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ANNALS OF HEALTH LAW
Advance Directive

THE STUDENT HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The Annals of Health Law and Life Sciences is proud to present the second issue of the thirty-fourth volume of our online, student-written publication, *Advance Directive*. This *Spring 2025 Advance Directive* Issue focuses on trending topics reflecting access to healthcare issues.

The *Spring 2025 Advance Directive* Issue explores a wide variety of topics within the current healthcare framework of United States regarding various restrictions on healthcare and the populations these restrictions affect. Our student authors have also proposed adjustments to the current implementation, legal guidance, and regulatory landscape of healthcare accessibility.

This Issue will examine topics ranging from social determinants of health and HIPAA to tax incentives that can improve accessibility. The articles in this Issue analyze longstanding problems plaguing the United States healthcare industry, showing the persistent disparity in access to healthcare, driven by systemic barriers such as socioeconomic status, geographic location, and institutional bias. The range of topics specifically covered includes: expanding language access, changes in telehealth and telemedicine, antitrust issues, and the expansion of end-of-life care. This wide range of topics exemplifies the diverse legal challenges and systemic barriers confronting access to healthcare in the United States today.

The Annals of Health Law members deserve special recognition for their diligence and commitment in curating the thoughtful articles featured in this Issue. We would like to thank Megan Baumgardner, our *Annals* Editor-in-Chief, for her unwavering leadership and guidance. We would also like to thank and acknowledge our *Annals* Executive Board Members: Alessandra Barbuto, Kayla Bradley, Payton Moore, Rae-Ali Raymond, and Maya Smith for all their hard work. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professors Nadia Sawicki and Charlotte Tschider and Kristin Finn for their insight and dedication.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

Sarah Knoll
Advance Directive Executive Editor
Annals of Health Law
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Incentivizing Equity: A Tax-Based Approach to Expanding Healthcare Access in Underserved Communities

Ramhith Akurati

I. INTRODUCTION

Access to healthcare remains a persistent challenge in the United States, particularly for individuals in rural and low-income communities.[1] Despite numerous legislative efforts, disparities in healthcare access continue to widen due to a combination of financial, geographic, and systemic barriers.[2] While tax incentives have been employed to encourage health insurance coverage and infrastructure investment, these measures often fail to adequately address the underlying issues of provider shortages and high out-of-pocket costs for patients.[3]

Tax policy has historically played a significant role in shaping economic and social outcomes, and a more strategic approach to healthcare-related tax incentives could serve as a powerful mechanism for expanding access to care.[4] However, the current framework of incentives lacks uniformity, effectiveness, and targeted support for both providers and patients in underserved areas.[5] This article argues that a comprehensive tax policy framework, which balances provider incentives, direct patient subsidies, and telehealth infrastructure investment, is essential to reducing healthcare disparities.

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[1] Nambi Ndugga et al., *Disparities in Health and Health Care: 5 Key Questions and Answers*, KFF (Aug 14, 2024), https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/.
[2] Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, 123 TRANSACTIONS OF THE AM. CLINICAL & CLIMATOLOGICAL ASS'N 167, 167–70 (2012).
[3] *See* Nancy De Lew et al., *A Layman's Guide to the U.S. Health Care System*, 14 HEALTH CARE FINANCIAL REV. 151, 152 (1992) (discussing how employer-provided health insurance is encouraged through tax incentives, but having insurance doesn't necessarily limit a patients out-of-pocket health expenses).
[4] Mahdi Kooshkebaghi et al., *Explaining Specific Taxes Management and Use in the Health Sector; a Qualitative Study*, 22 BMC HEALTH SERV. RSCH. 1 (2022).
[5] John D. Colombo, *Federal and State Tax Exemption Policy, Medical Debt and Healthcare for the Poor*, 51 ST. LOUIS U. L. J. 433 (2007).

Part II provides a background on existing tax incentives related to healthcare and their intended impact. Part III identifies key deficiencies in these policies, including their fragmented nature, limited reach, and inability to address provider shortages and patient affordability. Parts IV and V propose a new tax policy framework, including how to implement the tax incentives to address these shortcomings, as well as the future impacts of the proposed solution. Finally, Part VI discusses the potential limitations of this approach and how, despite these barriers, the proposal should still be implemented.

II. HISTORY OF TAX CREDITS IN HEALTHCARE

Tax incentives have long been used as a mechanism to influence economic and social policies, including those related to healthcare.[6] In the United States, various tax credits and deductions have been implemented to encourage insurance coverage, healthcare infrastructure investment, and provider participation in underserved areas.[7] However, these incentives often fall short of fully addressing healthcare access disparities.[8]

The Premium Tax Credit ("PTC") was introduced as part of the Affordable Care Act ("ACA") to assist low- and middle-income individuals in purchasing health insurance through the federal and state marketplaces.[9] The PTC reduces the cost of premiums for eligible enrollees based on income

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[6] Robert S. Bromberg, *Financing Healthcare and the Effect of the Tax Law*, 39 L. & CONTEMP. PROBS. 156 (1975).
[7] *Summary of the Affordable Care Act*, KFF (Apr. 25, 2013), https://www.kff.org/affordable-care-act/fact-sheet/summary-of-the-affordable-care-act/.
[8] Douglas M. Mancino, *The Impact of Federal Tax Exemption Standards on Health Care Policy and Delivery*, 15 HEALTH MATRIX 5 (2005).
[9] *Eligibility for the Premium Tax Credit*, INTERNAL REVENUE SERV., https://www.irs.gov/affordable-care-act/individuals-and-families/eligibility-for-the-premium-tax-credit (last visited Jan. 23, 2025).

level and family size.[10] While the credit aims to lower the financial burden of health insurance and increase overall coverage rates among low-income populations, it does not extend to individuals below 100% of the federal poverty level in states that did not expand Medicaid.[11] Moreover, it does not address out-of-pocket expenses such as copays, deductibles, or costs associated with seeking care in areas with provider shortages.[12]

The New Markets Tax Credit ("NMTC") is designed to incentivize private investment in economically distressed communities, including investments in healthcare facilities.[13] Under this program, investors receive a tax credit for investments made in qualifying projects, including hospitals, community health centers, and other medical facilities.[14] While the NMTC encourages the development of healthcare infrastructure in underserved areas by reducing investment risk and increasing financial incentives for private entities, it primarily supports capital investments rather than operational funding.[15] As a result, while infrastructure may improve, the availability of qualified medical professionals and affordable services often remains insufficient.[16]

Several states have implemented tax incentives aimed at addressing provider shortages by offering tax credits or loan repayment assistance to healthcare professionals who practice in designated Health Professional

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[10] *The Premium Tax Credit – The Basics*, INTERNAL REVENUE SERV., https://www.irs.gov/affordable-care-act/individuals-and-families/the-premium-tax-credit-the-basics (last visited Mar. 9, 2025).
[11] *Id.*
[12] *Id.*
[13] *New Markets Tax Credit Program*, U.S. DEP'T OF TREASURY: CMTY. DEV. FIN. INST. FUND, https://www.cdfifund.gov/programs-training/programs/new-markets-tax-credit (last visited, Jan. 23, 2025).
[14] *Id.*
[15] Martin D. Abravanel, *New Markets Tax Credit (NMTC) Program Evaluation*, URBAN INST., 10–11 (April 2013), https://www.cdfifund.gov/sites/cdfi/files/documents/nmtc-program-evaluation-final-report.pdf.
[16] *New Markets Tax Credit Program*, *supra* note 13.

Shortage Areas ("HPSAs") or Medically Underserved Areas ("MUAs").[17] These programs seek to retain healthcare providers in high-need regions by mitigating financial burdens associated with medical education and practice expenses.[18] However, state-level programs are inconsistent and often lack sufficient funding to attract and retain a significant number of providers.[19] Additionally, these incentives are typically time-limited, leading to attrition once the benefits expire.[20]

Overall, while these tax incentives contribute to improved healthcare access, they fail to provide a comprehensive solution. The limitations of these programs highlight the need for a more targeted and integrated tax policy that directly addresses affordability, provider distribution, and infrastructure expansion in underserved communities.

III. PROBLEMS WITH THE CURRENT TAX STRUCTURE

The current tax incentive structure is fragmented and inconsistent, lacking a national, standardized approach to healthcare-related tax incentives.[21] Federal and state programs often operate independently of one another, resulting in a patchwork of policies that vary in scope, eligibility, and effectiveness.[22] Without a cohesive national strategy, disparities in access

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[17] Chase DiMarco, *Tax Incentives for Medical Preceptors: A Complete State-by-State Guide*, FIND A ROTATION (Nov. 26, 2023), https://findarotation.com/tax-incentives-for-medical-preceptors/.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *See e.g., Congress Introduces the Community Health Worker Access Act*, PARTNERS IN HEALTH (Mar. 7, 2024), https://www.pih.org/article/congress-introduces-community-health-worker-access-act.
[22] Colombo, *supra* note 5, at 437.

persist, particularly for individuals in rural and low-income communities where provider shortages and high costs remain significant barriers.[23]

Existing tax incentives primarily focus on insurance premiums, such as the PTC under the ACA, which helps lower insurance costs for some individuals.[24] However, these incentives do little to address out-of-pocket expenses such as copays, deductibles, and prescription medication costs.[25] Many uninsured or underinsured individuals, particularly those in non-Medicaid expansion states, do not benefit from the PTC and face significant financial barriers to accessing care.[26] As a result, having insurance does not always equate to affordable or accessible healthcare.[27]

Additionally, current policies fail to adequately incentivize healthcare providers to practice in HPSA's and MUA's.[28] While some state-level programs offer tax credits or loan repayment assistance for medical professionals working in these areas, these incentives are often insufficient to offset the financial burdens associated with medical education debt and the lower reimbursement rates common in underserved regions.[29] Providers frequently opt for higher-paying positions in urban or well-resourced areas, exacerbating workforce shortages where they are most needed.[30]

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[23] Stacy Becker et al., *Exploring the Potential of Tax Credits Funding Population Health*, NAT'L ACAD. OF MED. (Sept. 24, 2018), https://nam.edu/wp-content/uploads/2018/09/Exploring-the-Potential-of-tax-credits-for-funding-population-health.pdf.
[24] *Eligibility for the Premium Tax Credit*, *supra* note 9.
[25] Marketplace Affordability Project, *Building on the Affordable Care Act: Strategies to Address Marketplace Enrollees' Cost Challenges*, CTR. ON BUDGET & POL'Y PRIORITIES (Apr. 10, 2024), https://www.cbpp.org/research/health/building-on-the-affordable-care-act-strategies-to-address-marketplace-enrollees.
[26] *Id.*
[27] *Id.*
[28] Christopher Brunt, *Health Professional Shortage Area Bonus Payments and Access to Care Under Medicare*, SSRN (Apr. 23, 2024), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4538753.
[29] *Id.*
[30] *Id.*

Furthermore, there is a lack of tax incentives targeted at telehealth expansion and mobile healthcare units, leaving critical gaps in infrastructure investment.[31] The COVID-19 pandemic demonstrated the value of telehealth in reaching remote and underserved populations, yet tax policies have not been updated to fully support its integration into the healthcare system.[32] Investments in broadband expansion, telehealth technology, and mobile clinics remain limited, restricting the ability of rural and low-income communities to access timely and specialized medical care.[33] Without financial incentives to support these initiatives, many healthcare providers and organizations lack the resources to implement sustainable telehealth solutions.[34]

The failure of existing tax policies to provide comprehensive solutions to these issues underscores the need for a more integrated and targeted approach. A restructured tax incentive framework must address both financial and geographic barriers to care by focusing on direct patient support, provider incentives, and infrastructure development. Without such reforms, the healthcare access gap will continue to widen, disproportionately affecting those who are already most vulnerable.[35]

IV. NEW TAX FRAMEWORK

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[31] *See e.g., IRS Outlines Changes to Health Care Spending Available Under CARES Act*, INTERNAL REVENUE SERV. (June 17, 2020), https://www.irs.gov/newsroom/irs-outlines-changes-to-health-care-spending-available-under-cares-act (describing how a change to allow telehealth services to be covered under a high deductible health care plan ended in 2024).

[32] Julia Shaver, *The State of Telehealth Before and After the COVID-19 Pandemic*, 49 PRIMARY CARE 517 (2022).

[33] *Id.*

[34] *Id.*

[35] *Health Access in Rural Communities*, RURAL HEALTH INFO. HUB, https://www.ruralhealthinfo.org/topics/healthcare-access (last visited Jan. 23, 2025).

This tax proposal introduces four distinct tax credits that together form a comprehensive framework to address healthcare access disparities. These credits—targeting healthcare providers, low-income patients, telehealth infrastructure, and private-sector investments—work together to reduce financial and geographic barriers to healthcare.[36] By implementing these incentives, the federal government would foster a more equitable healthcare system, encouraging healthcare professionals to serve in underserved areas, support patients in need, enhance digital health infrastructure, and stimulate private investment in public health initiatives.[37] This multi-faceted approach is designed to address the complexities of healthcare access while promoting long-term, sustainable improvements in public health.[38]

First, a new Access to Care Tax Credit ("ACTC") should be implemented through federal legislation to directly incentivize healthcare providers to practice in underserved areas. This refundable tax credit would be available to healthcare professionals who commit to serving in HPSAs or MUAs, with additional incentives for those in high-need specialties such as mental health and maternal care. Providers must serve a minimum percentage of Medicaid, uninsured, or low-income patients to qualify, and compliance would be tracked through state Medicaid agencies. Enacting this tax credit through legislation ensures a consistent, enforceable framework that encourages long-term provider commitment to these areas. By structuring these incentives within the tax code, Congress can create a reliable funding mechanism that reduces provider shortages and improves healthcare access in underserved regions.

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[36] Till Barnighausen & David E. Bloom, *Financial Incentives for Return of Service to Underserved Areas: A Systemic Review*, 9 BMC HEALTH SERVS. RESEARCH 1 (2009).
[37] *Id.*
[38] *Id.*

Additionally, a refundable tax credit should be introduced for low-income patients to help cover the costs of telehealth visits, preventive care, and prescription medications. This credit would be applied directly at the point of care through digital vouchers, reducing financial barriers and encouraging the use of essential healthcare services. Legislative action would be required to integrate this program within the existing tax infrastructure, ensuring that it is accessible to eligible individuals and efficiently administered by federal and state agencies. This action would involve amending the Internal Revenue Code to authorize refundable tax credits for eligible healthcare expenses, establishing guidelines for digital voucher issuance and redemption, and directing the IRS and HHS to coordinate on oversight and enforcement. Additionally, Congress would need to allocate funding to support the administrative framework, ensuring seamless implementation and preventing fraud. By tying financial relief directly to healthcare utilization, this tax credit would promote preventive care, reduce emergency room visits, and lower overall healthcare costs.

To further enhance healthcare access, a Telehealth and Infrastructure Investment Credit should be established through federal law to incentivize healthcare organizations investing in telehealth infrastructure, mobile clinics, and rural broadband expansion for healthcare purposes. This credit would be administered through HHS in collaboration with the IRS. HHS would be responsible for determining eligibility criteria, verifying provider and patient participation, and ensuring compliance with healthcare regulations. The IRS would oversee the financial aspects, including processing tax credits, issuing digital vouchers, and conducting audits to prevent fraud or misuse. The two agencies would coordinate through data-sharing agreements and joint oversight mechanisms to streamline implementation, ensuring that funds are properly allocated and that the program effectively expands healthcare access

in underserved communities. By incorporating these incentives into federal legislation, the government can provide long-term financial support to expand healthcare access beyond traditional brick-and-mortar facilities. This policy would directly encourage investment in digital health solutions by offering targeted tax credits to healthcare organizations, technology providers, and infrastructure developers that expand telemedicine services, implement remote patient monitoring, and improve broadband access in underserved areas. By reducing the financial burden associated with adopting these technologies, the tax incentives would make it more feasible for healthcare providers to integrate digital tools into their practice, ultimately increasing provider reach and improving patient accessibility in remote and underserved regions.

Finally, tax benefits should be offered to private companies that fund community health initiatives or develop healthcare-related employee volunteer programs. These incentives would encourage private-sector investment in public health, with oversight from HHS to ensure that participating organizations meet measurable community health improvement standards. Implementing these policies through tax legislation would establish a framework that fosters collaboration between the public and private sectors, utilizing financial incentives to encourage meaningful healthcare improvements. By structuring tax benefits around measurable outcomes, this initiative would incentivize continuous private investment in community health programs, leading to long-term improvements in health equity and access.

Through these legislative tax incentives, the federal government can effectively align financial motivation with public health objectives, creating a sustainable system in which providers, patients, and private entities are all incentivized to contribute to expanded healthcare access. These structured

incentives would ensure that financial resources are directed where they are most needed, reducing disparities and fostering long-term improvements in the healthcare system.

V. IMPACT OF PROPOSED TAX CREDITS

The proposed tax credits have the potential to transform healthcare access across the United States by directly addressing disparities in provider distribution, patient access to care, and the overall efficiency of healthcare delivery.[39]

The tax credits will encourage healthcare professionals to serve in areas that have traditionally faced significant healthcare provider shortages.[40] By incentivizing healthcare professionals to practice in underserved areas, the ACTC could significantly reduce the shortage of providers in HPSAs and MUAs, leading to improved access to essential healthcare services for marginalized populations. The targeted incentives, particularly for specialties like mental health and maternal care, will ensure that communities facing the greatest need receive the care they require. Over time, this redistribution of healthcare providers will help balance the availability of healthcare services across both rural and urban settings.

The refundable tax credit for low-income patients will reduce financial barriers to accessing healthcare services. By helping cover costs for telehealth visits, preventive care, and prescription medications, this tax credit will promote the utilization of essential healthcare services, particularly for individuals who may otherwise avoid care due to cost. This, in turn, will lead

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[39] Cinzia Di Nova et al., *Do Healthcare Tax Credits Help Poor-Health Individuals on Low Incomes?*, 19 THE EUR. J. OF HEALTH ECON. 293 (2018).
[40] *Id.*

to better health outcomes by prioritizing preventive care, reducing emergency room visits, and lowering the overall healthcare burden.

With the creation of a Telehealth and Infrastructure Investment Credit, healthcare organizations will be incentivized to expand telehealth capabilities and mobile clinics, particularly in underserved and rural areas. The expansion of telehealth infrastructure, supported by the ACTC, will increase access to healthcare for individuals in remote locations, allowing them to receive consultations, diagnoses, and ongoing care from their homes, reducing the need for travel and improving continuity of care.

By offering tax benefits to private companies that invest in community health initiatives, the incentives will foster stronger collaboration between the public and private sectors. These partnerships will drive meaningful, long-term improvements in community health, particularly in underserved regions. By directing resources into areas that have long struggled with limited access to quality care, the policy will help to establish better healthcare infrastructure, improve provider availability, and increase access to essential services. Over time, this targeted investment will reduce health disparities, allowing underserved populations to receive timely, affordable, and comprehensive care. The framework will provide companies with incentives to invest in sustainable healthcare solutions that improve the overall health landscape, contributing to long-lasting positive outcomes in health equity.[41]

The structured incentives within the tax credit framework will not only address short-term healthcare access challenges but also create a sustainable

[41] Diana Farrell et al., *Deferred Care: How Tax Refunds Enable Healthcare Spending*, JPMORGAN CHASE & CO. INST. (Jan 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3098854.

system for long-term improvements in healthcare access.[42] By ensuring that financial resources are allocated efficiently and tied to measurable outcomes, these tax credits will help ensure that healthcare providers, patients, and private-sector partners continue to contribute to and benefit from an increasingly equitable healthcare system.

In sum, the tax legislation has the potential to significantly improve healthcare access by reducing disparities in provider distribution, encouraging the utilization of essential healthcare services, and fostering private-sector investment in community health initiatives. These combined effects will lead to a more equitable, efficient, and sustainable healthcare system that better serves all populations, especially those facing financial and geographic barriers to care.

VI. POTENTIAL LIMITATIONS

One primary concern is the financial burden on the federal government. Implementing refundable tax credits for healthcare providers, telehealth infrastructure, and patient subsidies would require substantial budget allocations.[43] Policymakers may be hesitant to approve such expenditures, particularly in an era of fiscal restraint and increasing national debt.[44] However, this concern overlooks the long-term cost savings generated by improving healthcare access. Preventive care and early treatment reduce emergency room visits, hospitalizations, and overall healthcare expenditures. Additionally, the structure of these credits ensures that funds are allocated

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[42] Katherine Baicker & Jonathan S. Skinner, *Health Care Spending Growth and the Future of U.S. Tax Rates*, 1 NAT'L BUREAU OF ECON. RSCH. 1 (2011).
[43] Sarah Rosenbaum & Ross Margulies, *Tax-Exempt Hospitals and the Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice*, 126 L. & THE PUB.'S HEALTH 283 (2011).
[44] Mark A. Peterson, *The Ideological and Partisan Polarization of Healthcare Reform and Tax Policy*, 65 TAX L. REV. 627 (2012).

efficiently, targeting providers and patients most in need rather than creating broad spending. By designing the tax credits to be phased in over time and incorporating performance-based metrics, policymakers can mitigate concerns about excessive costs while ensuring maximum impact.

