Nos. 21-2480, 21-2573

IN THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

WHOLE WOMAN'S HEALTH ALLIANCE, et al.,

Plaintiffs-Appellees,

v.

TODD ROKITA, in his official capacity as Attorney General of the State of Indiana, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana, No. 1:18-cv-01904-SEB-MJD
The Honorable Sarah Evans Barker

BRIEF OF LAUREL HEALTH ADVISORS LLC AS AMICUS CURIAE IN SUPPORT OF APPELLEES AND AFFIRMANCE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-2480, 21-2573

Short Caption: Whole Woman's Health Alliance v. Rokita

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Laurel Health Advisors LLC

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Manatt, Phelps & Phillips, LLP (Benjamin G. Shatz, Julian Polaris)

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Attorney's Signature: s/ Benjamin G. Shatz Date: November 8, 2021

Attorney's Printed Name: Benjamin G. Shatz

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

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STATEMENT OF INTEREST[1]

Laurel Health Advisors LLC performs research and offers policy advice regarding the impact of telehealth on healthcare access and quality. Our leadership brings decades of experience to these tasks:

- In addition to academic and consulting positions, Chief Executive Officer Yael Harris formerly served as the Director of the Office of Health Information Technology & Quality at the Health Resources & Services Administration, and also as the Director of the Division of Healthcare Quality in the Office of Disease Prevention & Health Promotion, both within the U.S. Department of Health & Human Services (HHS).
- President and Chief Operating Officer Jason Goldwater began his career at HHS working on issues related to healthcare technology, and has since deepened his expertise through numerous research and consulting positions, including as a Senior Director for the National Quality Forum, a national nonprofit that develops widely used healthcare quality standards.

In these positions, we have led national efforts to develop measures to assess telehealth quality and access to medical services. Most recently, we

[1] No counsel for a party authored any portion of this brief, nor did any party or their counsel make a monetary contribution intended to fund the preparation of this brief. All parties have consented to the filing of this amicus brief.

completed a cost-benefit study on the use of telehealth during the COVID-19 pandemic, which has been presented to Congress and the White House.

Our interest in this case pertains to the challenged state laws that restrict the use of telehealth technologies in connection with certain medical services. In this brief, we aim to supplement the Court's understanding of telehealth in general, including the important role that telehealth plays in enhancing healthcare access, quality, and efficiency. Any decision regarding the use of telehealth in a specific scenario—as a matter of law or as a matter of clinical appropriateness—should take into account the growing acceptance of telehealth as part of the standard of care in the American healthcare system.

SUMMARY OF ARGUMENT

Telehealth is quickly becoming part of the standard of care in the United States. As it has become increasingly common for patients and providers to communicate by virtual means, a growing evidence base demonstrates that most healthcare services can be delivered safely and effectively by telehealth (also called "telemedicine"), including hybrid approaches that combine virtual and in-person visits. Accompanying these objective metrics are survey results showing that patients and providers are highly satisfied with their telehealth encounters. Telehealth thus provides a crucial opportunity to expand access to healthcare services—particularly in rural areas and other underserved communities—by allowing patients to meet with specialists through real-time video consultations that take place in their homes or nearby clinic locations.

Indiana is one of many states that promote the use of telehealth through "parity" laws that equalize healthcare coverage across telehealth and in-person service settings, as well as professional practice standards that make existing patient protections applicable to the digital domain.[2] And like all states, Indiana further liberalized its telehealth laws in response to the COVID-19 pandemic in order to facilitate the continued provision of healthcare services while minimizing the need for in-person interactions. This natural experiment increased awareness of, and comfort with, telehealth

[2] *See* Ind. Code §§ 27-8-34-6, 25-1-9.5-7, 25-1-9.5-8; *see also Policy Trend Maps*, Ctr. for Connected Health Policy (last visited Nov. 7, 2021), https://www.cchpca.org/policy-trends/.

modalities among consumers, providers, and public officials, and led many states and federal agencies to permanently broaden their telehealth policies.

