and determining the provisions of and specific language used in the medical staff bylaws. In some cases, the prerogatives and obligations of members might be spelled out in great detail; in other cases, a few sentences providing a general description might be adequate."[3]

For instance, one hospital's credentialing standards may require that a physician perform a certain type of procedure five times annually to maintain privileges to perform the procedure. Another hospital may require the same procedure to be performed twenty times annually as a condition of maintaining privileges to perform the procedure. Yet another hospital's credentialing standards may contain no annual requirement, but apply a general provision that a physician be trained and competent in a particular area of practice to maintain privileges. All three scenarios are acceptable under federal law, state law, and other compliance standards for credentialing. Moreover, these scenarios may be multiplied exponentially

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[3] THE JOINT COMMISSION, *Medical Staff Handbook: A Guide to Joint Commission Standards* (3d ed. 2011), at 3.

since each medical procedure would be subject to distinct credentialing standards.

Negligent credentialing claims, if recognized, would most certainly result in inconsistent, unpredictable liability determinations for Kentucky hospitals. To continue the scenarios above, a rural Kentucky hospital may only encounter a handful of patients each year in need of a particular procedure, so the hospital sets a credentialing standard that permits a physician to maintain privileges if he or she performs the procedure at least five times annually. Clinical evidence and patient outcomes may show that the hospital's credentialing standard is reasonable and appropriate to assure proficiency to perform the procedure. However, a claimant need only allege that the rural hospital failed to meet "some" standard to preserve a negligent credentialing claim. If the rural hospital's five-procedure standard is compared to an academic medical center's standard of twenty procedures annually, the rural hospital may be perceived to have missed the mark. Yet the comparison is incongruent, not because the hospital failed to meet the bar, but because the claimant was permitted to set the bar unattainably high.

The consequence of the tort is that, over time, Kentucky patients will experience further limitations on access to medical care as hospitals are forced to modify the services they provide. Those limitations will not be based upon actual proficiency of physicians, but rather the perceptions of risks associated with unreasonable or inapplicable standards. Claimants

would have nothing to lose by tacking on a negligent credentialing claim to their case. On the other hand, hospitals and the communities they serve would have much to lose by defending against negligent credentialing claims. Hospitals would face the impossible task of meeting standards they can neither discern nor achieve as a result of disparate, unpredictable outcomes of civil litigation.

The parties urging this Court to recognize the tort of negligent credentialing have argued that Kentucky statutes, regulations and The Joint Commission standards support recognition of such claims. A review of pertinent federal law, Kentucky law, and accreditation standards reveals that this assertion is unsupported. None of the aforementioned authorities create a uniform process or standard for credentialing applicable to all hospitals. Furthermore, none of these authorities give support for negligent credentialing claims.

Hospitals seeking Medicare reimbursement must satisfy the conditions of participation outlined in 42 C.F.R. part 482. These conditions require that hospitals "examine the credentials of all eligible candidates for medical staff membership" and "[i]nclude criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges." 42 C.F.R. § 482.22(a)-(c). Federal law requires only that qualifications for medical staff participation be established; it does *not* mandate what those qualifications and criteria must

be for participating hospitals. Under federal law, hospitals have authority and discretion to establish their own credentialing standards.

Similarly, the Kentucky Cabinet for Health and Family Services ("Cabinet") has declined to mandate uniform credentialing standards for Kentucky hospitals. Kentucky hospital licensure regulations only require hospitals to "develop and adopt policies or bylaws" that "[s]tate the necessary qualifications for medical staff membership including licensure to practice medicine"; "[d]elineate the clinical privileges of staff members"; and "[e]stablish a procedure for granting and withdrawing staff privileges." 902 KAR 20:016 § 3(8)(b)(1)-(2). The Cabinet does *not* specify the credentialing standards a hospital must implement. The medical staff at any given hospital has the power to develop its own credentialing and privileging process, subject to approval by its governing authority.

Finally, a look to accreditation standards yields no support for negligent credentialing claims. KRS 216B.185 permits the Office of the Inspector General to "accept accreditation by the Joint Commission or another nationally recognized accrediting organization with comparable standards and survey processes . . . as evidence that a hospital demonstrates compliance with all licensure requirements." KRS 216B.185(1). However, Kentucky law does *not* require that hospitals be accredited by an accrediting organization. Moreover, hospitals that elect to become accredited may choose among various accreditation agencies, and standards vary by agency.

An examination of the most well-known accrediting agency, The Joint Commission, shows that its accreditation standards also do not mandate uniform credentialing standards.[4] Rather, accreditation standards require only that hospitals use a defined process based on recommendations by the hospital's medical staff and approved by the hospital's governing body.[5] Aside from a few minimum criteria, such as verification of a practitioner's identity and licensure, hospitals have the authority and discretion to establish their own credentialing standards.[6] Stated another way, "[t]he medical staff bylaws, rules, and regulations create a framework within which medical staff members can act with a reasonable degree of freedom and confidence."[7]

The latitude and discretion afforded to hospitals and their medical staff are appropriate and necessary to allow each facility to tailor its credentialing standards to evolving facts and circumstances. This is essential to maintaining hospitals' abilities to recruit qualified physicians and render accessible, cost-efficient medical care.