Another challenge is ensuring provider participation in underserved areas. While tax incentives may encourage some healthcare professionals to serve in HPSAs and MUAs, financial incentives alone may not be sufficient to overcome non-monetary deterrents such as inadequate medical infrastructure, high patient loads, and lower quality of life in rural areas. Nevertheless, tax credits for telehealth expansion, mobile clinics, and broadband infrastructure ensure that providers in rural and underserved areas have the resources necessary to deliver high-quality care. Furthermore, the requirement that providers serve a minimum percentage of Medicaid, uninsured, or low-income patients helps create a more predictable patient base, stabilizing revenue and making long-term practice in these areas more viable. Historical data from similar incentive programs, such as the National Health Service Corps, suggest that financial incentives significantly improve provider distribution when combined with infrastructure support and professional development opportunities.[45]

Administrative complexity is also a consideration. Implementing a new tax credit system would require significant coordination between the IRS, HHS, and state Medicaid agencies. However, the IRS and HHS have a long history of administering tax-based healthcare programs, such as the Premium Tax Credit under the Affordable Care Act. Lessons learned from these initiatives provide a roadmap for structuring an efficient and fraud-resistant system. By leveraging existing Medicaid data to track compliance and using

[45] Barnighausen & Bloom, *supra* note 36, at 2.

digital verification methods for patient subsidies, administrative burdens can be minimized. The collaboration between agencies would not require the creation of entirely new systems but rather the enhancement of existing ones, streamlining implementation while maintaining strong oversight.

Finally, while corporate participation in healthcare investment incentives carries the risk of exploitation, properly designed tax benefits with clear requirements and measurable outcomes can drive meaningful contributions to community health. Rather than offering unrestricted tax benefits, the policy would require participating companies to demonstrate verifiable outcomes, such as increased healthcare access in designated areas or quantifiable improvements in patient health metrics. The IRS and HHS can work together to enforce compliance through annual reporting requirements and periodic audits, ensuring that the tax incentives drive genuine improvements rather than serving as unwarranted financial gains for companies.

VII. CONCLUSION

The existing tax incentive structure is inadequate in addressing the pressing issue of healthcare disparities. The proposed tax framework offers a more targeted, comprehensive approach that focuses on provider incentives, direct patient subsidies, and infrastructure investments. By incentivizing healthcare professionals to serve in underserved areas and supporting telehealth and medical infrastructure, this policy can bridge significant access gaps. Additionally, by reducing out-of-pocket costs for patients, it aims to lower financial barriers to care. Through a unified tax incentive system, policymakers can drive healthcare access and equity, ensuring that individuals in both urban and rural communities, regardless of their financial situation, can access the medical care they need. This

framework not only improves the distribution of healthcare providers but also fosters long-term systemic improvements to the healthcare landscape, making it more inclusive and sustainable for future generations.

Bridging the Privacy Gap: Integrating Social Determinants of Health with HIPAA

Philip J. Cramer

I. BUILDING TRUST IN A DATA-DRIVEN HEALTHCARE LANDSCAPE

In today's digital era, information is one of our most valuable assets.[1] Patients' trust in healthcare providers, institutions, and policymakers to protect sensitive information is essential for ensuring effective access to and utilization of healthcare services.[2] When collected and shared carefully and in compliance with regulations, patients' sensitive information can improve patient outcomes, enhance standards of care, and identify public health trends.[3] Today's data-driven healthcare system increasingly relies on nonmedical information, the social determinants of health ("SDOH"), for healthcare-related decisions.[4] Without trust, even well-intentioned initiatives risk being underutilized, especially as SDOH data plays a growing role in decision-making.[5]

The idea that privacy must be sacrificed for innovation overlooks the significant risks of unregulated SDOH data.[6] SDOH data includes any

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[1] Michael P. Goodyear, *Circumscribing the Spider: Trademark Law and the Edge of Data Scraping*, 70 U. KAN. L. REV. 295, 295 (Dec. 2021).
[2] Michael Thiede, *Information and Access to Health Care: Is There a Role For Trust?*, 61(7) SOC. SCI & MED. 1452, 1452, 1457 (Oct. 2005) ("[T]rust is a multi-directional phenomenon.").
[3] *See generally* ST. CATHERINE UNIV., *How Patient Data Can Improve Health Outcomes* (Jan. 7, 2021), https://www.stkate.edu/academics/healthcare-degrees/patient-data-health-outcomes (highlighting that access to comprehensive patient data enhances care, safety, efficiency, and supports improved decision-making); WORLD ECON. F., *How to Harness the Power of Health Data to Improve Patient Outcomes* (Jan. 5, 2024) https://www.weforum.org/stories/2024/01/how-to-harness-health-data-to-improve-patient-outcomes (noting how integrating wearable and health app data with clinical data improves outcomes by identifying health issues early).
[4] *Social Determinants of Health (SDOH)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 17, 2024), https://www.cdc.gov/about/priorities/why-is-addressing-sdoh-important.html; *see also* Anya E. R. Prince, *Location as Health*, 21 HOUS. J. HEALTH L. & POL'Y 43, 54-55 (2021).
[5] *See* Thiede, *supra* note 2 at 1452; *see also* Sarah Wood, *Big Data's Exploitation of Social Determinants of Health: Human Rights Implications*, 22 COLUM. SCI. & TECH. L. REV. 63, 65 (2020) ("[B]ig data analytics are rapidly increasing and are now 'posed to affect every aspect of our lives and environments.'").
[6] W. Nicholson Price II, *Problematic Interactions Between AI and Health Privacy*, 21 UTAH L. REV. 925, 935 (arguing that if health privacy is worth protecting, then there is no reason to limit its application as HIPAA's current regulatory framework does).

information "collected, combined, or analyzed to predict health outcomes of individuals," regardless of whether it is protected, publicly available, or collected commercially, privately, or by the government.[7] Big data analytics aggregates one's lifestyle and life circumstances into predictive tools, making SDOH data as valuable as traditional health data.[8] Despite its growing role in healthcare,[9] SDOH data lacks the privacy protections granted to other sensitive information under the Health Insurance Portability and Accountability Act's ("HIPAA") Privacy Rule.[10] Americans are increasingly skeptical about how their data is handled, and the current regulatory gaps disproportionately impact historically underserved and systemically disadvantaged communities.[11] HIPAA's limitations are well-documented,[12] yet discussions on how SDOH data fits within existing privacy frameworks and the legislative reforms needed to address its gaps remain limited.[13] Although modernizing HIPAA requires multiple updates, this article argues

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[7] Wood, *supra* note 5, at 64-65 (2020) (providing a definition of SDOH data and scope of what it encompasses).
[8] *Id.*
[9] *Id.* at 69 (noting that large amounts of data are needed to link social, economic, and environmental factors to individuals' health, which may be produced in the form of consumer data such as "internet search histories, social networking data, shopping habits, [and] wearable fitness tracker data.").
[10] *See id.* at 81 (noting that U.S. privacy laws take a sectoral approach, failing to uniformly regulate data use across industries and leaving SDOH data vulnerable to aggregation and repurposing by entities outside healthcare).
[11] *See* Brooke Auxier et al., *Americans and Privacy: Concerned, Confused and Feeling Lack of Control Over Their Personal Information*, PEW RSCH. CTR. (Nov. 15, 2019), https://www.pewresearch.org/internet/2019/11/15/americans-and-privacy-concerned-confused-and-feeling-lack-of-control-over-their-personal-information/; *see generally* MARY K. WAKEFIELD ET AL., THE FUTURE OF NURSING 2020-2030: CHARTING A PATH TO ACHIEVE HEALTH EQUITY, 34 (2021) (noting that "historically disadvantaged groups trail dramatically behind others by many measures of health."); *see also Discrimination*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/discrimination (last visited Feb. 14, 2025).
[12] Price II, *supra* note 6, at 935.
[13] Wood, *supra* note 5, at 81 (2022).

that a key step is revising the Privacy Rule to classify SDOH data as protected health information ("PHI").

II. HIPAA'S EVOLUTION IN SAFEGUARDING HEALTH DATA IN A DIGITAL WORLD

Enacted in 1996, HIPAA[14] aimed to improve the efficiency and effectiveness of the U.S. healthcare system.[15] Initially, HIPAA focused on insurance portability, minimizing fraud, and streamlining administrative processes.[16] As healthcare digitized, Congress tasked the Department of Health and Human Services ("HHS") with developing privacy and security standards, initially addressing electronic transactions before expanding to broader privacy and security concerns.[17] These efforts solidified HIPAA as the primary federal framework for patient data protection.[18]

PHI covers any individually identifiable health information ("IIHI") stored or transmitted electronically, in writing, or verbally by covered entities and business associates.[19] PHI includes demographic, genetic, and other data related to an individual's "past, present, or future physical or mental health or condition," healthcare services received, or payment for those services, provided it identifies the person or could reasonably be used to do so.[20] To regulate PHI, the Privacy Rule,[21] published in 2000 and revised in 2003,[22]

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[14] Health Insurance Portability and Accountability Act of 1996, Pub. L. No 104-91, 110 Stat. 1936 (Aug. 21, 1996).
[15] *HIPAA for Professionals*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/ (last updated July 19, 2024).
[16] Steve Alder, *Why is HIPAA Important*, HIPAA J. (Jan. 10, 2025), https://www.hipaajournal.com/why-is-hipaa-important/.
[17] Stever Alder, *HIPAA History*, HIPAA J. (Jan. 2, 2025), https://www.hipaajournal.com/hipaa-history/.
[18] *Id.*
[19] 45 C.F.R. § 160.103 (defining PHI).
[20] *Id.* (defining IIHI).
[21] 45 C.F.R. §§ 164.500-534 (codifying Subpart E–Privacy of IIHI).
[22] Alder, *supra* note 17.

sets national standards for managing PHI access, use, and disclosure.[23] HHS maintains that the Privacy Rule's primary goal is to balance patients' privacy with the need for information sharing to improve healthcare quality and protect public health.[24]

While the Privacy Rule restricts PHI, certain exceptions allow its use and disclosure without patients' authorization for treatment, payment, and healthcare operation activities ("TPO"), as well as public health activities.[25] HHS justifies these exceptions by emphasizing that individuals expect PHI to be used for such "essential" functions and that they minimize barriers to healthcare access, aligning their stated goal of balancing privacy with efficiency.[26] Additionally, HIPAA's "minimum necessary" standard restricts PHI use and disclosure to what is critical for achieving its intended purpose, limiting unwarranted PHI exposure.[27] The Privacy Rule also grants individuals rights over their PHI, including receiving a notice of privacy policies[28] and a log of disclosures,[29] requesting privacy protections,[30]

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[23] *The HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/index.html (last updated Sept. 27, 2024).
[24] *Summary of the HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (last updated Oct. 19, 2022) (underscoring the Privacy Rule's goal "to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the [public] . . . .").
[25] 45 C.F.R. §§ 164.506(c), 512(b) (codifying TPO activities and the public health activities exception).
[26] *Uses and Disclosures for Treatment, Payment, and Health Care Operations*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html (last updated July 26, 2013).
[27] 45 C.F.R. §§ 164.502(b), 514(d) (defining the minimum necessary standard).
[28] 45 C.F.R. § 164.520 (codifying the requirement to provide a notice of privacy practices for PHI).
[29] 45 C.F.R. § 164.528 (codifying the right for an individual to receive an accounting of disclosures of their PHI).
[30] 45 C.F.R. § 164.522(a) (codifying the right for an individual to request privacy protections for PHI).

accessing[31] and amending[32] records, and filing complaints with HHS for alleged HIPAA violations.[33]

Since 2003, HIPAA has expanded to address security and enforcement gaps. The 2005 Security Rule[34] introduced administrative, physical, and technical measures for securing electronic PHI ("ePHI"), allowing flexibility for entities' varying structures and capabilities.[35] The 2009 HITECH Act[36] strengthened HIPAA by incentivizing electronic health record ("EHR") systems' implementation, raising noncompliance penalties, and expanding business associates' oversight.[37] It also introduced the Breach Notification Rule,[38] requiring HIPAA-regulated entities to report data breaches.[39] Together, HIPAA's updates are the "federal floor" for patient data protection.[40]

III. THE PRIVACY LOOPHOLE: HOW SDOH DATA ELUDES HIPAA PROTECTIONS

Despite recent reforms, HIPAA has failed to keep pace with the evolving health information landscape, leaving critical privacy gaps as SDOH data use

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[31] 45 C.F.R. § 164.524 (codifying the right of an individual to access their PHI).
[32] 45 C.F.R. § 164.526 (codifying the right of an individual to correct their PHI).
[33] 45 C.F.R. § 160.306 (codifying the right of an individual to file a complaint with HHS).
[34] 45 C.F.R. §§ 164.302-318 (codifying Subpart C–Security Standards for the Protection of ePHI).
[35] *Summary of the HIPAA Security Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html (last updated Dec. 30, 2024).
[36] Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009).
[37] Steve Alder, *What is the HITECH Act?*, HIPAA J. (Jan. 2, 2025), https://www.hipaajournal.com/what-is-the-hitech-act/.
[38] 45 C.F.R. §§ 164.400-414 (codifying Subpart D – Breach Notification of Unsecured PHI).
[39] *Breach Notification Rule*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html (last updated July 26, 2013).
[40] *HIPAA for Professionals*, *supra* note 15; *U.S. Privacy Laws*, ELEC. PRIV. INFO. CTR., https://epic.org/issues/privacy-laws/united-states/ (last accessed Feb. 14, 2025) ("HIPAA . . . provides the 'federal floor' of privacy protection for health information in the United States, while allowing more protective state laws to continue in force.").

expands beyond its regulatory scope. Modern research underscores SDOH's significance as direct medical care accounts for 10-20% of an individual's health outcomes, while SDOH influences 80-90%.[41] Despite this, the U.S. prioritizes spending on traditional medical care over social services, leading to worse health outcomes than countries that spend more on addressing SDOH.[42]

SDOH refers to the nonmedical factors influencing health outcomes and is commonly organized between economic conditions, education, healthcare availability, living environments, and social factors.[43] Addressing SDOH involves ensuring safe housing, reliable transportation, clean air and water, access to a nutritious diet, and opportunities for physical activity.[44] Although SDOH data is typically collected by providers regulated by HIPAA, financial institutions, social media platforms, and other data brokers have begun aggregating and analyzing SDOH data to predict health outcomes, assess risk, and influence healthcare and insurance decisions.[45] This is particularly

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[41] Sanne Magnan, *Social Determinants of Health 101 for Health Care: Five Plus Five*, NAT'L ACAD. OF MED. (Oct. 9, 2017) https://nam.edu/social-determinants-of-health-101-for-health-care-five-plus-five/; *see generally* Ashish K. Jha, *Tackling the Social Determinants of Health: Small Steps on a Long Journey*, JAMA FORUM (Jan. 27, 2016), https://jamanetwork.com/channels/health-forum/fullarticle/2760185 (demonstrating that discussions about SDOH's impact on health outcomes date back to 1848 when "German physician Rudolf Virchow, the father of modern pathology, wrote: 'Do we not always find the diseases of the populace traceable to defects in society?'").

[42] *The Need*, NAT'L CTR. FOR MED.-LEGAL P'SHIP, https://medical-legalpartnership.org/need (last accessed Feb. 13, 2025) (comparing health outcomes in the U.S. where $0.90 is spent on social services for each $1 spent on health care with other first-world countries where $2 is spent on social services for each $1 spent on health care).

[43] *Social Determinants of Health*, WORLD HEALTH ORG., https://www.who.int/health-topics/social-determinants-of-health (last accessed Feb. 13, 2025) (noting that SDOH include the "conditions in which people are born, grow, work, live and age," and the economic, social, and political systems shaping daily life); *Social Determinants of Health (SDOH)*, *supra* note 4.

[44] *Id.*

[45] *Using Z Codes*, CTRS. FOR MEDICAID & MEDICAID SERVS., https://www.cms.gov/files/document/zcodes-infographic.pdf (last accessed Feb. 12, 2025) (noting that health care providers, social workers, community health workers, case managers, and nurses can collect SDOH data); Mona Sobhani, *HIPAA Isn't Enough: All Our*

alarming when studies indicate that social media behavior may provide insight into mental health conditions, and financial data can reveal patterns correlated with chronic disease risks.[46] Therefore, addressing SDOH is critical to advancing health equity, but ensuring the privacy and responsible use of SDOH data must be considered simultaneously.

The Privacy Rule defines PHI based on *who* manages the information and the *nature* of the data collected.[47] Unfortunately, the privacy protections afforded to individuals and their right to control their health data are "largely illusory given the many possible avenues of compromise."[48] This reality is demonstrated by the fact that the Privacy Rule and HIPAA's other regulations only apply to covered entities and business associates, resulting in many health data collectors falling outside HIPAA's jurisdiction.[49] This gap was even acknowledged in the Privacy Rule's legislative history, where "HHS felt it lacked jurisdiction to regulate downstream uses of PHI by non-HIPAA-regulated data recipients."[50]

Data is Health Data, U.S.C. CTR. FOR BODY COMPUTING (Jan. 29, 2019), https://cbc.ict.usc.edu/un-sensored/hipaaisnotenough/.

[46] Sobhani, *supra* note 45; *see also* Price II, *supra* note 6, at 934-35 (discussing how "the triangulation of health information from non-health data" may result in biased decision-making).

[47] 45 C.F.R. § 160.103 (defining PHI).

[48] Price II, *supra* note 6, at 936.

[49] 45 C.F.R. § 160.103 (defining "covered entities" as health care providers, health plans, and health care clearinghouses and "business associates" as any third-party that handles PHI on behalf of a covered entity); *see also* Stacey A. Tovino, *Artificial Intelligence and the HIPAA Privacy Rule: A Primer*, 24 HOUS. J. HEALTH L. & POL'Y 77, 86-87 (2025) ("[L]eaving many health information collectors, creators, users, and disclosers (including those involved in predictive and generative AI) unregulated.").

[50] Barbara J. Evans, *The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI*, 50 FLA. ST. U.L. REV. 741, 754 (2023) (citing to the Standards for Privacy of IIHI, 64 Fed. Reg. 59918, 59923 (proposed Nov. 3, 1999) (to be codified at 45 C.F.R. pts. 160-164) ("[W]e are . . . faced with creating new regulatory permissions for covered entities to disclose health information, but cannot directly put in place appropriate restrictions on how many likely recipients of such information may use and re-disclose such information.")).

Moreover, HIPAA does not protect the privacy of *all* health information but governs only the use and disclosure of PHI.[51] Therefore, SDOH data collected by non-HIPAA-regulated entities remains unprotected.[52] For example, sensitive health-related information, such as housing stability, employment status, and spending habits, is collected and analyzed without the privacy safeguards applicable to traditional medical records.[53] This issue is exacerbated by the growing use of predictive analytics and AI-driven risk modeling in healthcare, which leverages unregulated SDOH data, without transparency or consent, to assess individuals' health risks and eligibility for coverage.[54] Additionally, algorithmic models can combine datasets to infer or re-identify individuals, further increasing privacy risks.[55] Unlike PHI, patients lack a legal right to access, correct, or restrict their SDOH data, leaving them vulnerable to privacy violations and algorithmic discrimination.

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[51] 45 C.F.R. §§ 164.502-514 (codifying requirements relating to "uses" and "disclosures"); *see* Evans, *supra* note 50, at 754-55 ("[C]alling [HIPAA a] 'privacy law' is a misnomer: for example it does not restrict data collection.").

[52] Sobhani, *supra* note 45; *see generally Social Determinants of Health Database*, AGENCY FOR HEALTHCARE RSCH. & QUALITY, https://www.ahrq.gov/sdoh/data-analytics/sdoh-data.html (last updated June 2023), (providing that the SDOH database compiles information from sources that may not be regulated covered entities, like the U.S. Census Bureau and Environmental Protection Agency); *Your Rights Under HIPAA*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. FOR CIV. RTS., https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html (last reviewed Jan. 19, 2022) (listing examples of organizations not subject to the Privacy and Security Rules).

[53] *See generally Your Health Data and HIPAA*, AM. HEALTH INFO. MGMT. ASSOC., https://ahimafoundation.ahima.org/understanding-the-issues/your-health-data-and-hipaa/ (last updated Feb. 28, 2023) (identifying technology companies, such as Meta and Google, found to collect patient data from covered entitles via data scraping tools like Meta Pixel to enhance targeted advertising); *HUD Research Roadmap FY 2020–FY 2024*, U.S. DEP'T OF HOUS. & URBAN DEV., OFF. OF POL'Y DEV. & RSCH. (Nov. 2020) https://www.huduser.gov/portal/sites/default/files/pdf/Research-Roadmap-2020.pdf (noting that the U.S. Department of Housing and Urban Development administers programs, such as low-rent public housing, assisted multifamily housing, and tenant-based rental assistance, then uses the data to inform policy decisions).

[54] Neel Yadav et al., *Data Privacy in Healthcare: In the Era of Artificial Intelligence*, 14 INDIAN DERMATOLOGY ONLINE J. 788, 789 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10718098/pdf/IDOJ-14-788.pdf.