As with such laws in other states, Indiana's telehealth laws generally apply broadly across healthcare providers, services, and settings. This approach evinces an understanding that, in specific clinical scenarios, decisions about the appropriate use of telehealth are best left to patients and their providers, and should not be micromanaged by health plans or state officials.

ARGUMENT

I. Telehealth Is Now an Established Means of Delivering Healthcare Services.

The past decade has revolutionized the use of virtual communication tools to connect patients and healthcare providers.[3] Progress was proceeding steadily as patients and providers gained awareness of, and comfort with, telehealth technologies, although the overall proportion of telehealth visits remained low, in part because of restrictive coverage and reimbursement policies for telehealth under certain public and private health plans.

[3] *See, e.g.*, AMA Digital Health Research, *Physicians' Motivations and Requirements for Adopting Digital Health: Adoption and Attitudinal Shifts from 2016 to 2019*, Am. Med. Ass'n (AMA) (Feb. 2020), https://www.ama-assn.org/system/files/2020-02/ama-digital-health-study.pdf (finding that, from 2016 to 2019, "adoption of digital tools has grown significantly among all physicians"); Jiani Yu et al., *Population-Level Estimates Of Telemedicine Service Provision Using An All-Payer Claims Database*, 37:12 Health Affairs (Dec. 2018), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05116 (in Minnesota, the number of annual telehealth visits increased by a factor of 7.7 from 2010 to 2015).

After the onset of the COVID-19 pandemic, telehealth utilization surged as patients and providers sought ways to maintain access to services while minimizing the contagion risks inherent in face-to-face interactions. With respect to outpatient services (i.e., services other than those delivered in a hospital, nursing home, or other inpatient/residential institution), telehealth accounted for nearly 15% of total visits during the peak pandemic period in March–April 2020; since summer 2020, the proportion of telehealth outpatient visits has remained steady in the range of 6% to 8.5%.[4] Similarly, a McKinsey study found that, across multiple provider types, the volume of monthly telehealth claims has stabilized at roughly 38 times the average volume before the pandemic.[5] Among patients and providers who used telehealth during the pandemic, significant majorities report a desire to continue using telehealth in the future.[6]

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[4] Ateev Mehrotra et al., *The Impact of COVID-19 on Outpatient Visits in 2020: Visits Remained Stable, Despite a Late Surge in Cases*, Commonwealth Fund (Feb. 22, 2021), https://www.commonwealthfund.org/publications/2021/feb/impact-covid-19-outpatient-visits-2020-visits-stable-despite-late-surge.

[5] Oleg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?*, McKinsey & Co. (July 9, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality.

[6] *Telehealth Impact: Patient Survey Analysis*, COVID-19 Healthcare Coalition (last updated Apr. 11, 2021), https://c19hcc.org/telehealth/patient-survey-analysis/ (Seventy-three percent of patients agree with the statement "I will continue to use telehealth services in the future."); *Telehealth Impact: Physician Survey Analysis*, COVID-19 Healthcare Coalition (last updated Nov. 16, 2020), https://c19hcc.org/telehealth/physician-survey-analysis/ (Sixty-eight percent of healthcare professionals agree with the statement "I am personally motivated to increase use of telehealth in my practice.").

As these data suggest, the pandemic has spurred a permanent change in the attitudes of patients, providers, and policymakers about telehealth's role in America's healthcare delivery system. The rise in telehealth during the pandemic was facilitated by a variety of federal and state policy actions that lifted regulatory barriers and mandated coverage for services delivered via telehealth, and although such actions were initially implemented on a temporary basis, many have since been made permanent, or are being considered as part of longer-term reforms.[7] In Indiana, for example, Governor Holcomb signed legislation on April 20, 2021 that, among other things, significantly expands the range of providers who are able to bill the Medicaid program for telehealth services and guarantees Medicaid patients the right to receive telehealth services in their home (or any other location of their choosing).[8]

II. Telehealth Is an Effective Alternative to In-Person Services for Most Patients in Most Clinical Scenarios.

To ensure quality of care across healthcare settings, Indiana law provides that a practitioner who delivers services via telehealth "shall be held to the same standards of appropriate practice as those standards for health

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[7] *See* JoAnn Volk et al., *States' Actions to Expand Telemedicine Access During COVID-19 and Future Policy Considerations*, Commonwealth Fund (June 23, 2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/jun/states-actions-expand-telemedicine-access-covid-19; Jared Augenstein et al., *Tracking Telehealth COVID-19 Policy Changes*, Manatt Health (Nov. 4, 2021), https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat.