II. Negligent credentialing claims would negatively impact Kentuckians' access to necessary medical care.

Should the Court recognize the tort of negligent credentialing, the negative consequences will deeply impact Kentucky's largely rural population

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[4] *See* THE JOINT COMMISSION, *Comprehensive Accreditation Manual for Hospitals* (2016), at MS.06.01.03-MS.06.01.13; MS.08.01.3.
[5] THE JOINT COMMISSION, *Comprehensive Accreditation Manual for Hospitals* (2016), at Elements of Performance for MS.06.01.03, 1-3.
[6] *See id.* at Elements of Performance for MS.06.01.03, 5-6.
[7] THE JOINT COMMISSION, *Comprehensive Accreditation Manual for Hospitals* (2016), at Medical Staff Overview, MS-1.

and health care landscape. Kentucky's hospitals face unprecedented challenges in meeting the health care needs of Kentucky's citizens—challenges largely shaped by the Commonwealth's rural demographics. The majority of Kentucky's population resides outside of cities and metropolitan statistical areas. Kentucky is an aging, unhealthy state as a whole, ranking 44th out of the 50 states in overall health measures in 2015.[8] Kentucky ranks second in the nation in smoking rates, fifth in obesity rates, and ninth in the percentage of the population that does not exercise.[9]

Unlike many states that recognize the tort of negligent credentialing, Kentucky's hospitals are largely rural and operated on a not-for-profit basis. Without support or citation, the Kentucky Court of Appeals noted an "almost-universal shift in hospital ownership and management from small, charitable organizations to those for-profit corporations." (Op. at 12, *Adams v. Lake Cumberland Reg. Hosp.*, No. 2013-CA-000983-MR (Ky. App. Mar. 11, 2016).) However, this purported trend is demonstrably untrue for Kentucky. There are 109 private, non-governmental hospitals in Kentucky.[10] Eighty of those hospitals, or 73%, are non-profit, IRS 501(c)(3) entities.[11] Sixty-eight of those hospitals—over half—are located outside of a metropolitan statistical area and thus are considered to be rural.[12] Twenty-eight currently operating rural

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[8] United Health Found., *America's Health Rankings, available at* http://www.americashealthrankings.org/explore/2015-annual-report/measure/Overall/state/KY (last accessed Dec. 19, 2016).
[9] KY. HOSP. ASS'N, *Kentucky Hospital Statistics,* May 2015, at 119.
[10] *Id.* at 5.
[11] *Id.*
[12] *Id.*

Kentucky hospitals are critical access hospitals,[13] at least 35 miles from another acute care facility and containing 25 or fewer acute care beds. *See* 42 U.S.C. § 1395i-4(c)(2)(B).

In the Commonwealth, nearly all critical access hospitals are located many miles from a trauma center, a hospital which specializes in treating traumatic conditions. Therefore, the healthy operation of rural hospitals is especially vital to Kentucky's health care infrastructure. Consider the traumatically injured patient that must endure extended EMS transport because a rural hospital did not credential a qualified member of the medical staff on a procedure necessary to effectively treat the patient. While the hospital may have averted a negligent credentialing claim, the patient has lost invaluable time, and perhaps his or her life. This occurs not because the available physician was incompetent to perform the procedure, but because the liability environment caused credentialing standards to be set so high that no physician could achieve privileges based on patient volume.

Hospitals in rural areas have difficulty attracting and retaining physicians and skilled employees. As noted in Appellant's Brief, Kentucky ranked 36th out of 50 states in active physicians per 100,000 population.[14] Kentucky has 148 federally-designated health professional shortage areas ("HPSAs") for primary care services, and 166 HPSAs for mental health

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[13] *Id.* at 6-8.
[14] Ass'n of Am. Med. Colleges, *Kentucky Physician Workforce Profile* (2015), *available at* https://www.aamc.org/download/447180/data/kentuckyprofile.pdf (last accessed Dec. 19, 2016.)

services.[15] Similarly, Kentucky has 102 federally-designated medically underserved areas, a designation based on the area's population, the number of full time equivalent primary care physicians, and other factors.[16] The shortage of primary care providers in rural areas in Kentucky is so severe that, "[i]n order to meet the standards for primary care and family practice manpower recommended by the U.S. Council on Graduate Medical Education, Kentucky would need approximately 600 additional family medicine practitioners."[17]

Expanding liability for hospital credentialing will exacerbate the lack of physicians in rural areas. Moreover, negligent credentialing claims are unnecessary because current legal remedies adequately recognize and compensate the harms that health care recipients may experience, as discussed in Appellant's Brief. (Appellant's Br. 7-9.) Placing ambiguous and impractical standards—for which no evidence-based methodology exists—on these already overtaxed hospitals when current remedies at law are sufficient to redress plaintiffs' injuries will compromise their ability to provide critical health care services and will further lessen some of the most vulnerable

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[15] U.S. Dep't of Health and Hum. Services, *Health Resources and Services Admin. Data Warehouse*, data as of Dec. 19, 2016, *available at* https://datawarehouse.hrsa.gov (search "Data by Tool" by choosing "HPSA by State and County"; then choose Kentucky and "All Counties") (last accessed Dec. 19, 2016).

[16] *Id.*, *available at* https://datawarehouse.hrsa.gov (search "Data by Tool" by choosing "MUA/P by State and County"; then choose Kentucky and "All Counties") (last accessed Dec. 19, 2016).

[17] Baretta R. Casey, M.D., Judy Jones, J.D., David A. Gross and Lola Dixon, *Rural Kentucky's Physician Shortage: Strategies for producing, recruiting, and retaining primary care providers within a medically underserved region*, J. OF THE KY. MED. ASS'N, Sept. 2005, at 3, *available at* https://ruralhealth.med.uky.edu/sites/default/files/docshortage.pdf (last accessed Dec. 19, 2016).

Kentuckians' access to same. Judicial recognition of a new cause of action would act only to harm Kentucky's hospitals and the patients they serve.

CONCLUSION

For the foregoing reasons, *amicus curiae*, the Kentucky Hospital Association, respectfully requests that this Court reverse the Court of Appeals' majority opinion and reject negligent credentialing as a cause of action in Kentucky.

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