[55] *Id.*

Although academics and policymakers have extensively proposed HIPAA protections to include digital health data from wearables[56] and mobile apps[57] and alignment with global data privacy frameworks,[58] far less attention has been given to the regulatory gap surrounding SDOH data despite its increasing role in healthcare decision-making. Without appropriate safeguards, SDOH data may be used in healthcare decisions without accountability or recourse. Thus, federal intervention is critically needed to protect privacy and prevent misuse.

IV. MODERNIZING HIPAA TO PROTECT SDOH DATA

Patients deserve the same level of protection for nonmedical health-related data, such as SDOH, as they do for traditional PHI. To address gaps in the Privacy Rule's definition of PHI, HIPAA must be modernized to include SDOH data explicitly. The Privacy Rule defines PHI as IIHI created, received, or maintained by covered entities, which excludes SDOH data, even when directly used to assess an individual's health or inform healthcare decisions.[59] This necessary reform may be implemented by amending PHI's definition to include SDOH, requiring covered entities to comply with HIPAA's privacy and security requirements.

A targeted amendment to the definition of PHI is legislatively feasible for several reasons. First, it aligns with HIPAA's original purpose of protecting sensitive health information. Additionally, it does not expand HIPAA's jurisdiction to *all* SDOH data; it simply ensures that SDOH data is protected when used in health-related contexts. Moreover, bipartisan support exists to

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[56] John T. Katuska, *Wearing Down HIPAA: How Wearable Technologies Erode Privacy Protections*, 44 IOWA J. CORP. L 385, 390 (2018).
[57] *See* Jianyan Fang, *Health Data at Your Fingertips: Federal Regulatory Proposals for Consumer-Generated Mobile Health Data*, 4 GEO. L. TECH. REV. 125, 127 (2019).
[58] Michael L. Rustad & Thomas H. Koenig, *Towards a Global Data Privacy Standard*, 71 FLA. L. REV. 365, 371 (2019).
[59] 45 C.F.R. § 160.103 (defining PHI).

increase privacy protections in healthcare data.[60] Furthermore, policymakers have growing support for drafting more straightforward, single-issue bills.[61]

The proposed amendment could be integrated into the existing IIHI definition, a subset of PHI. The current definition of IIHI is

> information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.[62]

Section (2) could be revised to state that IIHI

> relates to past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, *including where such information incorporates, reflects, or is derived, directly or indirectly, from an individual's social determinants of health* . . . .

Additionally, to provide further clarity, SDOH should be defined separately within the Privacy Rule as

> the nonmedical information about an individual, including but not limited to economic stability, education, health care access, online behaviors, community identifiers, and other environmental factors, that may impact or be used is used in the provision of health care to an individual, such as treatment, payment, operations, underwriting, risk assessment, or predictive modeling.

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[60] Marianne Kolbasuk McGee, *Americans Privacy Rights Bill: Implications for Health Sector*, BANK INFO SEC. (April 12, 2024), https://www.bankinfosecurity.com/american-privacy-rights-bill-implications-for-health-sector-a-24849.
[61] One Bill, One Subject Transparency Act, H.R. 91, 118th Cong. (2023).
[62] 45 C.F.R. § 160.103 (defining IIHI).

By incorporating SDOH data into HIPAA's definition of PHI, the proposed amendment begins to address the loophole allowing non-HIPAA regulated entities to collect, analyze, and use sensitive health-adjacent data without oversight. This reform ensures that housing stability, employment status, financial history, and other SDOH factors are appropriately factored into healthcare decisions. Additionally, covered entities will be encouraged to strengthen oversight and accountability in collecting, sharing, and integrating SDOH data into healthcare operations. This amendment is narrowly tailored to avoid unnecessary regulatory overreach, a concern that HHS raised in developing the Privacy Rule. Moreover, this change expands patients' rights to access, correct, and request restrictions on their SDOH data just as they would with traditional PHI. This results in SDOH data being used responsibly, fairly, and transparently while mitigating the risk of inaccurate or discriminatory data usage. Without this change, SDOH data will continue to be exploited, exacerbating disparities in healthcare while eroding public trust in health systems.

To reinforce the need for this amendment, existing state privacy laws can serve as legal precedents for regulating health-adjacent personal information, like SDOH, and applying it to businesses on a broader scale than HIPAA's covered entities.[63] For example, the California Consumer Privacy Act ("CCPA"), effective in 2020, applies to for-profit businesses that meet specific revenue or customer thresholds and grants consumers rights over their personal information.[64] This includes data "that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably

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[63] *U.S. State Laws*, ELEC. PRIV. INFO. CTR., https://epic.org/issues/privacy-laws/state-laws/ (last accessed Mar. 9, 2025) ("Congress has failed to pass a comprehensive federal privacy law. To fill this void, an increasing number of states have passed laws that aim to protect people's privacy and security.").

[64] *California Consumer Privacy Laws*, BLOOMBERG L., https://pro.bloomberglaw.com/insights/privacy/california-consumer-privacy-laws/ (last accessed Mar. 9, 2025).

be linked, directly or indirectly, with a [specific individual] or [their] household," such as purchase history, internet browsing behavior, and inferences drawn to create consumer profiles.[65] This personal information overlaps with SDOH information collected by non-HIPAA regulated entities, demonstrating how privacy laws can extend beyond the healthcare sector. Similarly, the Virginia Consumer Data Protection Act ("VCDPA"), which took effect in 2023, applies to businesses processing personal data of Virginia residents and defines personal data broadly as any information "linked or reasonably linkable" to an individual."[66] The VCDPA strengthens privacy protections beyond HIPAA by safeguarding sensitive data, including health information, race, ethnicity, religious beliefs, and geolocation data.[67]

While state-level privacy laws like the CCPA and VCDPA establish protections beyond HIPAA and its covered entities, their protections are fragmented and limited primarily to specific jurisdictions. As a result, non-HIPAA regulated entities can still collect, analyze, and monetize SDOH data without uniform oversight or HIPAA protections. To address this, federal intervention may be necessary to prevent commercial misuse of SDOH data beyond healthcare settings.

One such approach would be to expand oversight of federal consumer privacy protections by leveraging the Federal Trade Commission ("FTC"). The FTC has the authority to regulate unfair and deceptive practices in the

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[65] *Id.*; *see also California Consumer Privacy Act (CCPA)*, STATE OF CAL. DEP'T OF JUST. (Mar. 13, 2024), https://oag.ca.gov/privacy/ccpa.
[66] *Virginia Consumer Data Protection Act (VCDPA)*, BLOOMBERG L., https://pro.bloomberglaw.com/insights/privacy/virginia-consumer-data-protection-act-vcdpa/ (last accessed Mar. 9, 2025); *The Virginia Consumer Data Protection Act*, ATT'Y. GEN. OF VA. (Jan. 1, 2023), https://www.oag.state.va.us/consumer-protection/files/tips-and-info/Virginia-Consumer-Data-Protection-Act-Summary-2-2-23.pdf; Va. Code Ann. § 59.1-575.
[67] Va. Code Ann. § 59.1-575.

commercial use of personal data.[68] Thus, the FTC could also be empowered to investigate and enforce privacy violations related to SDOH data collected by non-HIPAA regulated entities. At a minimum, this additional involvement would deter entities from using predictive analytics to draw sensitive health-related inferences from SDOH data without appropriate transparency and consumer consent.

However, FTC enforcement alone cannot fully safeguard SDOH data used in healthcare. While the FTC can help curb misuse of SDOH data in commercial settings, HIPAA-covered entities require clearer regulatory guidance on adequately managing and classifying SDOH data. Without specific safeguards for compliance, covered entities may struggle to determine which SDOH data qualifies as PHI and how to handle it under HIPAA's framework. To ensure regulatory clarity, HHS must establish clear guidelines for the appropriate collection, classification, and use of SDOH data in healthcare.

Several measures may be necessary to integrate SDOH data into HIPAA protections to support implementation and compliance. Most importantly, HHS must issue guidance that helps covered entities accurately identify, classify, and distinguish SDOH data within the revised PHI definition. This can be accomplished efficiently by using an accepted definition of SDOH

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[68] Federal Trade Commission Act, 15 U.S.C. § 45; *see also* Press Release, FED. TRADE COMM'N, *FTC Approves Final Order Settling Charges Against TRENDnet, Inc.* (Feb. 7, 2014) https://www.ftc.gov/news-events/news/press-releases/2014/02/ftc-approves-final-order-settling-charges-against-trendnet-inc/ (marketing internet-connected cameras with inadequate security, leading to unauthorized access of private video feeds was deemed unfair and deceptive by the FTC); Press Release, FED. TRADE COMM'N, *Gateway Learning Settles FTC Privacy Charges* (July 7, 2004) https://www.ftc.gov/news-events/news/press-releases/2004/07/gateway-learning-settles-ftc-privacy-charges/ (changing a privacy policy without notice, resulting in unauthorized sharing, was deemed unfair and deceptive by the FTC).

that is already organized into distinct domains: financial security, educational opportunities, healthcare access, living conditions, and social connections.[69]

Concrete examples should follow these domains to illustrate what constitutes SDOH data. For example, financial security includes employment status and income level, educational opportunities include literacy levels and access to quality early childhood education, healthcare access includes transportation and availability of primary care providers, and living conditions include housing stability. Social connections are the most challenging domain to define due to varying personal experiences. However, existing data points, such as household size for family support networks, the existence and participation of community or religious groups, and experiences of discrimination, should serve as sufficient examples.

HHS should also include explicit examples of what is *not* SDOH to assist with classifying SDOH data. For instance, individuals' behaviors, like smoking or diet, natural environmental factors, like the seasons, and medical conditions, may be influenced by SDOH but are not themselves determinants. Additionally, data points used in big data analytics to predict personal preferences should not automatically qualify as SDOH unless explicitly relied upon in healthcare decision-making or directly linked to health outcomes. Without clear limitations, nearly any data source could be reinterpreted as SDOH, creating compliance uncertainty for covered entities. Clear parameters will ensure that only data directly linked to healthcare access, outcomes, or risks is classified as SDOH, preventing regulatory confusion and unintended data restrictions. This safeguard will help covered entities focus on data that meaningfully impacts health while avoiding overreach into unrelated personal information.

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[69] *Social Determinants of Health*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health (last visited Feb. 14, 2025).

To aid in implementing the proposed amendments to HIPAA, HHS can develop a decision-making framework for covered entities. This could be similar to HHS's "General Rules" for the Security Rule, which outlines requirements and provides direct references to the regulations.[70] The framework should offer a structured process for legal and compliance teams to evaluate data based on its relevance to health outcomes, its collection by covered entities, and its role in healthcare decision-making. This structured process could incorporate practical tools, such as decision trees or checklists, to support systematic evaluation and documentation of whether specific data aligns with regulatory standards and healthcare objectives. Additionally, the framework should outline clear steps for maintaining compliance, including updating Notices of Privacy Practices, revising Business Associate Agreements, and implementing internal audit policies to monitor the use of SDOH data.

A tiered classification system could further streamline compliance by distinguishing between different types of SDOH data. Commonly accepted SDOH data, like housing instability recorded during patient intake, should automatically qualify as PHI for immediate protection under HIPAA. Less direct indicators, such as consumer purchasing history, should require further assessment based on context, usage, and whether they inform healthcare decisions. This approach would give covered entities a structured, risk-based method to determine SDOH classification while reducing unnecessary compliance burdens.

While these measures would significantly improve HIPAA's ability to regulate SDOH data, they would not fully address the broader issue of SDOH data privacy outside the healthcare system. A longer-term solution would require an entirely new, comprehensive federal privacy law to regulate the

[70] *Summary of the HIPAA Security Rule*, *supra* note 35.

use of SDOH data beyond HIPAA-covered entities. If proposed, it should be similarly modeled after existing state laws like the CCPA and VCDPA that guided the HIPAA amendments proposed above. A comprehensive federal law should also require companies outside the healthcare sector to obtain explicit consent before collecting or sharing SDOH data and impose restrictions on how it is used for profiling, risk assessment, or targeted advertising. This requirement would ensure that privacy protections extend beyond HIPAA-covered entities and apply to any organization processing SDOH data for commercial purposes. Passing a standalone bill may be too difficult due to the significant time, political negotiation, and financial investment required. Alternatively, this reform could be integrated into broader health data privacy legislation or included in future expansions of HIPAA, like the HITECH Act.[71] However, this article's proposal does not attempt to create a comprehensive federal privacy law because such an effort may be too inefficient. Strengthening HIPAA's current framework offers an immediate and feasible solution to protect SDOH data in healthcare settings.

While classifying SDOH data as PHI is a critical first step, it is not the only step needed to strengthen health privacy protections.[72] Additional safeguards, such as requiring explicit patient authorization or heightened informed consent for using and disclosing SDOH data, would further protect patient autonomy and prevent misuse.[73] However, integrating SDOH into

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[71] Alder, *supra* note 37 ("The Health Information Technology for Economic and Clinical Health Act or HITECH Act is the part of the American Recovery and Reinvestment Act of 2009 that . . . strengthened the privacy and security provisions of HIPAA. . . . The major components of the HITECH Act are the . . . provisions that were subsequently integrated into HIPAA.").

[72] Price II, *supra* note 6, at 936 ("Tinkering with HIPAA to smooth out its inequalities and patchiness is a first step, but only a first step.").

[73] *See generally* Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 821, 823 (2016) (discussing nonmedical information as material to a patient's diagnosis and treatment in the context of a physician securing informed consent).

HIPAA's protections maintains alignment with the regulation's original intent to protect patient privacy while ensuring responsible, efficient, and effective use of the data in healthcare.[74]

Despite the benefits of integrating SDOH into HIPAA, some critics argue that expanding PHI's definition is impractical because it will lead to a continuous, never-ending cycle of "whack-a-mole" as data analytics extract health insights from unconventional sources "that were once unimaginable," such as social media.[75] While this concern is valid, this amendment does not attempt to capture all possible future data sources or require an exhaustive, ever-expanding definition of PHI. Instead, it targets a specific, identifiable problem: the unregulated use of SDOH data in healthcare decision-making.

V. A PATH TO TRUSTWORTHY DATA USE IN HEALTHCARE

As healthcare decision-making becomes increasingly data-driven, SDOH data plays a crucial role in predicting health outcomes, assessing risk, and shaping coverage decisions. Yet, this highly sensitive data remains unprotected under HIPAA's existing framework, leaving patients vulnerable to privacy violations and discrimination.

Modernizing HIPAA to include SDOH data is a critical first step in closing privacy gaps, expanding protections, and giving patients greater control over data that is as personal and influential as traditional health information. However, HIPAA reform alone is not enough. A broader regulatory strategy is needed to ensure privacy protections extend across industries, safeguard SDOH data within healthcare, and prevent exploitation by non-HIPAA regulated entities. As the healthcare landscape evolves, keeping HIPAA

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[74] *Summary of the HIPAA Privacy Rule*, *supra* note 24.
[75] James Stramm, *Responding to the Digital Health Revolution*, 28 RICH. J.L. & TECH. 86, 133 (2021).

aligned with modern privacy challenges is essential to preserving both innovation and patient trust.

Cross-Border Chaos: The Ethical Dilemma of Global Clinical Trials in the Absence of an International Data Privacy Framework

Hannah Dawson

I. INTRODUCTION: THE PRIVACY PITFALL – ETHICS AND CHAOS IN GLOBAL CLINICAL TRIALS

Global clinical trials comprise an industry worth billions of dollars that has experienced tremendous growth and transformation in recent years.[1] One notable recent transformation within this industry is a rising trend toward decentralized clinical trials.[2] In the traditional centralized model, study participants travel to a central location for in-person appointments at which the data is manually collected.[3] Decentralized trials, on the other hand, represent a digital shift in which study participants use technology to participate remotely regardless of their physical location.[4] Despite some benefits, this shift away from the traditional centralized model presents many risks and challenges, particularly from data privacy and protection perspective at the international scale. Regulation in this international context

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[1] *See U.S. Clinical Trials Industry is Rising Rapidly USD 35.1 BN by 2030*, BIOSPACE (Oct. 19, 2023), https://www.biospace.com/u-s-clinical-trials-industry-is-rising-rapidly-usd-35-1-bn-by-2030 (valuing the U.S. clinical trial market size at 23.83 billion USD in 2022, which is prediction to surpass 35.1 billion USD by 2030); *Clinical Trials Market Size to Increase USD 153.59 Billion by 2033*, BIOSPACE (Apr. 9, 2024), https://www.biospace.com/clinical-trials-market-size-to-increase-usd-153-59-billion-by-2033 (estimating the global clinical trial market at 81.90 billion USD in 2023, with a projected increase to 153.59 billion USD by 2033) (hereinafter "Global Clinical Trial Market Value").

[2] *See* Global Clinical Trial Market Value, *supra* note **Error! Bookmark not defined.** ("Data management segment held a significant share in 2023 and is anticipated to show a similar trend over the forecasted period. The segment growth is…coupled with a growing trend towards decentralized trials.").

[3] *Decentralized Clinical Trials (DCT)*, ORACLE, https://www.oracle.com/life-sciences/clinical-trials/decentralized-clinical-trials/#rc30p1 (last accessed Mar. 9, 2025); *see also Centralized or Decentralized Clinical Trials? Exploring the Pros and Cons*, OXIMIO, https://oximio.com/resources/centralized-or-decentralized-clinical-trials-exploring-the-pros-and-cons/ (last accessed Mar. 9, 2025) (discussing the challenges of centralized trials and decentralized trials).

[4] ORACLE, *supra* note 3; *see also What Are Decentralized Clinical Trials*, MEDRIO (May 24, 2024), https://medrio.com/blog/what-are-decentralized-clinical-trials/ (discussing benefits of decentralized clinical trials, in addition to challenges such as data security and privacy concerns and data management).

is by no means uniform; rather, global clinical trials must comply with the varying data protection laws of every country in which the trial is being conducted—under the decentralized model, this means every country in which a study participant is located.[5] This quickly becomes complicated when the laws vary in scope and levels of restriction from country to country.[6] Such inconsistencies and increasingly restrictive data protection laws have started to have an impact on the administration of clinical trials – particularly *where* such trials are conducted.[7]

According to a recent 2022 study, there has been a significant increase in movement of clinical trials to developing countries with lower levels of data protection and regulatory oversight.[8] This increased movement of clinical trials to developing countries creates a tension between health equity and a potential for exploitation.[9] On one hand, the administration of clinical trials can help to promote new medical advancements and increase access to

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[5] *See* JÉRÔME ARMELLINI ET AL., SEIZING OPPORTUNITIES: OVERCOMING THE CHALLENGES OF DECENTRALIZED CLINICAL TRIALS IN ASIA PACIFIC 7 (IQVIA, Inc. 2023) ("Confidentiality, data privacy and security play a critical role in [decentralized clinical trials] and it is vital to comply with the varying data protection laws across countries.").

[6] *See, e.g.*, Mallory Acheson, *Data Privacy Laws and Clinical Trials: The Complicated Intersection of Protecting Patient Data and Clinical Research*, NELSON MULLINS (Jan. 24, 2023), https://www.nelsonmullins.com/insights/alerts/privacy_and_data_security_alert/all/data-privacy-laws-and-clinical-trials-the-complicated-intersection-of-protecting-patient-data-and-clinical-research (discussing application of the United States' Health Insurance Portability and Accountability Act (HIPAA) and the European Union's General Data Protection Regulation (GDPR) to clinical research; generally speaking, the GDPR is broader in scope compared to the HIPAA); *China's Personal Information Protection Law (PIPL)*, U.C. IRVINE OFFICE RSCH.: HUM. RSCH. PROTS. (Mar. 9, 2022), https://news.research.uci.edu/irb-hrp/chinas-personal-information-protection-law-pipl/ [hereinafter *China's PIPL*] (discussing application of China's Personal Information Protection Law (PIPL) to research settings, indicating that it is "similar but more stringent than" the E.U.'s GDPR).

[7] *See generally* Elad Yom-Tov & Yishai Ofran, *Implementation of Data Protection Laws in the European Union and in California is Associated with a Move of Clinical Trials to Countries with Fewer Data Protections*, FRONTIERS MED., Nov. 9, 2022. (discussing findings from a study conducted in 2022 which suggested that the implementation of stricter data protection laws in the European Union is associated with a move of clinical trials to countries with fewer data protections).

[8] *Id.* at 8.

[9] Katrin Weigmann, *The Ethics of Global Clinical Trials*, 16 EMBO REP. 566, 566 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4428044/pdf/embr0016-0566.pdf.

healthcare in the communities in which they are hosted.[10] On the other hand, however, less regulatory oversight enables study sponsors to evade important requirements such as informed consent.[11] As a potential remedy to strike the balance, this article proposes the implementation of a binding international treaty overseen by a global body that would mandate uniform data protection standards across jurisdictions.