[8] Ind. Pub. Law 85 (Apr. 20, 2021).

care services provided at an in-person setting."[9] Moreover, state law vests each individual practitioner with the power to refuse an employer's directive to provide telehealth services if, in the practitioner's view, the use of telehealth would "negatively impact the patient's health" or "result in a lower standard of care."[10]

These standards are prudent, and are also easily satisfied: The evidence shows that patient outcomes from telehealth-supported services are generally equal to, or better than, the outcomes from in-person services. Moreover, both patients and providers report high levels of satisfaction with telehealth.

A. Telehealth Demonstrates Equal or Improved Quality as Compared to In-Person Care.

A growing body of literature establishes that telehealth provides a safe and effective alternative to in-person visits for many healthcare services. Of course, in-person interaction remains a necessary component for certain services, such as radiological scans, infusion chemotherapy, or surgical procedures. However, for the many services that can be delivered via telehealth consistent with the standard of care, telehealth has been found to result in either equal or improved quality of care for patients.

Telehealth has been studied extensively by the federal Agency for Healthcare Research and Quality (AHRQ), a sub-agency within HHS. In a

[9] Ind. Code § 25-1-9.5-7(a).

[10] Ind. Code § 25-1-9.5-7(e).

2020 report, AHRQ concluded that the "evidence-base for telehealth is strong," with "systematic reviews confirm[ing] that telehealth improves health outcomes, utilization, and cost of care for a host of chronic diseases."[11]

Among those systematic reviews was a 2019 AHRQ-commissioned study in which, after reviewing more than 230 published studies, researchers concluded that telehealth consultations generally produced "either better outcomes or no difference" as compared to in-person care.[12] Notably, the review included high-risk services and settings, demonstrating that telehealth need not be relegated to routine services. For example, the researchers concluded that:

- When emergency medical services personnel respond to a severe heart attack, patient mortality rates are "significantly lower" if "telehealth [is] used to allow an emergency medicine physician or specialist to contribute to patient assessments and decisions about prehospital treatment and transport."[13]

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[11] *Evidence Base Supporting Telehealth*, in *Telediagnosis for Acute Care: Implications for the Quality and Safety of Diagnosis*, Agency for Healthcare Research & Quality (AHRQ) (Aug. 2020), https://www.ahrq.gov/patient-safety/reports/issue-briefs/teledx-2.html.

[12] Annette M. Totten et al., *Telehealth for Acute and Chronic Care Consultations*, Comparative Effectiveness Review No. 216, AHRQ at ii (Apr. 2019), https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-216-telehealth-final-report.pdf.

[13] *Id.* at 73.

- In hospital emergency departments, "specialty remote consultations increase appropriate transfers and admissions while decreasing … the amount of time spent in an emergency department."[14]
- For patients admitted to the intensive care unit (ICU), mortality decreased if they had access to a "remote ICU," meaning an off-site team of intensivists, critical care nurses, and sometimes administrative assistants, who "monitor ICU patients and provide consultation and management assistance."[15]

AHRQ followed up with a 2020 issue brief that focused specifically on the accuracy of diagnoses made by telehealth, and reiterated the "strong evidence base" showing that, particularly for "nonurgent complaints in primary care settings, diagnostic accuracy" appears to be "roughly comparable in telediagnosis versus face-to-face encounters."[16]

As these reviews demonstrate, telehealth is an effective—and sometimes a superior—alternative to in-person visits for a wide range of healthcare services, including diagnostic assessments and remote consultations in high-risk clinical scenarios.

B. Patients and Providers Are Highly Satisfied with Telehealth Technologies.

Numerous research studies document patients' satisfaction with care delivered via telehealth. As compared to in-person services, many patients

[14] *Id.* at 127.

[15] *Id.* at 18.

[16] *Evidence Base Supporting Telehealth,* note 11, above.

report *higher* levels of satisfaction for telehealth because they value the convenience telehealth affords them and the ability to connect with a provider from a private space. In a recent study conducted by the COVID-19 Healthcare Coalition—which includes the American Medical Association and the American Telemedicine Association—researchers surveyed 2,000 people who received services by telehealth during the COVID-19 pandemic. More than 70% of patients reported feeling "confident that [their] health concern could be addressed" during their telehealth visit, feeling a "personal connection with the provider" during the visit, and leaving the visit feeling "very satisfied with the care [they] received."[17] Similarly, in a 2020 survey of Californians, one third of respondents said they were "more satisfied" with their telehealth visits than with in-person healthcare services, with another third reporting that they were "just as satisfied."[18] Some patients continue to prefer in-person visits, of course, which underscores the importance of patient choice: Patients should be permitted to consult with their providers either virtually or in person, as long as the selected medium is both mutually acceptable and clinically appropriate.

Providers, too, recognize that the growing use of telehealth has ushered in positive changes. When the COVID-19 Healthcare Coalition surveyed more

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[17] *Telehealth Impact: Patient Survey Analysis*, note 6, above.

[18] Jen Joynt et al., *Listening to Californians with Low Incomes: Health Care Access, Experiences, and Concerns Since the COVID-19 Pandemic,* Cal. Health Care Foundation (Oct. 8, 2020), https://www.chcf.org/publication/listening-californians-low-incomes/.

than 1,500 healthcare professionals nationwide, more than half reported that "telehealth has improved the satisfaction of [their] work," with another 25% reporting no change in satisfaction.[19] Moreover, nearly 70% of professionals feel "personally motivated to increase use of telehealth" in delivering healthcare services.[20]

These data show that telehealth visits are not only clinically effective, but are also acceptable to—or even preferred by—many patients and healthcare providers.

III. Telehealth Expands Access to Care for Patients.

Because telehealth technologies allow patients and providers to connect remotely, they play a vital role in expanding patients' access to healthcare services, particularly in rural or medically underserved areas, where primary care physicians and specialists are in particularly short supply. In Indiana, nearly one in three people lives in a federally designated Health Professional Shortage Area (HPSA) for primary care physicians,[21] and two in three live in an HPSA for psychiatrists.[22] Telehealth services can alleviate these shortages by reducing the physical maldistribution of providers, allowing patients in

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[19] *Telehealth Impact: Physician Survey Analysis*, note 6, above.

[20] *Id.*

[21] *Primary Care Health Professional Shortage Areas (HPSAs),* Kaiser Family Foundation (last updated Sept. 30, 2020), https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas-hpsas/.

[22] *Mental Health Care Health Professional Shortage Areas (HPSAs)*, Kaiser Family Foundation (last updated Sept. 30, 2020), https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/.

underserved areas to connect with distant practitioners without the need for lengthy patient travel. Depending on the scenario, patients may connect with a provider from their own home, or may travel to a nearby "originating site," such as a local hospital community health clinic, where the telehealth visit can be integrated into the provision of in-person healthcare services.[23]

Even under a hybrid telehealth model, patients may be able to receive all necessary in-person services close to home, while avoiding the need to travel much farther to consult with a distant specialist.[24] For example, in a 2017 study analyzing a hybrid telehealth model within a large rural health system over a period of seven years, researchers found that telehealth visits resulted in 5.3 million fewer miles driven, representing nearly $3 million in avoided travel expenses.[25] Aside from these direct impacts, telehealth also

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[23] *See, e.g.,* Hector E. James, *Pediatric Neurosurgery Telemedicine Clinics: A Model to Provide Care to Geographically Underserved Areas of the United States and Its Territories*, J. Neurosurg. (Dec. 2016), https://doi.org/10.3171/2016.6.PEDS16202 (describing a Georgia clinic that connected local families with a Florida-based pediatric neurosurgery team to confirm diagnoses and discuss treatment options).

[24] *See, e.g.*, Bestsennyy et al., note 5, above ("Near-virtual office visits extend the opportunity for patients to conveniently access care outside a provider's office, by combining virtual access to physician consults with 'near home' sites for testing and immunizations, such as worksite clinics or retail clinics.").