II. BACKGROUND ON THE CURRENT LANDSCAPE OF GLOBAL CLINICAL TRIALS: A COMPLEX WEB OF INCONSISTENT DATA PROTECTION LAWS

Clinical trials are an important mechanism within the healthcare industry, as they involve strict oversight of the testing of the safety and efficacy of different medical interventions before they can be made available on the market.[12] There is currently no uniform binding international regulatory framework that provides guidance regarding data privacy considerations in global clinical trials.[13] Instead, the current landscape resembles that of a minefield in which a global trial must take care to comply with all of the data protection laws of the countries in which it is being held.[14] Depending on the jurisdiction, it can be vital to define both the data being collected and the entity collecting the data in order to discern whether a particular data protection law applies.[15]

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[10] *Id.*
[11] *Id.*
[12] *Step 3: Clinical Research*, FOOD & DRUG ADMIN. (last updated Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research.
[13] *See* Weigmann, *supra* note 9, at 567 (mentioning *moral* guidelines for conducting research in international settings, but noting that they are not legally binding).
[14] Abigail Beaney, *Lack of Consistency with Data Protection Poses Pain Point For Biotechs and Sponsors*, CLINICAL TRIALS ARENA (Jan. 29, 2024), https://www.clinicaltrialsarena.com/features/data-protection-laws-difficult-multi-country-trials/?cf-view.
[15] *See* Acheson, *supra* note 6 (discussing the importance of defining roles and data collected in assessing the application of HIPAA and the GDPR in clinical research).

The term "study sponsor" refers to the entity—most often, a pharmaceutical company—that funds the clinical trial.[16] Generally, study sponsors have four main responsibilities: selection of qualified investigators, provision of study protocols and subsequent updates, ongoing monitoring and review of the study, and record maintenance.[17] The study sponsor can also play a role in the selection of study sites.[18] Investigators, unlike study sponsors, operate more at the patient level. They are the individuals who are responsible for the administration of the study drug to the study volunteers and maintain case histories for each participant.[19] In some jurisdictions, the distinction between investigator and sponsor is important as only one falls within the scope of the relevant data protection laws.[20] Other jurisdictions, however, do not make such a distinction.[21] Clinical trials tend to generate high volumes of collected data – a trend that is only expected to rise as study protocols become more complex and more data sources become available.[22] The type of data collected varies from study to study, however, it typically

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[16] *Meet the Clinical Trial Team: The Clinical Trial Sponsor*, METASTATIC TRIAL TALK (July 3, 2023), https://metastatictrialtalk.org/inside-clinical-trials/clinical-trial-sponsor/.
[17] J. Mark Waxman, *The Difference Between Sponsors and Investigators*, RELIAS MEDIA (Oct. 1, 2001), https://www.reliasmedia.com/articles/119153-the-difference-between-sponsors-and-investigators.
[18] *Id.*; Elizabeth Weeks-Rowe, *The Art of Investigational Site Relationships with Sponsors/CROs*, ACRP (Apr. 12, 2024), https://acrpnet.org/2024/04/12/the-art-of-investigational-site-relationships-with-sponsors-cros.
[19] Waxman, *supra* note 17.
[20] *See, e.g.*, *When is a Researcher Considered to be a Covered Health Care Provider Under HIPAA?*, U.S. DEP'T HUMAN & HEALTH SERVS., https://www.hhs.gov/hipaa/for-professionals/faq/314/when-is-a-researcher-considered-a-covered-health-care-provider-under-hipaa/index.html [hereinafter *Researcher Under HIPAA*](last revised Nov. 27, 2007) (indicating that investigators fall within the scope of the U.S.'s HIPAA and thus must comply with its requirements); Acheson, *supra* note 6 (indicating that sponsors do not fall within the scope of HIPAA).
[21] *See, e.g.*, *The GDPR and Its Impact on the Clinical Research Community (Including Non-EU Researchers)*, ADVARRA (May 24, 2018), https://www.advarra.com/blog/the-gdpr-and-its-impact-on-the-clinical-research-community-including-non-eu-researchers/ (indicating that sponsors fall within the GDPR's scope, contrary to HIPAA).
[22] Todd Johnson, *The Future of Clinical Trials: Turning Data Chaos into Trial Intelligence*, APPLIED CLINICAL TRIALS (June 3, 2022), https://www.appliedclinicaltrialsonline.com/view/the-future-of-clinical-trials-turning-data-chaos-into-trial-intelligence.

relates to either personally identifiable information ("PII"), personal health information ("PHI"), or biometric information.[23] PII is the broadest type of data set, which generally comprises information that identifies an individual, such as a person's name, social security number, and home address.[24] PHI comprises individually identifiable health information that is related to an individual's health, health care, or payment for healthcare.[25] Biometric data is the narrowest subset which refers to data related to an individual's unique physical characteristics.[26] In the E.U., for example, more sensitive biometric data is subjected to further restrictions.[27] In the U.S., on the other hand, there is no federal law that specifically address biometric data; however, various state laws have begun to emerge on the issue.[28] It is important to note that it often is not just the data itself that is protected, as there are various legal frameworks that also apply to the collection, use, and storage of the data in these clinical research settings.[29] How this conduct is regulated, however, varies greatly from jurisdiction to jurisdiction.[30]

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[23] Acheson, *supra* note 6 (stating that clinical trials involve the collection of personal health information); *Future Use of Biological Specimens Collected Under Clinical Protocols*; UNIV. ALA. BIRMINGHAM, https://www.uab.edu/research/home/future-use-of-biological-specimens-collected-under-clinical-protocols (last accessed Mar. 10, 2025) ("There has been increasing concern in the biomedical community about the use of biological specimens obtained during clinical research.").

[24] Jordan Richards, *Differences Between PII and Biometric Data*, USA EMP. LAWS. (Feb. 3, 2023), https://www.usaemploymentlawyers.com/blog/2023/february/differences-between-pii-and-biometric-data/.

[25] Liyanda Tembani, *Is Biometric Data PHI?*, PAUBOX (Oct. 2, 2023), https://www.paubox.com/blog/is-biometric-data-phi.

[26] Richards, *supra* note 24.

[27] *See* ADVARRA, *supra* note 21 (discussing how the E.U.'s GDPR imposes further restrictions on sensitive personal data).

[28] *See Data Privacy and Biometric Technology Use*, THOMSON REUTERS (July 22, 2024), https://www.thomsonreuters.com/en-us/posts/corporates/biometric-tech-use/.

[29] *See, e.g.*, Acheson, *supra* note 6 (discussing the differing applications of the E.U.'s GDPR and the U.S.'s HIPAA to data practices in the clinical trial context).

[30] *See, e.g.*, *Researcher Under HIPAA*, *supra* note 20 (generally explaining regulation of data practices under HIPAA in the U.S.); ADVARRA, *supra* note 21 (discussing how, unlike HIPAA, the E.U.'s GDPR applies to pseudonymized data and imposes further restrictions on sensitive personal data); *China's PIPL*, *supra* note 6 (noting that China's PIPL is "similar but more stringent than" the E.U.'s GDPR and contains strict regulations regarding the transfer of data).

There are generally two "models" of monitoring and data collection in clinical trials: centralized and decentralized. The traditional centralized model—under which data is manually collected during in-person visits at a central location—is considered to generate higher quality data, as in-person monitoring allows for more control over the data collection process.[31] However, the centralized model is not without its limitations, as it often presents challenges related to patient recruitment and retention.[32] Thanks in large part to technological advancements which have facilitated remote participation in clinical trials, the move towards a decentralized model has not only helped to address these challenges, but has additionally helped to improve patient diversity, timelines and reduce trial costs.[33] Further, these advancements likely facilitate globalization of clinical trials. Unfortunately, however, the decentralized model is not a perfect one.[34] The heightened globalization increases cross-border activity, which further complicates compliance due to the inconsistencies in data protection laws across jurisdictions.

III. THE CHALLENGE OF A LACK OF BINDING INTERNATIONAL GUIDANCE ON UNIFORM DATA PROTECTION IN GLOBAL CLINICAL TRIALS

The lack of uniformity in data protection regulations on an international scale has created a void which has been filled by inconsistencies across the

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[31] OXIMIO, *supra* note 3.
[32] *Id.*
[33] *See Central Monitoring is the Key to Data Integrity in Decentralized Clinical Trials*, MEDIDATA (Dec. 6, 2021), https://www.medidata.com/en/life-science-resources/medidata-blog/central-monitoring-in-decentralized-clinical-trials/ ("DCTs present both opportunities and challenges for data collection and analysis. Data is collected from a wide array of divergent high-volume and high-velocity sources, and many do not follow existing CDISC standards. While this data democratization opens up ample opportunities to explore novel endpoints using advanced analytics, it also introduces security risks and data monitoring challenges.").
[34] *See* OXIMIO, *supra* note 3 (discussing the challenges of the decentralized clinical trial model).

various countries in which clinical trials are held.[35] It appears as though these inconsistencies amongst international data protection laws, in addition to the emergence of increasingly restrictive approaches to data protection, has started to cause a shift in the locations at which clinical trials are conducted.[36] This subsequent shift implicates a number of ethical considerations, as certain types of locations have started to become targets due to their vulnerability to exploitation.

A 2022 study analyzed all U.S.-based and foreign-based clinical trials that are registered on the U.S. clinical trial registry, particularly before and after May 25, 2018.[37] This date is significant because it is when the E.U. implemented the General Data Protection Regulation ("GDPR"), increasing strictness of data protection laws.[38] The study's findings are potentially revelatory of the impact inconsistent data protection laws may have on study sponsors' research site selections for global clinical trials. The study revealed a significant increase in the number of early phase trials in countries that did not implement data privacy regulations like the GDPR.[39] Specifically, the impact of the restrictive regulation was strongly suggested by the study's finding that the most significant rise in these countries with low level data protections occurred *after* the implementation of the GDPR.[40] The study further attempted to highlight the ethical implications of the findings by applying a "freedom score" to each country in order to generally reflect the level of civil liberties within each country.[41] The results indicated

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[35] *See, e.g.*, Acheson, *supra* note 6 (discussing the U.S.'s HIPAA and the E.U.'s GDPR); *China's PIPL*, *supra* note 6 (discussing China's PIPL); *see also Cross-border Guide to Clinical Trials and Privacy*, DLA PIPER, https://www.dlapiperintelligence.com/clinicaltrials (last accessed Mar. 10, 2025) (covering data privacy regulations across 25 international jurisdictions).
[36] Yom-Tov, *supra* note 7.
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*

that the countries having lower freedom scores experienced the largest increase in the number of clinical trials.[42] In other words, countries where citizens have less civil freedoms are seemingly becoming targets as potential locations for study sites.

This increased movement is the result of an absent binding international regulation that pertains to data protection—when data protection regulation is decided on a jurisdictional basis, it creates the present scenario in which entities can essentially pick and choose jurisdictions having more favorable (i.e., less restrictive) laws. This presents numerous ethical considerations that need to be balanced. On one side is the potential for exploitation of communities with less regulatory oversight, or as it is sometimes referred to in the clinical research context, the phenomena of "ethics dumping."[43] This phenomena can occur with any clinical trial, but is particularly common with those considered to be "unethical or unpalatable."[44] These "unpalatable" studies typically involve complex or high-mortality medical conditions, such as HIV and other sexually transmitted diseases, and cancer.[45] This is particularly problematic considering the health risks that are inherent to clinical trials, which are testing drugs of which safety and potential side effects are not yet known.[46] The result is an extreme power imbalance under which study sponsors can take advantage of vulnerable communities and evade requirements that are in place to protect the patient's best interests.[47] This power imbalance is a result of the weaker data protection laws of these countries and the inadequate representation and protection of the subjects

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[42] *Id.*
[43] Weigmann, *supra* note 9.
[44] Yom-Tov, *supra* note 7.
[45] Mohammad Hosseini & Adam DiMascio, *Investigation of Ethics Dumping Cases*, NORTHWESTERN FEINBERG SCHOOL MED.: NEWSLETTER (Apr. 2024), https://www.feinberg.northwestern.edu/research/about/newsletter/2024/04/bt-galter-story.html.
[46] Weigmann, *supra* note 9.
[47] *Id.*

themselves, which typically falls to Institutional Review Boards ("IRBs") and government entities in other countries with stronger protections.[48] Furthermore, patient recruitment tends to be facilitated in low-income communities, as participation in clinical trials is the only access to healthcare some people have in these communities.[49]

Despite the heightened risk for exploitation, the administration of clinical trials in such countries also carries a potential to benefit the communities, particularly as it relates to health inequity. In fact, underrepresentation of developing countries in global clinical trials is a contributing factor to the sustenance of health inequity in those countries.[50] This is illustrated by the fact that diseases considered to be relevant to high-income countries are seven to eight times more likely to be the subject of a clinical trial than diseases which are considered relevant only to low- and middle-income countries.[51] A variety of social factors influence the health status of a person, such as education and income level, employment status, gender, and ethnicity.[52] Health inequity, which generally refers to "systematic differences in the health status or in the distribution of health resources between different population groups," is a problem commonly faced by low-income communities, which don't generally have adequate access to healthcare.[53] The costs of health inequity can be felt on both an individual

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[48] *Id.*; *see also, e.g.*, Robert L. Klitzman, *US IRBs Confronting Research in the Developing World*, 12 DEVELOPING WORLD BIOETHICS 63, 63-64 (2012) (describing how one third of African nations do not have a national Institutional Review Board ("IRB"), and how, in countries such as Latin America, Tanzania, and South Africa, the majority of IRB members are male).
[49] *Id.*
[50] Chalachew Alemayehu et al., *Barriers for Conducting Clinical Trials in Developing Countries: A Systematic Review*, 17 INT'L J. EQUITY & HEALTH 1, 1 (2018), https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-018-0748-6 (noting that 80% of clinical trials listed on clinicaltrials.gov are conducted in developed countries).
[51] *Id.* at 2.
[52] *Health Inequities and Their Causes*, WORLD HEALTH ORG. (Feb. 22, 2018), https://www.who.int/news-room/facts-in-pictures/detail/health-inequities-and-their-causes.
[53] *Id.*

and societal level. On an individual level, such disparities can result in increases in child and maternal mortality rates, tuberculosis-related deaths, premature deaths due to noncommunicable diseases, and decreased life expectancy.[54] The impact of such disparities on a societal level include financial losses that are linked to health inequities, such as increased welfare payments and health care costs and lowered productivity and tax payments.[55] The globalization of clinical trials can help to combat health inequity. Firstly, clinical trials present numerous public health benefits, such as increasing access to healthcare and promoting new medical treatments and advancements.[56] Additionally, the hosting clinical trials in certain communities can help to build up the local healthcare and research capacities, which in turn can boost the economy and local infrastructure.[57] However, it is vital that a balance be maintained between the risk for exploitation and the promotion of health equity. This article presents a potential solution where it would not be necessary to sacrifice consistency in order to achieve such a balance.

IV. A PATH TO ETHICAL CONSISTENCY: HOW A BINDING INTERNATIONAL TREATY COULD SAFEGUARD UNIFORM DATA PROTECTION IN CLINICAL TRIALS

To mitigate the chaos of the current landscape of inconsistent regulations and ensure international enforcement of strong data protections regardless of location, a more effective approach would be the establishment of a legally binding international treaty or regulatory framework, overseen by a global body such as the World Health Organization ("WHO") or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"). This treaty would mandate uniform data protection

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[54] *Id.*
[55] *Id.*
[56] Weigmann, *supra* note 9, at 566.
[57] *Id.*

standards across all jurisdictions, ensuring compliance in the design, conduct, recording, and reporting of clinical trials. Specifically, this article proposes a treaty which implements language that resembles a patchwork of sources such as the GDPR and the ICH's Good Clinical Practice guidelines ("GCPs"). In practice, the treaty would have a binding international effect on all member countries.[58]

As one of the more restrictive data protection laws, this article seeks to essentially implement the language from the GDPR into the treaty's text to ensure that patient data is protected, regardless of the study participant's physical location.[59] Almost the entirety of the GDPR would be implemented, with a particular focus on Article 4, Chapters 2-4, and 8.[60] The GDPR's Article 4 outlines various definitions, the following of which are considered of particular importance for the purpose of this proposal:

> (1) 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical,

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[58] *See Human Rights Treaties Benefit the World's Most Oppressed*, VAND. U. (June 17, 2019), https://news.vanderbilt.edu/2019/06/17/human-rights-treaties-benefit-the-worlds-most-oppressed/ (describing how, from a human rights perspective, international treaties, "even if they don't work perfectly, can still greatly benefit some of the world's most vulnerable people").

[59] *See The EU General Data Protection Regulation*, HUM. RTS. WATCH (June 6, 2018), https://www.hrw.org/news/2018/06/06/eu-general-data-protection-regulation?gad_source=1&gclid=Cj0KCQjwqcO_BhDaARIsACz62vNVYC2yQnKFCt1ML1xZSZh-ckwHUAnukygjZ66u5F23U5-a4bIVrbgaAo4mEALw_wcB (discussing how the GDPR "is one of the strongest and most comprehensive attempts globally to regulate the collection and use of personal data by both governments and the private sector" and contains safeguards which are "particularly important for human rights in the digital age").

[60] *See* Regulation 2016/679 of 27 April 2016, General Data Protection Regulation, 2016 O.J. (L 119) 1, 35-39 [hereinafter *GDPR*] (outlining the implementation of GDPR requirements for handling personal data, patient consent, and sensitive data); *id.* at 39-47 (outlining requirements for transparency and rights subjects have to their data); *id.* at 47-60 (outlining requirements for data controllers and processors, data sharing and security, data breaches, and data protection officers); *id.* at 80-83 (outlining remedies, liability, and penalties in the event of non-compliance).

> physiological, genetic, mental, economic, cultural or social identity of that natural person;
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> . . .
>
> (7) 'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; . . .
>
> (8) 'processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller[.][61]

The proposed treaty would implement the above definitions in order to ensure that the regulation applied to all data collected in clinical trials, as well as all entities involved in the data collection and management of clinical trials. The general language of the GDPR's Chapter 2 would be implemented in order to include requirements on the handling of personal data and consent.[62] More specifically, the proposed treaty would also include the GDPR's specific language regarding sensitive data:

> …personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation[.][63]

Like the GDPR, the proposed treaty would contain additional restrictions on sensitive data as defined above.[64] These restrictions would help to ensure greater care is taken with the type of data that is typically collected in clinical trials, with a greater emphasis on patient consent.[65] The language of Chapter

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[61] *Id.* at 33.
[62] *See generally id.* at 35-38.
[63] *Id.* at 38.
[64] *See generally id.* at 38-39.
[65] *See generally* Jane S Saczynski et al., *Commonly Utilized Data Collection Approaches in Clinical Research*, 126 AM. J. MED. 946 (2013), https://pmc.ncbi.nlm.nih.gov/articles/PMC3827694/ (discussing types of data collected in clinical trials, including biological samples which are commonly "used to profile participants metabolic, proteomic, or genomic status" in order to better understand their health); GDPR, *supra* note 60, at 38 (requiring explicit patient consent for specified purposes).

3 of the GDPR generally relates to transparency and people's data rights, and would be implemented in the proposed treaty to ensure similar rights apply here, such as the right of access, the rights to rectification and erasure, the right to restriction of data processing, and the rights to data portability and objection.[66] Chapter 4 of the GDPR is particularly important here, as it outlines the responsibilities of data controllers and data processors.[67] Implementing the GDPR's language, both here and from Article, 4 as discussed above, helps to ensure that both study sponsors and investigators would fall within the scope of the treaty, and thus be subject to its regulations.[68] Such responsibilities for data controllers would include, for example, data security maintenance, documentation of compliance, data minimization, and data pseudonymization.[69] Similarly, data processors would be required to maintain data security, ensure compliance with the treaty's regulations, as well as with the instructions and limitations provided by the data controller.[70] Chapter 8 of the GDPR is also of importance, as it outlines remedies, liability, and penalties in the event of non-compliance.[71] The proposed treaty seeks to include the same provisions which provide data subjects with the right to an effective judicial remedy against either a controller or processor.[72] The use of third parties, such as Contract Research Organizations ("CROs"), would not enable a controller to escape liability here.[73] Like the GDPR, the proposed treaty would provide the following regarding such proceedings:

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[66] *See generally* GDPR, *supra* note 60, at 39-47.
[67] *See generally id.* at 47-60.
[68] *See* ADVARRA, *supra* note 21 (indicating that sponsors fall within the GDPR's scope).
[69] GDPR, *supra* note 60, at 47-48, 52.
[70] *Id.* at 49, 52.
[71] *Id.* at 80-83.
[72] *Id.* at 80.
[73] *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009) (establishing that a sponsor could be sued in connection with a clinical trial in which the duties were handled by a third party CRO; case later ended in settlement); *see also What Does a Contract Research*

> Proceedings against a controller or a processor shall be brought before the courts of the Member State where the controller or processor has an establishment. Alternatively, such proceedings may be brought before the courts of the Member State where the data subject has his or her habitual residence, unless the controller or processor is a public authority of a Member State acting in the exercise of its public powers.[74]

It may seem problematic to open up proceedings to multiple jurisdictions, as one may argue that it implicates the same concerns regarding inconsistency. However, that would not be the case here, as any court holding such proceedings would be bound to follow the regulations under the proposed treaty, which largely follows the unambiguous language of the GDPR. Such a lack of ambiguity leaves less room for differing interpretations, thus reducing inconsistency. Penalties available under the proposed treaty would be subject to the same guidelines outlined in Article 83 of the GDPR, with any monetary amounts being converted to the relevant currency as necessary.[75]

In addition to the GDPR, this proposal looks to the Good Clinical Practice guidelines ("GCPs") formulated by the ICH as another source for instruction. Unlike the GDPR, the GCPs are more concerned with ethical and scientific quality than data privacy.[76] However, this set of guidelines places an emphasis on informed consent which is particularly applicable to the ethical implications of the problem discussed in this article.[77] Specifically, the GCPs recognize that conducting clinical trials in developing countries may

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Organization Do?, LINDUSHEALTH, https://www.lindushealth.com/blog/what-does-a-contract-research-organization-do (last accessed Mar. 10, 2025) ("A Contract Research Organization (CRO) is a professional entity that offers a spectrum of services to facilitate clinical trials," such as regulatory affairs management, trial planning, site selection, monitoring, data management, etc.).

[74] GDPR, *supra* note 60, at 80.

[75] *See id.* at 82-83.

[76] *See Updates to the ICH GCP (Good Clinical Practice) Guidelines: Quick Review*, PREMIER RSCH. (Jan. 31, 2018), https://premier-research.com/perspectives/updates-to-the-ich-gcp-good-clinical-practice-guidelines-quick-review/.

[77] MAUREEN BENNETT AND JAN MURRAY, CONDUCTING CLINICAL TRIALS IN THE US AND ABROAD: NAVIGATING THE RISING TIDE OF REGULATION AND RISK 13 (Squire, Sanders & Dempsey L.L.P., 2009).

implicate unique considerations in regard to informed consent.[78] To mitigate this, the GCPs outline additional measures which may be necessary for study participants who may be considered part of a "vulnerable population" in order to ensure that the objectives of informed consent are adequately met.[79] This proposal seeks to include the same definition for "vulnerable populations:"

> "Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate."[80]

Like the GCPs, the proposed treaty would seek to require additional measures to be taken for study participants in vulnerable populations—both in regard to data protection, and informed consent. Such measures would again reflect those outlined by the GCPs, and require the sponsor to ensure the following:

> (1) that all documentation regarding data management and informed consent is prepared in the appropriate native language(s); (2) that such documentation is "appropriately written for subjects who may be illiterate or have minimal reading or writing skills and that, as necessary, authorized unbiased persons serve as witnesses or parties who might further explain the study to a subject; (3) "that appropriate means of signifying consent are allowed and documented by the Study team (which may in some circumstances include oral assent or assent by fingerprint or other mark);" (4) "that even if community leaders or other family members may be involved in the consent process due to local cultural or religious norms, that the free-will of the subject to participate in the Study is confirmed; and" (5) "that subjects understand and agree to proposed use of blood, urine or other samples."[81]

Including a definition for vulnerable populations and requiring additional measures to be taken for study participants within such populations helps to

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[78] *Id.*
[79] *Id.* at 13-14.
[80] *Id.* at 13.
[81] *Id.* at 14.

strike the balance previously discussed in that it acknowledges the heightened risk for exploitation in these communities without excluding them from the benefits incurred by participation in clinical trials.

To ensure compliance, the proposed international treaty could be binding to all signatory countries such that failure to comply would result in sanctions, such as monetary fines and/or removal from accessing and registration on the WHO International Clinical Trials Registry Platform ("ICTRP").[82] The ICTRP is a platform managed by the WHO that comprises a network of clinical trial registries.[83] Clinical trial registration is vital, as the Declaration of Helsinki[84] requires that every clinical trial must first be registered in a publicly accessible database before the first subject is recruited.[85] Access to the ICTRP not only lists trial registries, but also helps to facilitate patient recruitment and collaboration amongst researchers, and improve awareness of similar or identical trials so as to avoid unnecessary duplication.[86] Therefore, a country losing access to the ICTRP listing would be incredibly detrimental—if registries from a particular country were unable to be listed internationally, such as through the ICTRP, the public registration requirement under the Declaration of Helsinki would not be satisfied, and therefore, the country would effectively be precluded from participating in global clinical trials.[87] Furthermore, patient recruitment, collaboration efforts, and general trial awareness within the non-complying country would

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[82] *See Clinical Trials*, WHO, https://www.who.int/health-topics/clinical-trials#tab=tab_2 (last accessed Mar. 10, 2025).
[83] *See Trial Registration*, WHO, https://www.who.int/clinical-trials-registry-platform/network/trial-registration (last accessed Mar. 10, 2025).
[84] *See Declaration of Helsinki[:] Medical Research Involving Human Participants*, WORLD. MED. ASS'N, https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/ (last visited Apr. 13, 2025) (Providing a brief background on the Declaration of Helsinki, which is a periodically-reviewed set of ethical principles developed by the World Medical Association for medical research involving human subjects in response to unethical medical practices that occurred during World War II).
[85] *Id.*
[86] *Id.*
[87] *Id.*

be greatly impacted without access to such a valuable source of information and exposure.[88]

V. BUILDING A STRONGER FRAMEWORK FOR DATA PROTECTION IN GLOBAL CLINICAL TRIALS

In conclusion, the inconsistencies among data protection laws render compliance difficult in global clinical trials and is part of the growing problematic trend towards administering clinical trials in countries with fewer protections and regulatory oversight. Although conducting clinical trials in these countries is not inherently bad, the potential benefits must be weighed against the risk of exploitation. The implementation of an international treaty that addresses data privacy considerations is one way to potentially strike this balance, as it can help to simplify compliance and diverse patient recruitment practices while still holding study sponsors accountable under a binding uniform regulation that adequately protect the interests of the patient.

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[88] *Id.*; *see also* Philipp Storz-Pfennig, *Potentially Unnecessary and Wasteful Clinical Trial Research Detected in Cumulative Meta-Epidemiological and Trial Sequential Analysis*, 82 J. CLINICAL EPIDEMIOLOGY 61, 62 (2017) (describing how unnecessary clinical trials can give rise to "a problematic situation regarding efficiency ("waste") and ethics").

Unspoken Inequities: Breaking Language Barriers in Healthcare

Michelle Dolecki

I. THE URGENCY OF LANGUAGE ACCESS

Access to healthcare means access to information, but for millions of Americans, language is a barrier that cannot be ignored. According to the U.S. Census Bureau, twenty-two percent of Americans speak a language other than English at home.[1] Limited English Proficient ("LEP") individuals primarily speak a language other than English and have limited proficiency in speaking, writing, or comprehension.[2] In healthcare, communication is not just about convenience. It is imperative for accurate diagnosis and proper treatment. As the system moves towards patient-centered care, patients must be given the information needed to make informed decisions about their healthcare. Currently, two federal laws mandate language access services: Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act ("ACA"). Despite the existence of these laws, gaps in their framework and inconsistent enforcement leave LEP patients facing barriers to equitable healthcare. Though the U.S. healthcare system seemingly prioritizes patient choice, millions of people are left without a meaningful one.

This article evaluates the linguistic and cultural barriers that preclude access to healthcare in the United States. It argues that the Civil Rights Act and the Affordable Care Act are insufficient to address these barriers, leaving LEP populations underserved. Gaps in these statutes leave room for untrained interpreters and physicians, a lack of resources, and limited

[1] U.S. CENSUS BUREAU, *Language Spoken at Home*, https://www.census.gov/acs/www/about/why-we-ask-each-question/language/.
[2] U.S. DEP'T JUST., *Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals*, https://www.lep.gov/sites/lep/files/media/document/2020-03/042511_QA_LEP_General_0.pdf.

compliance efforts. This article advocates for legislative reforms, such as amending current language access laws and enacting additional statutes that mandate interpreter certification and increase regulation to bridge the healthcare access gap for LEP individuals.

II. LEGAL PROTECTIONS FOR LANGUAGE ACCESS

The Civil Rights Act and the Affordable Care Act are the two federal laws that govern language access rights in the United States. Title VI of the Civil Rights Act states: "No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance".[3] The Supreme Court has interpreted "national origin discrimination" under Title VI of the Civil Rights Act to include language discrimination.[4] Therefore, healthcare providers who receive federal funding, such as Medicare or Medicaid reimbursement, must comply with this provision to prevent language discrimination in their practices.[5] Providers must take reasonable steps to ensure access to services for LEP individuals. The U.S. Department of Health and Human Services ("HHS") is responsible for enforcing language access laws, such as the Civil Rights Act.[6] Providers may follow the HHS Language Plan, which sets out practical guidance for agencies to develop access plans.[7]

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[3] 42 U.S.C. § 2000d.
[4] *See* Lau v. Nichols, 414 U.S. 563, 568 (1974) (demonstrating where the Supreme Court held that a public school system's failure to provide English language instructions to non-English speaking students violated Title VI); *see also* 65 Fed. Reg. 50,121 (Aug. 16, 2000) (reiterating Title VI requirements that federal fund recipients must take reasonable steps to insure LEP people have equal access).
[5] Lau v. Nichols, 414 U.S. at 568.
[6] Alice Hm Chen, et al., *The Legal Framework for Language Access in Healthcare Settings: Title VI and Beyond*, 22 J. GEN. INTERNAL MED. 362, 363 (Oct. 24, 2007), https://doi.org/10.1007/s11606-007-0366-2.
[7] U.S. DEP'T HEALTH & HUM. SERV., *Limited English Proficiency*, https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html.

Section 1557 of the Affordable Care Act extends the protection of the Civil Rights Act. It states that "a covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency".[8] Additionally, the Affordable Care Act provides that language assistance services be provided "free of charge, be accurate and timely, and protect the privacy and the independent decision-making ability of the individual with limited English proficiency".[9] These language assistance services include translation and interpretation, as well as the incorporation of taglines in the top fifteen non-English languages on significant documents.[10]

In 2024, HHS Office for Civil Rights ("OCR") issued a final rule updating the regulations implementing Section 1557 of the Affordable Care Act.[11] The rule defines a LEP individual as "an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English."[12] It also specifically ensures meaningful access for individuals whose primary language for communication is not English.[13] "Meaningful access" means ensuring that language barriers do not prevent individuals from obtaining necessary health services and care.[14]

III. THE BROKEN SYSTEM OF LANGUAGE ACCESS RIGHTS

Language access rights in the United States are currently regulated by the Civil Rights Act and the Affordable Care Act.[15] While these laws are meant to regulate language assistance services in the healthcare context, their current framework perpetuates linguistic and cultural barriers to healthcare

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[8] 45 C.F.R. § 92.201.
[9] *Id.*
[10] *Id.*
[11] U.S. DEP'T HEALTH & HUM. SERV., *Re: Language Access Provisions of the Final Rule Implementing Section 1557 of the Affordable Care Act* (Dec. 5, 2024), https://www.hhs.gov/sites/default/files/ocr-dcl-section-1557-language-access.pdf.
[12] *Id.*
[13] *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37522 (May 6, 2024) (to be codified at 45 C.F.R. pt. 92).
[14] 45 C.F.R. § 92.8(d).
[15] 42 U.S.C. § 2000d; 45 C.F.R. § 92.201.

access. The statutory language is too vague, and the laws do not account for interpreter and provider training, financial resources, and enforcement. Although HHS issues practical guidance, compliance efforts are lackluster. The Civil Rights Act and the Affordable Care Act should be amended to close the gap between legal rights and healthcare practices.

Language proficiency is a multifaceted barrier to healthcare access. Effective patient-physician communication is a critical tool for proper medical treatment. Physicians rely on patient narratives to assess symptoms and medical history, while patients must understand diagnoses to make informed treatment decisions. The American Medical Association ("AMA") defines informed consent as "communication between patient and physician to obtain authorization for a specific medical intervention."[16] Informed consent guarantees that patients have the capacity to understand health information and make intelligent choices regarding medical care.[17] Native English speakers already struggle making informed decisions because of the complexities of medical terminology.[18] This effect is exacerbated when a patient does not speak English as their first language.[19] Patients with LEP have difficulty obtaining, processing, and understanding basic health information needed to make informed decisions.[20] Due to poor health literacy, LEP patients face misdiagnoses, improper treatment efforts, and

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[16] Virtual Mentor, *The AMA Code of Medical Ethics Opinion 8.08: Informed Consent,* 7 AM. MED. ASS'N J. ETHICS 555, 555-56 (July 2012), https://journalofethics.ama-assn.org/article/ama-code-medical-ethics-opinions-informing-patients/2012-07.
[17] *Id.*
[18] Mara K. Youdelman, *The Medical Tongue: U.S. Laws and Policies on Language Access*, 27 HEALTH AFF. 424 (2008).
[19] *Id.*
[20] AM. MED. ASS'N, *Code of Medical Ethics Opinion 2.1.1: Informed Consent* (rev. 2016), https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/2.1.1%20Informed%20consent%20--%20background%20reports.pdf.

negative health outcomes.[21] They are less likely than native speakers to advocate for themselves, use preventative services, and ask questions about chronic diseases.[22] Language barriers cause LEP patients to experience distributive injustice - poor health outcomes as a result of decreased access to care.[23]

Beyond linguistic barriers, cultural differences between patients and physicians restrict healthcare access. In addition to distributive injustice, patients with LEP experience relational injustice – a devaluation of their identities.[24] Non-English speaking patients are often perceived as "outsiders" by physicians, thereby depersonalizing their healthcare experiences.[25] This may manifest in dangerous assumptions about patient attitudes towards health and treatment choices. While cultural beliefs and traditions influence patients' willingness to seek medical treatment and make decisions about medical procedures, physicians who assume patient decisions on this basis deprive patients of their right to informed consent. Interestingly, it was found that fifty-one percent of providers believed patients did not adhere to treatment because of culture or language, yet fifty-six percent reported receiving no cultural competency training.[26] Without adequate training, LEP patients are left to rely on their providers' internal biases, instead of their own informed choices.

Together, linguistic and cultural barriers perpetuate the spread of fear and misinformation among ethnic groups. LEP individuals tend to live in

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[21] Hilal Al Shamsi et al., *Implications of Language Barriers for Healthcare: A Systematic Review*, 35 OMAN MED. J. (Mar. 2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7201401/pdf/OMJ-35-02-1900033.pdf.
[22] Youdelman, *supra* note 18, at 424.
[23] Jason Espinoza and Sabrina Derrington, *How Should Clinicians Respond to Language Barriers That Exacerbate Health Inequity?*, AM. MED. ASS'N J. ETHICS (Feb. 2021), https://journalofethics.ama-assn.org/sites/joedb/files/2021-02/cscm3-2102.pdf.
[24] *Id.*
[25] *Id.*
[26] BRIAN D. SMEDLEY ET AL., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE 90 (2003).

communities where nationality-based stigmas are prevalent.[27] Fearing discrimination, incarceration, and deportation, such individuals tend to avoid healthcare services and delay care.[28] They are likely to consult physicians only when their condition is serious, life-threatening, or irreversible because of its late stage.[29] The National Science Foundation demonstrated that language is a powerful social cue that can influence trust.[30] Using a foreign or non-native language while communicating medical information influences judgment and decision making.[31] For example, this impact is particularly prevalent in vaccine hesitancy.[32]

While the Civil Rights Act and the Affordable Care Act were enacted to address language access rights, gaps in their current framework preclude healthcare compliance. Though the Supreme Court interpreted national origin discrimination under Title VI of the Civil Rights Act to include language discrimination, the word "language" is not explicitly mentioned in the statute.[33] The statute merely accounts for discrimination on the basis of race, color, or national origin.[34] The inclusion of language discrimination is based on the understanding that denying LEP patients meaningful opportunities constitutes discrimination based on national origin.[35] Title VI of the Civil Rights Act is extended by the Affordable Care Act provisions that require language services.[36] However, the Affordable Care Act falls short in

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[27] Carl L. Trube & Theresa P. Yeo, *Patients With Limited English Proficiency: A Challenge for Oncology Nursing Providers*, 27 CLINICAL J. ONCOLOGY NURSING 147, 148 (Apr. 2023), https://www.ons.org/system/files/journal-article-pdfs/TrubeApril2023CJON.pdf.
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] Janet Geipel et al., *Use of a Language Intervention to Reduce Vaccine Hesitancy*, SCI. REPS. (Jan. 7, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC8742025/pdf/41598_2021_Article_4249.pdf.
[33] Lau v. Nichols, 414 U.S. at 568.
[34] 42 U.S.C. § 2000d.
[35] 42 U.S.C. § 2000d.
[36] 45 C.F.R. § 92.201.

practice. It does not define the kinds of language services necessary, such as interpreters, and does not provide objective standards to evaluate the competency of such interpreters. Without conclusive and coordinated standards for language services, there is significant variability in institutional compliance.

The discrepancy between the purpose of the laws and their impact in practice is witnessed across the healthcare field. A study conducted by the University of California at Berkeley, pursuant to the National Health Law Program, found that in thirty-two of thirty-five surveilled cases, health care providers did not use competent interpreters.[37] In twelve of those cases, family members or friends were used as interpreters instead.[38] Another twelve cases failed to translate important medical documents like informed consent forms and discharge instructions.[39] Nearly all cases demonstrated poor documentation of the patient's limited English proficiency and the need for an interpreter in the first place.[40] As a result, many patients suffered irreparable harm or death.[41] Although the statutes are intended to avoid the effects of language discrimination, data shows serious adverse effects for LEP patients in particular. Medical interpreters are critical for care quality, positive health outcomes, and cost savings.[42] However, only thirteen percent of hospitals are compliant with the National Standards for Culturally and Linguistically Appropriate Services in Health Care ("CLAS").[43] These standards are a blueprint, but without effective enforcement, they fail to eliminate health care disparities.

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[37] Kelvin Quan et al., *The High Costs of Language Barriers in Medical Malpractice*, NAT'L HEALTH L. PROGRAM (2010).
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] Espinoza & Derrington, *supra* note 23.
[43] *Id.*

Even when healthcare institutions attempt to comply with current national language laws, LEP patients face a disparate impact because there are no interpreter mandates or training standards by law. The lack of trained medical interpreters forces healthcare providers to rely on unqualified individuals, such as family members or bilingual staff, instead.[44] The likelihood of errors and adverse effects is increased when someone without proper credentials translates.[45] Moreover, when translation services are underutilized, even when available.[46] Unless the patient indicates the need for an interpreter herself, providers may assume patients understand the information based on nonverbal cues like nodding or smiling.[47] Providers and patients also lack awareness of statutory rights, or see logistical hurdles to secure an interpreter.[48] Even when an interpreter is available, there is no national testing, licensure, or certification that guarantees a minimum level of competency to ensure healthcare interpreters provide "meaningful access" required by law.[49] Importantly, interpreters should not only be proficient in English and the patient's native language but must also understand medical and legal terminology to communicate diagnoses, courses of treatment, and legal forms.[50] As a result, many healthcare providers fail to comply with language access requirements in practice but are not penalized for their shortcomings.[51]

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[44] *Id.*
[45] *Id.*
[46] Alvaro DeCola, *Making Language Access to Health Care Meaningful: The Need for a Federal Health Care Interpreters' Statute*, 24 J. L. HEALTH 151 (2011).
[47] AGENCY FOR HEALTHCARE RSCH. AND QUALITY, *Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals* (Sept. 2012), https://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.
[48] DeCola, *supra* note 46.
[49] Exec. Order 13166, 65 Fed. Reg. 50121 (Aug. 16, 2000).
[50] DeCola, *supra* note 46.
[51] *Id.*

Finally, the financial burden of interpreter services deters providers from prioritizing language access rights.[52] This phenomenon is especially prevalent for smaller healthcare providers who lack the financial means and resources to provide interpreter and translation services without government assistance. By law, managed care organizations that receive federal financial assistance must comply with regulations requiring patients to have access to language services.[53] However, one of the greatest barriers to language access for LEP patients is a lack of widespread reimbursement for healthcare services.[54] Medicaid and the State Children's Health Insurance Program ("SCHIP") indicate that language services are eligible for federal matching funds.[55] Regardless, Medicaid operates on a state level where the state determines how its Medicaid program will provide reimbursement for interpretation services.[56] Physicians cannot receive payments for interpreter services unless the state provides them with reimbursement.[57] Interpreter fees vary depending on the language, the source of the interpreter, the interpreter's qualifications, and length of service.[58] Without distinct statutory language that regulates health care interpreters and their training, the enforcement of language access rights remains inconsistent and unpredictable.

IV. BRIDGING THE GAP FOR LANGUAGE EQUITY

The key to addressing inadequacies LEP patients is reforming the Civil Rights Act and the Affordable Care Act to properly address language assistance services. Studies demonstrate that when patients and physicians speak the same language, patient satisfaction, engagement, utilization of

[52] Youdelman, *supra* note 18.
[53] *Id.*
[54] Chen et al., *supra* note 6.
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] DeCola, *supra* note 46.

preventative services, and healthcare outcomes are improved.[59] This requires amending the statutory language to explicitly name linguistic discrimination and implement a federal certification program for medical interpreters. Enforcement efforts should be enhanced so violations of language access rights do not go unnoticed. In addition, resources should be reallocated to finance language assistance and align healthcare practices with legal provisions.