[25] Navjit W. Dullet et al., *Impact of a University-Based Outpatient Telemedicine Program on Time Savings, Travel Costs, and Environmental Pollutants,* Value in Health (Apr. 2017). Similarly, in 2018, the Centers for Medicare & Medicaid Services (CMS) estimated that the availability of telehealth saved Medicare patients approximately $60 million on travel, and projected that those savings would grow to $170 million by 2029. CMS, Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982, 55055 (Nov. 1, 2018).

improves patient access in more indirect ways, by reducing the burdens—such as time away from work, or arranging childcare—that would otherwise come with travel to provider locations.

IV. Telehealth Generates Operational Efficiencies and Positive Economic Benefits.

In addition to the benefits for patient health outcomes and patient access, the literature shows that telehealth has economic benefits for individual providers and for the health system overall.

For smaller and more remote providers, the use of telehealth can reduce the significant expenses associated with staffing primary care physicians and specialists on-site.[26] Moreover, providers report that offering telehealth as an option for patients reduces the number of "no shows," likely due to the increased convenience for patients.[27]

At a system level, the National Committee for Quality Assurance has concluded that telehealth supports providers in maintaining patient health and avoiding costly healthcare services such as hospital readmissions and

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[26] *Policy Brief: Emergency Medical Treatment and Active Labor Act (EMTALA) and Telehealth in Critical Access Hospitals*, Nat'l Rural Health Ass'n (May 2011), https://www.ruralhealth.us/getattachment/Advocate/Policy-Documents/EMATALAandTelehealthinCAHPolicyPaper.pdf.aspx?lang=en-US (noting that it can be a "significant expense" for small rural hospitals to staff an emergency room physician in accordance with federal requirements, and that the physician "may see few patients during their contracted hours of service").

[27] *Taskforce on Telehealth Policy: Findings and Recommendations*, National Committee for Quality Assurance (Sept. 2020), https://www.ncqa.org/programs/data-and-information-technology/telehealth/taskforce-on-telehealth-policy/taskforce-on-telehealth-policy-ttp-findings-and-recommendations/.

emergency department visits.[28] For example, a pre-pandemic study of Medicare claims data found cost savings of 6% by diverting members away from the emergency department through the use of telehealth, in addition to cost savings associated with avoided use of unnecessary imaging, lab tests, and antibiotics.[29] A forthcoming literature review authored by *amicus*'s leadership similarly finds that telehealth results in cost savings for the Medicare and Medicaid programs, with particularly large cost savings in rural counties that have low provider-to-patient ratios.[30]

CONCLUSION

Expanding access to telehealth creates significant benefits for both patients and providers. Virtual care platforms enhance the quality of care, improve access to care, increase patient satisfaction, and support overall health system efficiency. State actions that restrict telehealth access beyond the exigencies of clinical necessity are both unnecessary and unhelpful in advancing a more just and equitable healthcare system.

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[28] *Id.*

[29] *Id.*; *see also* Bestsennyy et al., note 5, above ("Evidence prior to COVID-19 shows that telehealth solutions deployed for chronic populations can improve total cost of care by 2 to 3 percent.").

[30] Jason C. Goldwater & Yael Harris, *A Cost-Benefit Analysis of Telehealth During COVID-19*, Ctr. Telehealth & eHealth Law (forthcoming, Nov. 2021).

November 8, 2021 MANATT, PHELPS & PHILLIPS, LLP

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CERTIFICATE OF COMPLIANCE

This amicus brief complies with this Court's length limitation because it contains **3,048** words, excluding exempted parts of the brief. This brief also complies with this Court's typeface and typestyle requirements because it has been prepared in a proportionally spaced typeface using Microsoft Word in 13-point Century Schoolbook font.

Dated: November 8, 2021 MANATT, PHELPS & PHILLIPS, LLP
By: *s/Benjamin G. Shatz*

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: November 8, 2021 MANATT, PHELPS & PHILLIPS, LLP
By: *s/Bess Hubbard*