Title VI of the Civil Rights Act states: "No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance".[60] Title VI should be amended to directly list language discrimination as prohibited instead of grouping it under the "national origin" umbrella. The current "national origin" language is too broad because national origin does not necessarily encompass language access rights. Groups have attempted to assert that the Title VI discrimination prohibition only applies to national origin, not its "disparate impact" on language discrimination.[61] The groups claim compliance with such a broad category is overly burdensome and renders the anti-discrimination provision substantively arbitrary.[62] Though plaintiffs were unsuccessful due to a lack of standing in that case, it flags an issue with the statutory language.[63] Title VI should be amended to clarify what constitutes "national origin" discrimination by designating language discrimination as prohibited separately. By making this distinction, the law

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[59] Alexander R. Green & Chijioke Nze, *Language-Based Inequity in Health Care: Who Is the "Poor Historian"?*, 19 AMA J. ETHICS 263 (Mar. 2017).
[60] 42 U.S.C. § 2000d.
[61] Nat'l Multi Hous. Council v. Jackson, 539 F. Supp 3d 425, 427 (D.D.C. 2008).
[62] *Id.* at 427.
[63] *Id.* at 428.

requires healthcare providers, among other entities, to be aware of language access rights.

In addition to amending Title VI to include language discrimination, Congress should enact a new statute entirely for federal interpreter certification. The proposed statute would mandate HHS to establish a federal certification program specifically for health care interpreters. It would ensure healthcare interpreters possess the skills to effectively facilitate conversations between physicians and LEP patients. For a healthcare provider to receive federal funding, he would be required to provide certified interpreters to LEP patients. Under the new certification program, healthcare interpreters would be required to meet a standard level of competency, guaranteeing the quality of their work.[64] The interpreters would be trained to possess a minimum skill level, such as understanding medical and legal terminology, as well as being adequately proficient in both English and the other language they are being certified in. This standard is necessary to secure the "meaningful access" required by current federal regulations and decrease the number of negative health outcomes due to a lack of effective communication.[65] Training and certification by an authority qualified to test these skills provides an objective verification of competence, rather than relying on subjective standards or assumptions that all interpreters possess necessary skills.[66] It also ensures that informed consent is facilitated so the LEP patient is making a medical treatment decision on the basis of objective knowledge rather than the provider's assumptions. The LEP patient would be adequately informed about the risks and benefits of a treatment plan before consenting to proceed with treatment.

In addition, a certification statute would prohibit individuals who have not demonstrated sufficient language proficiency and the knowledge, skills, and

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[64] DeCola, *supra* note 46, at 166.
[65] *Id.* at 165.
[66] *Id.*

abilities required of interpreters or translators from interpreting or translating in an "ad hoc" manner.[67] Meaning, issues that arise from family members or friends serving as interpreters would be avoided, as all interpreters would be licensed or certified pursuant to statutory guidelines. Currently, many healthcare facilities rely on family members or untrained staff to interpret, leading to miscommunication, misinterpretation, and thereby leaving patients to make uninformed decisions. Under the proposed law, only certified interpreters may provide medical translation services, preventing ad hoc interpretation by individuals lacking the necessary expertise to communicate medical and legal technicalities. By establishing interpreter certification standards and implementing provider training, the enactment of a new statute would ensure meaningful access to healthcare for LEP patients.

Beyond certifying medical interpreters by law, healthcare providers should also be trained to identify LEP patients and the need for interpreter services. The burden to identify the need for a language interpreter because a patient lacks the capacity to make informed decisions lies with the healthcare provider. Training providers to identify when a patient needs language assistance secures compliance with the provisions of the Civil Rights Act and the Affordable Care Act. Even when a patient can answer basic questions in English, limited English proficiency is not equivalent to having full understanding of a conversation in a medical context.[68] If a physician presumes the patient is competent in English, it is unlikely the patient will advocate for themselves to receive an interpreter.[69] Establishing federal mandates requiring cultural competency training for all healthcare professionals would ensure they understand the diverse needs of the

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[67] Allison Squires & Mara Youdelman, *Section 1557 of the Affordable Care Act: Strengthening Language Access Rights for Patients With Limited English Proficiency*, 10 J. NURSING REG. 65 (Apr. 2019).
[68] DeCola, *supra* note 46, at 172.
[69] *Id.*

populations they serve and avoid the detriments of cultural bias. To implement this mandate, providers should not only attend training but should add standard protocols for addressing language needs during patient interactions. These requirements may include screening for language proficiency to ensure no assumptions are made about a patient's ability to comprehend the English language. Providers would recognize subtle indicators that a patient may not fully grasp the medical information being provided, so providers can proactively facilitate communication. Though provider training programs may be expensive and time-consuming, specifically in rural or underfunded areas, federal funding may be allocated to provide community health centers with the education and outreach programs necessary to facilitate compliance with language services.

Besides statutory reform, linguistic and cultural barriers to healthcare access prevail among a lack of infrastructure necessary to provide adequate language services. Without adequate federal resources and funding, many healthcare facilities lack available and competent interpreters. In addition, physicians may be unaware of the existence of language assistance resources and rights. To combat a lack of awareness, health care providers should undergo training on their obligations per the Civil Rights Act and the Affordable Care Act on an annual basis as the laws update. However, physicians who point out limited interpreter availability were shown to underuse interpreter services even when readily available.[70] Therefore, training should educate not only on identifying LEP patients, but also to enhance compliance efforts and be aware of the consequences for falling out of compliance. Provider training would also streamline implementation of translation services to avoid administrative delays and educate providers on how interpreter services are covered by government funding.

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[70] Lisa C. Diamond et al., *Getting By: Underuse of Interpreters by Resident Physicians*, 24 J. GEN. INTERNAL MED. 256 (Dec. 17, 2008).

The integration of language services into existing healthcare facilities should be supported by federal funding to avoid resistance to change and the technical challenges of integration. Currently, states are not required to reimburse providers for the cost of interpreter services despite being obligated to make language services available to those with LEP.[71] Per the Centers for Medicare and Medicaid ("CMS") policy, reimbursement is permitted at a standard fifty percent rate for interpretation activities so long as they are separate from the rate of direct patient services.[72] To incentivize providers to comply with statutory regulations and promote equitable healthcare access, Medicare and Medicaid reimbursement programs should financially support one hundred percent of interpreter services.

Without full reimbursement, facilities are disincentivized from compliance with the statutory regulations. Medicare and Medicaid funds should be appropriately allocated from the government to cover the cost of on-demand interpreter services, provider and interpreter training, as well as the cost of translating essential documents. By leveraging government funding, healthcare providers that currently lack resources to offer language services to LEP patients will be equipped to do so. This approach bridges the gap between statutory provisions preventing language discrimination and barriers to implementation in healthcare practice.

While expanding language access provisions in healthcare is supported academically, the burden of implementation deters providers and legislators from making necessary reforms. Critics contend that mandated interpreter services and cultural competency training may impose an undue financial burden on healthcare institutions, particularly smaller clinics and rural

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[71] CTRS. FOR MEDICAID & MEDICARE SERV., *Translation and Interpretation Services*, https://www.medicaid.gov/medicaid/financial-management/medicaid-administrative-claiming/translation-and-interpretation-services/index.html.
[72] *Id.*

hospitals that operate with limited resources. One year of interpreter services for a single healthcare provider costs approximately $245,363.[73] Such a large number raises concerns about the feasibility of widespread adoption across the United States.[74] However, research indicates that investing in interpreter services yields significant long-term savings by reducing medical errors, readmission rates, and malpractice claims – all of which contribute to significant cost reductions overall.[75] Upfront expenses are justified when weighed against broader financial concerns and when supported by government funding. Incorporating language assistance costs into existing Medicare and Medicaid reimbursement structures allows all healthcare facilities to afford compliance without excessive financial strain. Reform statutes can ensure equitable access for LEP patients while still promoting cost efficiency.

To effectively address the linguistic and cultural barriers in healthcare access, legal reforms should be accompanied by enforcement mechanisms. Currently, HHS is the primary regulatory entity responsible for overseeing healthcare regulation.[76] To monitor compliance with language access requirements, HHS should increase oversight of the healthcare providers. HHS must monitor whether mandated interpreters are present in appropriate patient-physician interactions and whether interpreters meet certification standards. Enforcement efforts should be strengthened by both regular and randomized audits in addition to formal compliance reviews.

In addition to closer scrutiny from regulatory agencies, there should be stricter penalties for noncompliance such as civil sanctions and the threat of withdrawal from Medicare and Medicaid funding eligibility. Patients whose

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[73] Elizabeth A. Jacobs et al., *Overcoming Language Barriers in Health Care: Costs and Benefits of Interpreter Services*, 94 AM. J. PUB. HEALTH 856 (May 2004), https://pmc.ncbi.nlm.nih.gov/articles/PMC1448350/pdf/0940866.pdf.
[74] *Id.*
[75] *Id.*
[76] U.S. DEP'T HEALTH & HUM. SERV., *supra* note 11.

language access rights have been violated may also be offered remedies. For example, California allows civil claims against entities that fail to comply with the state's Title VI provisions.[77] To enhance federal accountability, legislation should be enacted to provide similar civil remedies for Title VI violations. Moreover, to ensure patients are aware of these legal rights, HHS should publish an order explaining how LEP patients can utilize these civil remedies. By strengthening enforcement mechanisms and legal remedies, language access requirements are not only mandated but meaningfully upheld in practice.

V. THE FUTURE OF EQUITABLE HEALTH CARE

Despite existing legal mandates, linguistic and cultural barriers continue to limit healthcare access for LEP populations. Statutory amendments that include interpreter certification and mandate cultural competency training will transform access to care from legal obligation to reality. By upholding language access rights, a healthcare system that serves patients equitably regardless of language spoken will be fostered.

[77] Youdelman, *supra* note 18.

Medicaid Work Requirements in Virginia: Impact on Healthcare Access and Vulnerable Populations

Kevin Gill

I. MEDICAID EXPANSION UNDER THE AFFORDABLE CARE ACT

Medicaid expansion has been one of the most significant healthcare policy developments in the United States over the past decade. The Affordable Care Act expanded Medicaid, allowing states to extend health coverage to low-income individuals earning up to 138% of the federal poverty level.[1] This expansion has led to improved healthcare access, reduced uncompensated care costs, and enhanced public health outcomes.[2] But as states have expanded Medicaid, some have also imposed work requirements, which mandate recipients to engage in community service, job training, or employment to keep their coverage.[3] Critics argue that job restrictions disproportionately harm vulnerable communities, while supporters claim they encourage economic self-sufficiency and reduce government dependence.[4] However, the effectiveness of these policies depends on implementation, as poorly structured requirements may cause coverage losses without achieving meaningful employment gains.

This article will examine the failed proposal for Medicaid work requirements in Virginia and their implications for healthcare access, particularly for vulnerable populations. It will assess how these requirements intersect with the social determinants of health, highlighting the potential barriers they create for low-income individuals seeking essential medical

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[1] *Medicaid Expansion & What It Means for You*, HEALTHCARE.GOV, https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/ (last visited Feb. 14, 2025).
[2] Jean P. Hall et al., *Medicaid Expansion as an Employment Incentive Program for People With Disabilities*, *Am. J. Public Health*, NAT'L LIBR. OF MED. (Sept. 2018) https://pmc.ncbi.nlm.nih.gov/articles/PMC6085052/.
[3] Akeiisa Coleman & Sara Federman, *Work Requirements for Medicaid Enrollees*, THE COMMONWEALTH FUND (Jan. 14, 2025), https://www.commonwealthfund.org/publications/explainer/2025/jan/work-requirements-for-medicaid-enrollees.
[4] ECON. POL'Y INST., *SNAP and Medicaid Work Requirements Would Hurt Workers and Families Without Increasing Employment* (Feb. 26, 2024), https://www.epi.org/publication/snap-medicaid-work-requirements/.

care. First, this article will discuss the background of Medicaid work requirements, including their policy rationale and historical context. Next, it will analyze how such requirements disproportionately impact marginalized communities, exacerbating existing health disparities. Additionally, this article will explore the broader effects of employment-based eligibility on healthcare access, economic stability, and overall well-being. Finally, this article will propose policy solutions to mitigate the adverse effects of Medicaid work requirements, advocating for alternatives that promote equitable healthcare access while addressing the underlying social determinants of health.

II. VIRGINIA'S MEDICAID EXPANSION HISTORY

Virginia's proposed work requirements mandated Medicaid beneficiaries aged nineteen to sixty-four to complete at least eighty hours per month of qualifying activities.[5] These activities included employment, job training, volunteer work, and education programs.[6] Certain exemptions applied, including individuals with disabilities, pregnant women, primary caregivers, and those undergoing substance abuse treatment.[7] Failure to meet the requirements may result in suspension or loss of Medicaid coverage.[8]

In 2017, Virginia's Democratic Governor, Terry McAuliffe, sought to expand Medicaid under the Affordable Care Act to cover 400,000 low-income residents.[9] However, Republican opposition in the General Assembly blocked his efforts, citing concerns over long-term state costs and

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[5] Coleman & Federman, *supra* note 3.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Laura Vozzella, *Virginia Senate Approves Medicaid Expansion to 400,000 Low-Income Residents*, WASH. POST (May 30, 2018) https://www.washingtonpost.com/local/virginia-politics/virginia-senate-approves-medicaid-expansion-to-400000-low-income-residents/2018/05/30/5df5e304-640d-11e8-a768-ed043e33f1dc_story.html.

federal funding reliability.[10] McAuliffe's expansion efforts failed due to fiscal concerns.[11]

In May 2018, Governor Ralph Northam enacted Medicaid expansion after a bipartisan compromise that included cost-sharing and work requirements.[12] Virginia submitted a waiver request to the Centers for Medicare & Medicaid Services ("CMS") to implement these requirements, which mandated that able-bodied adults work, volunteer, or take part in employment training.[13] However, before enforcement began, a 2020 federal court ruling struck down similar requirements in Arkansas, citing large coverage losses and failure to advance Medicaid's main objective of delivering healthcare.[14]

During the first Trump Administration, CMS promoted Medicaid work requirements as a way to encourage self-sufficiency and reduce dependency on government aid.[15] These were approved in some states under the argument that work participation could improve health and economic independence.[16] However, courts in states like Kentucky and New Hampshire blocked these rules, citing their adverse impact on coverage.[17]

Both administrative hesitancy and legal uncertainty ultimately led to the abandonment of Virginia's Medicaid work requirement program. The COVID-19 pandemic further delayed policy changes that could reduce

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[10] *Id.*
[11] *Id.*
[12] *Id*.
[13] URBAN INST., *Work Requirements Tool* (Virginia), https://apps.urban.org/features/workrequirements-tool/print_state.html?state=Virginia (last visited Mar. 20, 2025).
[14] Gresham v. Azar, 950 F.3d 93 (D.C. Cir. 2020).
[15] Danielle Garrett, *Why the Court Once Again Struck Down Federal. Approval of Medicaid Work Experiments*, THE COMMONWEALTH FUND (Mar. 28, 2019), https://www.commonwealthfund.org/blog/2019/why-court-once-again-struck-down-federal-approval-medicaid-work-experiments
[16] *Id*.
[17] *Id*.

coverage.[18] After taking office in 2021, President Biden ordered CMS to rescind previously approved waivers, arguing that work requirements disproportionately harmed vulnerable individuals and conflicted with Medicaid's mission.[19]

With a Democratic-controlled legislature and a Republican governor, Glenn Youngkin, Virginia's split government raises the prospect of fresh discussions on Medicaid work requirements in 2025. Restoring such provisions may be pushed by some Republican members, particularly if they reclaim complete legislative power.[20] Although Virginia does not currently have work requirements, a change in the legislative or executive branch might reignite the discussion and influence Medicaid coverage for almost 1.9 million Virginians.[21]

III. Risks and Consequences of Medicaid Work Requirements

Low-income individuals frequently face employment barriers, such as transportation challenges, limited childcare alternatives, and job market changes.[22] These non-medical factors that affect a person's health are known as the social determinants of health ("SDOH").[23] Virginians' SDOH has a significant influence on how successful work requirements are, therefore, any policy pertaining to Medicaid eligibility must take these elements into

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[18] *Medicaid Work Requirements: Current Waiver and Legislative Activity*, Kaiser Family Found. (Apr. 18, 2019), https://www.kff.org/medicaid/issue-brief/medicaid-work-requirements-current-waiver-and-legislative-activity/
[19] *Id*.
[20] Elizabeth Hinton et al., *Medicaid Work Requirements: Current Waiver and Legislative Activity*, Kaiser Family Found. (Nov. 21, 2024), https://www.kff.org/medicaid/issue-brief/medicaid-work-requirements-current-waiver-and-legislative-activity/.
[21] Medicaid / FAMIS / PACE Enrollment, Virginia Medicaid, https://www.dmas.virginia.gov/data-reporting/eligibility-enrollment/medicaid-famis-pace-enrollment/ (last visited Feb. 14, 2025).
[22] Paula Braveman et al., *The Social Determinants of Health: Coming of Age*, *Annual Review of Public Health*, 32:381–398 (2011), https://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031210-101218.
[23] *Id*. at 383.

consideration to guarantee that all citizens have fair access to healthcare. A failure to consider the SDOH in crafting Medicaid policies, such as work requirements, could result in the exacerbation of existing health disparities and increased barriers to accessing care. An example of this could be a Medicaid enrollee who works a variable-hour retail job that might fulfill the work requirement one month but not the next because of fewer shifts. Despite having a job, they run the danger of losing coverage because of this uncertainty.

The implementation of work requirements presents both legal and administrative complexities. In *Gresham v. Azar,* the U.S. Court of Appeals for the D.C. Circuit ruled that Arkansas' work requirements did not align with Medicaid's primary purpose of providing healthcare access, largely due to their flawed execution.[24] This ruling highlights that while work requirements may have merit in theory, they must be carefully structured to avoid widespread coverage losses. The court concluded that the policy caused large coverage losses without providing enough proof that it enhanced health outcomes or encouraged employment.[25] This decision set a precedent, leading to similar rulings in other states and effectively pausing the implementation of work requirements nationwide.[26]

Monitoring Medicaid work requirements also raises administrative costs, and many beneficiaries lose coverage due to reporting difficulties.[27] In Arkansas, between June 2018 and March 2019, more than 18,000 Medicaid recipients lost their coverage due to noncompliance with the reporting requirements, despite many being employed.

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[24] Gresham*,* 950 F.3.d. at 103.
[25] *Id*.
[26] Sarah Rosenbaum, *Why a Court Once Again Struck Down Federal Approval of Medicaid Work Experiments*, THE COMMONWEALTH FUND (Mar. 29, 2019), https://www.commonwealthfund.org/blog/2019/why-court-once-again-struck-down-federal-approval-medicaid-work-experiments.
[27] Coleman & Federman, *Work Requirements for Medicaid Enrollees*, *supra* note 3.

Many employees worked jobs with inconsistent schedules that clashed with the program's strict reporting framework.[28] Others struggled with the complicated online reporting system or were unaware of the requirements due to insufficient state outreach.[29] Some lacked the digital literacy or internet access needed to navigate the system.[30] Low-income and rural communities were disproportionately impacted by these administrative and logistical obstacles; many of them otherwise fulfilled the program's labor requirements but neglected to accurately report their hours.[31]

In Virginia, employed beneficiaries or those eligible for exemptions may struggle to meet reporting requirements, leading to unintentional disenrollment. As more uninsured people seek treatment in emergency rooms, the loss of Medicaid coverage could put further strain on hospitals and state-funded healthcare programs.

Supporters of work requirements argue that Medicaid was not designed to be a permanent benefit for able-bodied adults and that requiring employment or job training fosters self-sufficiency.[32] They cite studies suggesting that work incentives in public assistance programs can lead to higher employment rates and reduced government dependency over time. Some economists argue that maintaining Medicaid coverage without work incentives could discourage workforce participation, which may have long-term economic consequences.[33]

However, research from Arkansas suggests that work requirements have not led to sustained employment gains.[34] Instead, many people lost coverage

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[28] *Id*.
[29] *Id*.
[30] *Id*.
[31] ECON. POL'Y INST., *SNAP and Medicaid Work Requirements* (Mar. 1, 2019), https://www.epi.org/publication/snap-medicaid-work-requirements/
[32] House Budget Committee, *Making Medicaid Work for the Most Vulnerable*, H. Budget Comm. (Mar. 2021).
[33] *Id*.
[34] Coleman & Federman, *Work Requirements for Medicaid Enrollees*, *supra* note 3.

due to bureaucratic hurdles rather than actual unemployment.[35] Additionally, many Medicaid recipients already work in low-wage or inconsistent jobs, meaning the policy would penalize those who are employed but struggle with variable hours.[36]

A similar trajectory would result in higher uncompensated care expenses in Virginia, which would put a strain on taxpayers, state budgets, and hospitals.[37] Despite working, people with erratic work hours, poor internet connection, or language challenges are particularly susceptible to losing benefits. These factors put them at a disadvantage compared to others who can meet the requirements. To avoid unintended consequences that undermine economic self-sufficiency, Virginia must address these systemic challenges before imposing work requirements.

Work requirements may strain Virginia's healthcare system, particularly in rural areas, by reducing Medicaid payments and increasing uncompensated care costs.[38] Medicaid clients who are unable to obtain coverage due to employment obligations may delay seeking medical attention until their ailments worsen, which increases the need for ER visits. Hospitals are heavily burdened financially when uninsured people are unable to pay for treatments because emergency care is far more expensive than routine or preventive care.[39]

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[35] *Id*.
[36] KAISER FAMILY FOUND., *Understanding the Intersection of Medicaid and Work: An Update*, KAISER FAMILY FOUND. (Jan. 9, 2020), https://www.kff.org/medicaid/issue-brief/understanding-the-intersection-of-medicaid-and-work-an-update/
[37] Leighton Ku & Erin Brantley, *Medicaid Work Requirements: Who's at Risk?*, THE COMMONWEALTH FUND (Nov. 2018), https://www.commonwealthfund.org/sites/default/files/2018-11/Ku_Medicaid_work_requirements_ib.pdf
[38] *Id.*
[39] Sara R. Collins et al., *The Problem of Underinsurance and How Rising Deductibles Will Make It Worse*, THE COMMONWEALTH FUND (May 20, 2015), https://www.commonwealthfund.org/publications/issue-briefs/2015/may/problem-underinsurance-and-how-rising-deductibles-will-make-it

Furthermore, rising rates of uninsured working-age adults may result in higher expenditures for businesses, taxpayers, and state-funded health programs.[40] People who lose Medicaid coverage but are unable to pay for private insurance could skip out on essential medical care, which raises the risk of serious health issues that would eventually demand more expensive measures. Because poor health outcomes can lower workforce productivity and raise disability claims, further taxing public resources, the economic impact goes beyond the healthcare industry.

The *Gresham* ruling underscores the point that Medicaid is designed to ensure access to healthcare, not to impose conditions based on employment status.[41] By striking down work requirements, the ruling reaffirmed the principle that imposing additional barriers to Medicaid enrollment, particularly for populations that already face systemic employment obstacles contradicts the program's intent. Medicaid's mission to provide a safety net for those in need is effectively undermined when healthcare coverage is contingent on employment status. The decision reinforced the idea that any policy shift threatening healthcare access by imposing restrictive work conditions, especially if those disproportionately affecting vulnerable groups, could be challenged as violating the program's statutory objectives.

IV. Reforming Virginia's Medicaid Approach

Through its "Power Account" concept, Indiana's Medicaid expansion strategy, known as the Healthy Indiana Plan ("HIP"), employed a tiered benefits framework to promote individual accountability while maintaining

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[40] *Id*.
[41] Gresham, 950 F.3.d. at 103.

healthcare access for low-income individuals.[42] The program consists of two main tiers: HIP Plus and HIP Basic.[43]

HIP Plus, the preferred plan, offers comprehensive benefits such as vision, dental, and enhanced prescription drug coverage.[44] Participants must fund their Personal Wellness and Responsibility ("POWER") accounts, which work similarly to health savings accounts, on a regular basis to be eligible.[45] These income-based contributions, which normally range from $1 to $20 per month, guarantee affordability while encouraging fiscal discipline.[46] Non-disabled adults over the federal poverty line run the risk of losing coverage if they don't make these contributions, while those under the federal poverty line are automatically transferred to the HIP Basic plan.[47]

HIP Basic offers limited benefits, with copayments for many medical services and no dental or optical coverage.[48] The objective is to encourage individuals to actively engage in managing their healthcare while ensuring that essential services remain accessible. Indiana's plan encourages beneficiaries to pay for their healthcare by providing a choice of tiers, while also providing a safety net for those who cannot afford the costs.

A study conducted by the Lewin Group, and healthcare consulting firm, found that the program had led to improved coverage outcomes like lowering

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[42] HIP POWER Account, MHS IND., https://www.mhsindiana.com/members/hip/benefits-services/hip-power-account.html (last visited Feb. 14, 2025).
[43] The Lewin Group, Inc., *Healthy Indiana Plan 2.0: POWER Account Contribution Assessment*, IND. FAMILY & SOC. SERVS. ADMIN. (July 1, 2017), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-POWER-acct-cont-assesmnt-03312017.pdf
[44] *Id*.
[45] *Id*.
[46] *Indiana Family & Social Services Administration, Frequently Asked Questions*, IND. FAM. & SOC. SERVS. ADMIN., https://www.in.gov/fssa/hip/about-hip/frequently-asked-questions/ (last visited Mar. 30, 2025)
[47] *Id*.
[48] *Id*.

Emergency Room usage and emphasizing primary preventative care.[49] HIP Plus participants were 93% more likely to have had a primary care visit than those in the HIP Basic Plan.[50] These results suggest that incentivizing small monthly contributions for Medicaid recipients can improve healthcare engagement without sacrificing access to essential care.

Advocates for stricter work requirements argue that government assistance should be tied to economic participation whenever possible. They argue that work requirements mirror policies in other social programs like Temporary Assistance for Needy Families ("TANF") and the Supplemental Nutrition Assistance Program ("SNAP"), which have helped reduce long-term welfare dependency.[51]

However, Medicaid differs from TANF and SNAP because it is a healthcare program, not a cash assistance initiative. The primary goal is to ensure access to medical care, not to regulate employment. Unlike TANF recipients, many Medicaid enrollees already work but face job instability, which means they could be unfairly penalized for circumstances beyond their control.

The tiered system seeks to strike a balance between the need to support underserved communities with the objective of promoting self-sufficiency and employment. Basic healthcare services are still available to people who are unable to contribute, but the most extensive benefits are given to those who can work and fulfill program conditions. The system offers flexibility to accommodate those who face valid obstacles to entering the workforce,

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[49] *Healthy Indiana Plan 2.0 Evaluation Reveals Hoosier Success*, CITY-CNTY. OBSERVER (July 28, 2016), https://city-countyobserver.com/healthy-indiana-plan-2-0-evaluation-reveals-hoosier-success/?utm_source

[50] *Id*.

[51] Ku & Brantley, *supra* note 37, at 2.

such as chronic sickness, caregiving obligations, or economic downturns, by integrating employment training and exemption measures.[52]

A tiered Medicaid system can offer administrative efficiencies. The technology streamlines case management and lessens the need for in-depth, customized assessments by clearly defining eligibility levels based on program compliance. This kind of organization can reduce errors in eligibility determinations, expedite enrollment procedures, and increase program efficiency in general. Critics may argue that certain beneficiaries may struggle to move between categories, especially those who are temporarily struggling financially, highlighting the necessity of protections like grace periods and financial aid initiatives.

Still, there are worries about the possible disadvantages of a tiered structure. Basic care continues to be necessary, but it might not be enough for people with complicated medical requirements.[53] To prevent unforeseen coverage losses, policymakers must make sure the system is built with clear standards, easy-to-use enrollment processes, and suitable exemptions. Creating a program that is fair, easy to use, and centered on the long-term health outcomes of all participants is essential to its success.

To maintain the efficacy and equity of a tiered Medicaid system, Virginia must implement a comprehensive framework that places a high priority on accessibility, flexibility, and targeted assistance for vulnerable people. In addition to supporting seamless tier transitions, a well-designed eligibility and benefits administration system would give beneficiaries a clear awareness of their coverage alternatives. Virginia may guarantee that everyone, irrespective of tier placement, receives necessary healthcare services by incorporating preventative care incentives at all levels, such as access to telemedicine, mental health services, and chronic disease

[52] Braveman et al., *supra* note 22, at 385.
[53] Ku & Brantley, *supra* note 37, at 3.

management programs. Furthermore, by preventing abrupt coverage termination, a grace period system for individuals experiencing brief job disruptions would promote stability in healthcare access.

By incorporating these elements, Virginia could develop a Medicaid model that balances healthcare access with economic mobility, ensuring that beneficiaries receive the support they need while fostering workforce participation. Such an approach would align Medicaid with its foundational goal of providing healthcare to low-income individuals while incorporating modern strategies that encourage personal responsibility and economic self-sufficiency. Work requirements run the risk of escalating health inequities and restricting access to essential care if they are adopted without taking these larger considerations into account. Virginia needs to think about increasing access to healthcare, education, job training, and social support systems to develop a more comprehensive program. In addition to encouraging workforce engagement, addressing these issues will guarantee that all residents, regardless of job status, have access to the healthcare resources they need to live healthy, productive lives.

V. CONCLUSION

To provide greater access to healthcare, Virginia should adopt a supportive, incentive-based model that helps Medicaid recipients gain economic stability without the risk of losing coverage. The previous proposal did not adequately address the SDOH impacting individuals' ability to comply with work requirements. It was too strict a requirement attached to Medicaid, which aims to provide health insurance to disadvantaged populations. Requiring strict guidelines for beneficiaries to maintain coverage may create additional barriers for low-income individuals who already face challenges related to their SDOH. While rigid work requirements have led to unintended coverage losses, some argue that

incorporating work incentives in Medicaid could be a compromise that promotes personal responsibility while maintaining healthcare access. A more effective approach would be policies that encourage employment through job training and education while ensuring that coverage remains stable. Work incentives should be designed to support, rather than punish, low-income individuals navigating economic instability.

A tiered approach that incorporates work incentives while maintaining baseline healthcare access presents a more balanced alternative to rigid work requirements. Rather than simply rejecting work-based eligibility requirements, Virginia could opt for another route that promotes employment while making sure that those who face systemic obstacles, like erratic employment markets, childcare issues, or transportation constraints, do not lose necessary coverage. By integrating employment training, exemptions for vulnerable groups, and clear reporting mechanisms, Medicaid could strike a balance between fostering self-sufficiency and upholding its core mission of providing healthcare to those in need. A balanced approach that considers both economic realities and healthcare access can make Virginia a model for equitable Medicaid reform.

Providing Legislation for Diabetes Medical Supplies

Michael Guerrero

I. REVIEWING THE COMPLEXITIES OF DIABETES AND MEDICAL SUPPLIES

As of 2024, the Centers for Disease Control and Prevention ("CDC") reported that around 38 million people in the United States are diabetic.[1] There are three main types of diabetes: Type 1, Type 2, and Gestational Diabetes.[2] As diabetes is common, there are many technologies and devices available to make the condition more manageable, such as insulin pumps, continuous glucose monitors ("CGMs"), blood glucose meters, and other tools.[3] To combat hypoglycemia (low blood sugar), diabetics carry fast-acting sugar supplies, such as glucose tablets, juice boxes, or candy.[4] When attempting to enter a venue, diabetic patrons may be faced with unexpected challenges, where bag policies or other rules force them to leave their life-saving supplies behind, fight for their rights, or walk away, despite this kind of discrimination being a violation of federal law.[5]

This article will address the benefits of proposing legislation intended to define and protect diabetes medical supplies to prevent discrimination. First, this paper will discuss examples of discrimination that diabetics may experience when attending events at venues. Then, this article will analyze current law regarding discrimination while noting its deficiencies. To follow, new legislation to prevent diabetes discrimination at venues will be proposed.

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[1] CDC, Diabetics, *A Report Card: Diabetes in the United States Infographic* (2024).
[2] CDC, Diabetics, *Diabetics Basics* (2024).
[3] AM. DIABETES ASS'N, *Devices & Technology, Better blood glucose meters and more, Find the device that can make your life easier*, https://diabetes.org/about-diabetes/devices-technology (last visited Jan. 30, 2025).
[4] MAYO CLINIC, *Diabetic Hypoglycemia*, https://www.mayoclinic.org/diseases-conditions/diabetic-hypoglycemia/symptoms-causes/syc-20371525.
[5] AM. DIABETES ASS'N, *Fact Sheet on Discriminating in Public Places and Government Programs*, http://main.diabetes.org/dorg/PDFs/Advocacy/Discrimination/factsheet diabetesdiscriminationandpublicplacesandgovernmentprograms.pdf (last visited Mar. 27, 2025) (detailing how diabetics have feared discrimination at venues due to their supplies, which violates both the American Disabilities Act and The Rehabilitation Act of 1973).

After noting any counterarguments, this article will close by reinforcing the benefits of diabetics bringing discrimination claims.

II. THE VARIATION OF DIABETES DISCRIMINATION AT VENUES

Venues across the United States have different policies regarding admission for diabetics who require medical supplies.[6] There is a constant risk of discrimination for individuals with diabetic medication, whether due to bringing in outside food or drink, bringing bags to carry supplies beyond the permitted bag size, or bringing sharp objects, such as needles or lancets.[7] Since it is often up to individual venue employees to determine what patrons may bring into venues, such as sporting events,[8] there is a lack of uniformity for addressing what items diabetics may bring into a venue. Venues often also require exact dimensions for acceptable medical bags, which provides individuals a purview for what they can expect upon arrival.[9] However, it is upon arrival to a venue that a diabetic may face discrimination for having their medical supplies with them if they do not check a venue's policy beforehand.[10] It would be unreasonable to require a diabetic to *expect* such discrimination at a venue that they need to read a venue's bag policy before attending.

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[6] MLB*, Wrigley Field Information Guide, Bottles, Cans, and Outside Beverages,* https://www.mlb.com/cubs/ballpark/information/guide (last visited Feb. 8, 2025) (allowing outside food and drinks into the stadium under certain circumstances); Madison Square Garden*, Madison Square Garden FAQs*, Can I bring in outside food or beverage?, https://www.msg.com/madison-square-garden/faqs#venue (last visited Feb. 8, 2025) (asking that people with a medical condition that necessitates food or drink notify the venue in advance via phone or email).

[7] AM. DIABETES ASS'N, *supra* note 5.

[8] SOLIDER FIELD, *Bag Policy*, https://www.soldierfield.com/plan-your-visit/bag-policy (last visited Jan. 20, 2025).

[9] *Id.*

[10] Rob McMillan, *Security aggressively confronts diabetic man over snacks before Rams NFC championship game, fan says*, ABC EYEWITNESS NEWS (Feb. 8, 2022), https://abc7chicago.com/diabetes-sofi-stadium-super-bowl-lvi-location-in-los-angeles-ca/11546372/.

While diabetics require many supplies to keep them alive, only a handful are visible to the onlooker, and often diabetics become stereotyped or generalized as a result.[11] Devices more prominent on the body may appear as medically necessary based on the nature of the location and appearance of the tool. But not everything appears medically necessary to the average, nondiabetic onlooker. Specifically, items that provide sugar, like fruit snacks, sugar drinks, and glucose tablets, can become contentious as they generally do not directly present as medicine.[12] Venue employees may view this as an attempt to bring in outside food or drinks and forgo spending money at the venue. Since it is not always possible to immediately perceive these items as "medically necessary," it is likely that venue employees may react in a discriminatory manner because of inadequate training or education on diabetes.

There are countless instances of venues violating the law by denying diabetics access because of their insulin pumps, devices used in supplement of using insulin injections.[13] For example, in 2017, a water park refused a patron access to the facility's water slides until they removed their insulin pump.[14] Incidents like these put diabetics at risk of having their rights violated by being denied equal access to public spaces, since there seems to be an inadequate amount of education on how diabetic materials operate.[15]

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[11] Anne-Sopia Brazeau et al., *Stigma and Its Association With Glycemic Control and Hypoglycemia in Adolescents and Young Adults With Type 1 Diabetes: Cross-Sectional Study*, J. OF MED. RSCH. (Apr. 20, 2018), https://www.jmir.org/2018/4/e151/PDF.
[12] CDC, Diabetes, *Treatment of Low Blood Sugar (Hypoglycemia)* (May 15, 2024), https://www.cdc.gov/diabetes/treatment/treatment-low-blood-sugar-hypoglycemia.html.
[13] Kelly May, *Girl with diabetes banned from water slide because of insulin pump, mom claims*, FOXNEWS (Aug. 16, 2017), https://www.foxnews.com/lifestyle/girl-with-diabetes-banned-from-water-slide-because-of-insulin-pump-mom-claims; U.S. DEP'T OF JUST. CIV. RTS. DIV., 28 CFR Part 36 (Americans with Disabilities Act) (2010).
[14] *Id.*
[15] *Id*.

For instance, at the National Football Conference Championship, a diabetic man was ejected from SoFi Stadium for attempting to bring outside food and drinks for managing and preventing hypoglycemia into the stadium.[16] This situation occurred despite prior instances of the man being permitted to bring in outside food and drink into the stadium and the stadium policy, itself, offering medical exceptions to the typical prohibition of these items.[17]

Further, in 2003, the Department of Justice sought injunctive relief against a venue that refused to allow patrons to bring medical supplies, including needles, and food and drinks, even with a valid medical purpose.[18] There, the policy specifically noted that items, including diabetes supplies, would be reviewed by medical staff for their medical necessity, and, most pertinently, there was a prohibition on using insulin needles unless in the "First Aid Room."[19] The Department of Justice ("DOJ") determined that the separation of a diabetic from these supplies creates a "life-threatening" environment that causes a denial of "equal opportunity."[20] The DOJ also found that the venue had exhibited a "pattern or practice of discrimination" in violation of 28 C.F.R. 26 and 42 U.S.C. 12182 (a) and fined the venue $20,000 to be paid to the U.S. Treasury.[21]

III. ASSESSING CURRENT LAW INTENDED TO PREVENT DISCRIMINATION

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[16] Rob McMillian, *Security aggressively confronts diabetic man over snacks before Rams NFC championship game, fan says*, ABC7 CHICAGO (Feb. 8, 2022), https://abc7chicago.com/diabetes-sofi-stadium-super-bowl-lvi-location-in-los-angeles-ca/11546372/.
[17] *Id.*
[18] Consent Order and Final Judgment, United States of America v. SFX Ent., Inc., NO 02-CV-1929 (E.D.Pa. June 12, 2003) (noting where there was a venue policy expressly prohibiting "patrons from taking any syringes or needles used for medical purposes, including needles used for insulin and lancets for testing blood, into the concert venue unless secured in a first aid room.").
[19] *Id.*
[20] *Id.*
[21] *Id.*

When a venue requires a diabetic to dispose of their diabetes supplies in order to enter – supplies which are already costly – they force diabetics to face a potential medical crisis without their medical supplies or leave a venue they chose to attend.[22] It is a violation to prohibit access to venues because of medical supplies.[23] Title III of the American Disabilities Act ("ADA") clarifies that:

> "A public accommodation shall not subject an individual or class of individuals on the basis of a disability or disabilities . . . .to a denial of the opportunity of the individual or class to participate in or benefit from the goods, services, facilities, privileges, advantages, or accommodations of a place of public accommodation."[24]

While Title III of the ADA is intended to protect diabetics from discrimination, and has been generally successful, its lack of specificity regarding diabetics continues to leave a window open for discrimination towards diabetics. Because there is a variation in venue policy regarding medical supplies, there is a higher probability of employees having vastly different interpretations of what should be considered medically necessary.[25]

Discriminatory generalizations towards diabetics have existed for decades.[26] Currently, various civil rights laws attempt to prevent disability discrimination.[27] In addition to Title III of the ADA , 42 U.S.C. 12182 also

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[22] *Insulin pump costs*, MEDTRONIC, https://hcp.medtronic-diabetes.com.au/insulin-pump-costs (last visited Feb. 2, 2025) (stating the cost of a Medtronic Insulin Pump).
[23] Guide to Disability Right Laws, ADA (Feb. 28, 2020), https://www.ada.gov/resources/disability-rights-guide/.
[24] U.S. DEP'T OF JUST. CIV. RTS. DIV., 28 CFR Part 36 (Americans with Disabilities Act) (2010).
[25] BEYOND TYPE 1 EDITORIAL TEAM, *Sporting Events with T1D* (Feb. 10, 2017), https://beyondtype1.org/sporting-events-with-t1d/ ("Some (NOT all) sports venues have an entirely separate screening line for people with medical conditions.").
[26] Graham v. Connor, 490 U.S., 388, 388, (1989).
[27] ADA, *Guide to Disability Right Laws* (Feb. 28, 2020), https://www.ada.gov/resources/disability-rights-guide/#americans-with-disabilities-act-ada

prohibits such discrimination in public settings.[28] Particularly, 42 U.S.C. 12182 prohibits the discrimination of anyone due to their disability to limit them from "full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation."[29] Therefore, when a venue employee denies someone the opportunity of an experience at a venue due to a disability, they are violating the law.[30]

Additionally, the precedent of imposing fines on those found liable for disability discrimination provides that it is a feasible consequence for such actions.[31] 28 C.F.R. Part 36 lists various fines and penalties imposed due to discrimination.[32] A specific example of a fine is one that is: "not exceeding $110,000 for any subsequent violation occurring on or after September 29, 1999."[33] The law also notes that the judiciary shall consider "whether the entity could have reasonably anticipated the need for an appropriate type of auxiliary aid needed to accommodate the unique needs of a particular individual with a disability."[34] Therefore, the reasonableness of such accessibilities and accommodations at issue in the dispute are necessary in considering how to penalize places such as venues. Through legislation, such

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(delineating the several Acts provided for various settings to prevent discrimination); Prohibition of discrimination by public accommodations, 42 U.S.C. §12182 (discussing the prohibition of discrimination in public settings, but does not mention diabetes in the document).

[28] U.S. DEP'T OF JUST. CIV. RTS. DIV., 28 CFR Part 36 (Americans with Disabilities Act); Prohibition of discrimination by public accommodations, 42 U.S.C. §12182 (discussing the prohibition of discrimination in public settings, but does not mention diabetes in the document).

[29] Prohibition of discrimination by public accommodations, 42 U.S.C. §12182 (discussing the prohibition of discrimination in public settings, but does not mention diabetes in the document).

[30] U.S. DEP'T OF JUST. CIV. RTS. DIV., 28 CFR Part 36 (Americans with Disabilities Act), (2010).

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *Id.*

as 42 U.S.C. 1983, there is further precedent showing the unconstitutionality of refusing certain supplies that deprive diabetics of these life-saving aids.[35] Moreover, the deprivation of a patron's medically necessary devices should require consequences to be imposed on venue employees and venues themselves, as this is a Constitutional rights violation.

While 42 U.S.C. 12182 prohibits disability discrimination in public settings, such as venues, there is no explicit reference to diabetes anywhere in the document.[36] As a result, the possibility of diabetes discrimination still depends on whether a venue employee, such as security at the entrance, is able to determine the medical necessity of diabetes medical supplies. Therefore, there is insufficient specificity in legislation pertaining to the discrimination that diabetics may face, which causes venue policies that operate on a case-by-case basis to have little to no guidance on what diabetes supplies are medically necessary. The inconsistency in venue interpretation of what is medically necessary is a glaring threat to the health and safety of diabetics attempting to enter venues. Without explicit regulations on what is deemed medically necessary for diabetics at venues, the average onlooker may fail to ascertain the necessity of supplies that diabetics may need to carry with them to prevent hypoglycemia.[37]

Also, the creation of a caucus in the U.S. House of Representatives was intended to advocate for legislation for diabetics, while simultaneously educating Congress on how to further improve diabetics' quality of life.[38] It

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[35] 42 U.S.C. §1983 (2024); AM. DIABETES ASS'N, Inappropriate Law Enforcement Response to Individuals with Diabetes: An Introduction and Guide for Attorneys (Sept. 2014).
[36] Prohibition of discrimination by public accommodations, 42 U.S.C. §12182 (discussing the prohibition of discrimination in public settings, but does not mention diabetes in the document).
[37] CDC, s*upra* note 12.
[38] AM. DIABETES ASS'N, *Advocacy*, Federal Advocacy, https://diabetes.org/advocacy/federal-connected-congress (last visited Feb. 8, 2025).

would be beneficial to look to previously proposed Congressional legislation to learn what can be done to further reduce discrimination and improve the quality of life for diabetics.[39] For example, legislation such as the Access to Quality Diabetes Education Act of 2015 indicates that there is a preexisting belief that the further promotion of diabetes education would improve the greater welfare of diabetics.[40] The Act attempted to improve educational quality pertaining to diabetes for Social Security in telehealth environments.[41] Although nothing came from this bill, the precedential push for diabetes education in new spaces offers a basis that elevating education towards diabetics in particular would be beneficial.[42] Therefore, any new legislation requiring intensive diabetes education pertaining to medically necessary supplies and correlation to preventing health risks would improve the patron experience at venues. For example, the Act and its focus on elevating "access to diabetes self-management training by authorizing certified diabetes educators to provide diabetes self-management training services… ."[43] would be an important policy requiring venues to have their security personnel improve the intensity of training they receive related to diabetes. Altogether, an emphasis on improving diabetes education may help eliminate future discrimination.

IV. PROPOSED LEGISLATION TO REMEDY THE PROBLEM

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[39] U.S. HOUSE OF REPRESENTATIVES DIABETES CAUCUS, *Diabetes Legislation*, https://diabetescaucus-degette.house.gov/legislation (last visited Feb. 8, 2025); H.R. 1726 114th Cong. (referred to the S. Comm. on Health, Apr. 14, 2015) (describing the previous forms of legislation offered to improve the standards of education and care provided to diabetics).
[40] U.S. HOUSE OF REPRESENTATIVES DIABETES CAUCUS, *supra* note 39; H.R. 1726 114th Cong. (referred to the S. Comm. on Health, Apr. 14, 2015) (proposing various methods of outreach for educational benefit to health care employees to improve the quality of life of diabetics).
[41] H.R. 1726 114th Cong. (2015-16).
[42] H.R. 1726.
[43] *Id.*

Given the vast lack of specificity regarding diabetes medical supplies, there should be new legislation that works to eliminate diabetes discrimination. It would be beneficial to create a more detailed law specifically pertaining to diabetes while highlighting Title III. Any proposed legislation should begin broadly and become narrower with each section. First, legislation should note that the purpose of this legislation is to define what constitutes diabetic medical supplies, what specific actions constitute discrimination at venues, and consequences for disregarding the law. It would be pertinent to then provide specific definitions to key terms within the legislation, such as "medical supplies," "medically necessary," and "discrimination." Moreover, it would be beneficial to provide clear definitions and examples of concepts such as what constitutes a "venue", who are "diabetic patrons", defining medical supplies, and what consequences would be imposed. To create specific definitions, it would be useful to look to experts in the field of diabetes for their definitions of these terms.

Historically, the American Diabetes Association considers various forms of carbohydrate sources to treat hypoglycemia[44]. These considerations have been broken down into subcategories of sources, while also listing the amount of carbohydrates necessary to treat mild hypoglycemia.[45] Foods listed for treatment vary from glucose tablets and crackers to juice and soft drinks.[46] Symptoms that diabetics experience from hypoglycemia range from blurred vision, tremors, auditory processing problems, cognitive dysfunction, or even combativeness and seizures.[47] Consequently, because carbohydrate sources are directly noted as treating hypoglycemia for

[44] AM. DIABETES ASS'N, MED. MGMT. OF TYPE 1 DIABETES, 55 (Cecilia C. Low Wang & Avni C. Shah eds., 7th ed. 2016).
[45] *Id.*
[46] *Id.*
[47] *Id.* at 185.

diabetics to prevent symptoms for mild hypoglycemia,[48] they should be the main reference towards what should be considered as "medical supplies" in legislation. Therefore, legislation should incorporate the definition of medical supplies provided by the American Diabetes Association in conjunction with 28 C.F.R. 36's notation of what constitutes "auxiliary aids," so that there is a direct notation to what medical supplies are necessary for diabetics; one that a venue would not be financially responsible for providing.[49]

Another pertinent section of this legislation should be specific to diabetics who are traveling. Venues such as airports and train stations should adhere to this proposed law to prevent further discrimination on the basis of disability, rather than making their own medical assessments based on personal beliefs.[50] Again, the American Diabetes Association is a strong example of where to take inspiration from when considering circumstances in which this may be applicable.[51] Diabetics are specifically encouraged to carry "1.5 times a patient's projected needs…for the entire trip to accommodate delays and other potential travel mishaps." and that "[f]ood to treat hypoglycemia and for any meal that may be delayed by late arrival should also be carried with the patient."[52]

Thus, proposed legislation should cover all aforementioned fields to appear as:

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[48] *Id.* at 190.
[49] U.S. DEP'T OF JUST. CIV. RTS. DIV., 28 CFR Part 36 (Americans with Disabilities Act) (2010) ("The question of whether a person has a dis - ability should be assessed without regard to the availability of mitigating measures, such as reasonable modifications or auxiliary aids and service…").
[50] Joseph Shapiro & Allison Mollenkamp, *Despite calls to improve, air travel is still a nightmare for many with disabilities*, NPR (Nov. 8, 2021), https://www.npr.org/2021/11/09/1049814332/despite-calls-to-improve-air-travel-is-still-a-nightmare-for-many-with-disabilit (discussing a college student who was told by TSA that it did not appear like they needed their insulin pump).
[51] AM. DIABETES ASS'N, *supra* note 44.
[52] *Id.*

Legalizing the Necessity of Diabetes Supplies at Venues.

(A) Beginning in 2025, all public venues shall be required to permit diabetics to bring all necessary medical supplies into their premises after proof of disability.

(a) Public venues can be defined as any place in which any form of specified event is held.[53]

(b) Medical supplies should be considered, but subject to change, on the basis of medical advancement, blood glucose meters, insulin needles, insulin pumps, insulin pens, and personal supplies to treat hyperglycemia, diabetic ketoacidosis, and hypoglycemia.[54]

(c) Personal supplies to treat hypoglycemia can be items such as, but not limited to, due to product brand variation, glucose tablets, glucose gel, crackers or other candies, juices, or soft drinks.[55]

(d) Proof of disability can occur by: outward expression of disability towards medical staff.

(e) Outward expression can be either: showing a medical card, presenting the diabetes supplies one is carrying on their person, or a doctor's note.

(f) "Patron" is defined as someone who is attending a Venue and, through the means of purchasing goods to attend or while in attendance at the Venue.[56]

By stating the importance of these supplies, venues would be encouraged to understand the severity of the risk of discriminating against diabetics by prohibiting their medical supplies.

(B) The purpose of diabetics bringing in outside medical supplies, such as, but not limited to, outside food and drinks, is to prevent hypoglycemia,

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[53] Venue, MERRIAM-WEBSTER'S DICTIONARY, https://www.merriam-webster.com/dictionary/venue (last visited Jan. 20, 2025).
[54] AM. DIABETES ASS'N, *supra* note 3; MAYO CLINIC, *supra* note 4; Sours v. Big Sandy Reg'l Jail Auth., No.13-6370, 6th Cir., LEXIS 23256, at *479 (6th Cir. Dec. 5, 2014).
[55] MAYO CLINIC, *supra* note 4; Sours v. Big Sandy Reg'l Jail Auth., No.13-6370, 6th Cir., LEXIS 23256, at *479 (6th Cir. Dec. 5, 2014).
[56] *Patron*, MARRIAM-WEBSTER'S DICTIONARY, https://www.merriam-webster.com/dictionary/patron (last visited Mar. 9, 2025).

> which may present through mild, moderate, or severe symptoms such as tremors, irritability, seizures, or death.[57]

The next section of this legislation should require venues to have a brief training period on diabetes to avoid lawsuits against both the premises and its employees.

> (C) Each venue shall incorporate a health training course on the symptoms of hypoglycemia and hyperglycemia that diabetics may experience.[58] Training may consist of a healthcare professional providing an annual lecture regarding symptoms of hypoglycemia, hypoglycemia, and detailing how diabetics treat and manage this independently.

Additionally, the penalizations proposed should clarify that this legislation is not optional for public venues to adhere to; rather, failure to adhere to the law may result in severe consequences.

> (D) Failure to adhere to this law is subject to violation of ADA Title III and may be a violation of other rights as well. Venues will be subject to fines with payment beginning at $20,000 and may be subject to litigation. Continued failure to follow this law may result in further fines exceeding $20,000 and investigations.[59] Reports of more than three instances of an employee prohibiting these medical supplies into their employer's venue, the employee is to be terminated upon notice. If a Venue fails to terminate the Employee, it would be subject to investigation with injunctive and monetary consequences, such as temporary closure of the Venue, as penalization for failure to adhere to the law or fines.[60] Further failure to adhere to this legislation would result in prosecution by the Department of Justice with consequences leading to permanent closure of the building.[61]

Lastly, venues should be required to make accessible means of reporting these instances by including what is listed in subsection (E).

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[57] AM. DIABETES ASS'N, *supra* note 44.
[58] H.R. 1726 114th Cong., *supra* note 41 (encouraging the furtherment of diabetic education).
[59] Consent Order and Final Judgment, United States of America v. SFX Ent., Inc., NO 02-CV-1929 (E.D.Pa. June 12, 2003)
[60] *Id.*
[61] *Id.*

> (E) Venues will similarly be required to provide an accessible means of reporting instances of discrimination for their patrons[62] to use in order to track employee misconduct.[63] Accessible means of reporting are: speaking to an employee, using a call service, or reporting on the Venue's website. These reports should include a series of questions, including: date of occurrence, time of occurrence, location in venue, and (if possible) name of venue employee. If an employee's name is not accessible, such as if the employee refuses to provide it to the patron[64], based on the facts provided, venues should attempt to determine who was scheduled and shifted at the location in the venue. If no name can be determined by reasonable methods, the incident will be filed to analyze for any trends. Upon three reports of misconduct, an employee is terminated.

V. WHY DIABETES DISCRIMINATION CLAIMS ARE WORTHWHILE

A counterclaim to this legislation is that it may be too vague, considering how difficult it can be to prove discrimination. Additionally, there may be general wariness towards bringing a claim due to the concern that the complexities of one's disability pose a barrier to recovery.[65] There are also financial barriers that some may experience if bringing a complaint that may result in litigation.[66] That said, there is hope that The Office for Access to Justice, a subunit of the Department of Justice[67], is dedicated to communicating with "with disability communities and advocates to identify challenges faced in the civil and criminal justice systems; partnerships with agencies across the federal government; and by identifying evidence-based, people-centered approaches to legal system reform."[68] Therefore, because of

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[62] MARRIAM-WEBSTER'S DICTIONARY, *supra* note 56.
[63] *Contact Security*, Cubs.com, https://www.mlb.com/cubs/ballpark/fan-services (last visited Mar. 8, 2025).
[64] MARRIAM-WEBSTER'S DICTIONARY*, supra* note 56.
[65] Archives, U.S. DEP'T OF JUST., *Advancing Equal Access to Justice for Americans with Disabilities: Moving Towards Closing the Justice Gap on the 33rd Anniversary of the ADA* (July 26, 2023), https://www.justice.gov/archives/atj/blog/advancing-equal-access-justice-americans-disabilities-moving-towards-closing-justice-gap.
[66] *Id.*
[67] OFF. FOR ACCESS TO JUST., *Who We Are*, https://www.justice.gov/atj (last visited Apr. 9, 2025).
[68] U.S. DEP'T OF JUST.*, supra* note 65.

concerns about bringing claims such as these, there are designated governmental units intended to mitigate challenges relating to accessibility to government aid.[69] While there are challenges when bringing discrimination claims, the legislation proposed above would work to make the process more effective by posing clearer definitions and stricter penalties. By enacting legislation that protects the users of the supplies from discrimination, avoidable injuries are curtailed, conflicts with authorities are minimized, and potential lawsuits are mitigated. While it may appear that challenging a venue on the basis of a discrimination claim is too steep of a battle, the process is straightforward.

Currently, the ADA provides that someone may file a discrimination complaint by mail or online.[70] The complaint process includes seven steps in applying: providing contact information, stating what the concern was and where it occurred, listing any personal characteristics, when this occurred, a personal description, and reviewing before submission.[71] Additionally, to simplify the accessibility of information for people with disabilities, there are efforts made to make information publicly available that "includes simple explanations of the law designed for people without a legal or technical background."[72] Further, to help individuals with disabilities learn how to file a claim, states provide Court Disability Coordinators, who are useful guides throughout the process that every state is required to have in their courts.[73]

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[69] U.S. DEP'T OF JUST., *supra* note 65 ("In 2022, LAIR issued a Report, Access to Justice through Simplification, which provides a people-centered Roadmap to simplifying access to the federal government.").
[70] ADA, *File a Complaint* (last visited Mar. 20, 2025), https://www.ada.gov/file-a-complaint/.
[71] U.S. DEP'T OF JUST., Contact the Department of Justice to report a civil rights violation, https://civilrights.justice.gov/report/?utm_campaign (last visited Mar. 20, 2025).
[72] Legal Aid Interagency Roundtable, *Access to Justice through Simplification*, 2022, https://www.justice.gov/d9/2023-03/Legal%20Aid%20Interagency%20Roundtable%202022%20Report.pdf.
[73] Washington Couts, Court Program Accessibility (ADA and Washington State information) (last visited Mar. 20, 2025),

VI. CONCLUSION

Insufficient legislation and education regarding diabetes supplies have created inconsistent venue interpretations of what supplies a diabetic to bring may be permitted to bring into a venue. When the assessment of what is "medical necessity" is left to an individual, *other than the disabled individual*, it risks unsafe environments for diabetics who may be left without their lifesaving supplies if they want to enter certain venues. This is because the disconnect that venues seem to be finding in contrast to that of diabetics is that the varying interpretations of what supplies can be brought into a stadium are subject to staff determination as to their necessity. Therefore, creating dedicated legislation focused on defining what items are medically necessary, improving towards promoting diabetes education, and imposing specific consequences for discrimination would provide direct safeguards for diabetics who experience unnecessary discrimination at venues. Eliminating current inconsistent standards for venue policies and inadequate specificity in current legislation would therefore minimize discriminatory practices that slip through the cracks of the system. In conclusion, legislation protecting diabetes supplies is the best next step to ensure that all diabetics are able to experience a better quality of life at public venues.

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https://www.courts.wa.gov/?fa=home.sub&org=ada&page=model&layout=2&parent=about ("All state and local government entities, including courts, with 50 or more employees, must have a designated ADA Coordinator.").

From Pandemic to Present: The Rise of Digital Counseling Platforms Amidst Lack of Oversight and Standardization

Hyunji Haynes

I. THE NEED FOR STANDARDIZED OVERSIGHT IN DIGITAL MENTAL HEALTH CARE

Over the past decade, virtual therapy and digital counseling platforms have revolutionized access to mental healthcare, presenting a viable alternative to traditional face-to-face services. Companies offer video, phone, and text-based counseling, eliminating geographical and logistical barriers that often deter people from seeking mental health help.[1] The popularity of these platforms has grown in response to a surge in mental health awareness, driving a greater demand for accessible, affordable care.[2] This shift has been accelerated by the COVID-19 pandemic, not only normalizing digital counseling, but also exposing systemic gaps in mental healthcare access.[3]

While digital counseling platforms provide new opportunities for mental health intervention, they also raise a host of challenges relating to regulation, ethics, and quality control.[4] Fears around the credentials of practitioners, the privacy of data collected, and the commercialization of mental healthcare have led to advocacy for stricter consumer protections and standardized regulations.[5] These platforms can also inadvertently amplify inequalities by benefiting those who already have access to high-quality internet while excluding marginalized populations.[6] This paper will examine the ways

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[1] Rebecca Joy Stanborough & Hilary I. Lebow, *Comparing Talkspace and BetterHelp in 2025: Key Differences Explained*, HEALTHLINE (Jan. 27, 2025), https://www.healthline.com/health/talkspace-vs-betterhelp.
[2] John Torous et al., *Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow*, 7 JMIR MENT. HEALTH 1 (2020).
[3] Aneela Maqsood et al., *From Face-to-Face to Screen-to-Screen: Exploring the Multifaceted Dimensions of Digital Mental Health Care*, 15 FRONTIERS PSYCHIATRY 1, 2 (2024).
[4] Raymond R. Bond et al., *Digital Transformation of Mental Health Services*, 2 NPJ MENTAL HEALTH RSCH. 1, 5 (2023).
[5] Sharon Bassan, *Data Privacy Considerations for Telehealth Consumers amid COVID-19*, 7 J. L. & BIOSCI., 1, 7–9 (2020).
[6] Tyler J. Brewster, *Why We Should Fully Embrace Telehealth in a Post-Pandemic World*, 23 HOUS. J. HEALTH L. & POL'Y 115, 125 (2024).

digital counseling platforms broaden access to mental healthcare, identify regulatory and ethical challenges, and provide policy recommendations to ensure that these platforms remain accessible and effective.

II. THE EXPANSION OF DIGITAL COUNSELING AND REGULATORY GAPS

The COVID-19 pandemic represented a crossroads for the delivery of mental healthcare, leading to a massive pivot towards digital counseling platforms.[7] In the wake of that coalescing demand, federal and state governments relaxed telehealth prohibitions on a temporary basis, easing cross-state licensing provisions and reimbursement policies.[8] These emergency measures greatly increased access to mental health care, especially among those in rural areas.[9]

However, as pandemic-era policies started to wind down, gaps in regulatory oversight emerged.[10] Many temporary licensure waivers and reimbursement expansions expired, reinstating previous barriers to telehealth access.[11] Besides legislation such as the Psychology Interjurisdictional Compact ("PSYPACT"), which allows a therapist with their own interstate license to provide therapy in neighboring states, state licensure laws continue to pose barriers to therapists providing services across state lines.[12] While digital counseling platforms show no signs of losing their popularity,

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[7] Allyson E. Gold et al., *Socially Distant Health Care*, 96 TUL. L. REV. 423, 425 (2021).
[8] Gold, Gilbert, & McMichael, *supra* note 7, at 426, 445; Jayne Jacova Feld, *Medicare Telehealth Coverage, Set to Expire March 31, Extended to September 30,* PULMONOLOGY ADVISOR (Jan. 31, 2025), https://www.pulmonologyadvisor.com/features/medicare-telehealth-ending.
[9] David A. Hoffman, *Increasing Access to Care: Telehealth During COVID-19*, 7 J. L. BIOSCI. 1, 2 (2020).
[10] Gold, Gilbert, & McMichael, *supra* note 7, at 454–55.
[11] Minsoo Kwon, James René Jolin, & Carmel Shachar, *Telehealth After the Federal COVID-19 Public Health Emergency: Implications and Future Directions*, 52 J. L. MED. ETHICS 412, 413 (2024); U.S. DEP'T OF HEALTH & HUM. SERVS., *Barriers and Opportunities for Improving Interstate Licensure*, ASPE (2023), https://aspe.hhs.gov/sites/default/files/documents/405ad876b1de337a81b4db0257666586/barriers-opportunities-improving-interstate-licensure.pdf.
[12] *Licensure and Interstate Compacts*, NAT'L CONF. ST. LEGISLATURES, https://www.ncsl.org/health/the-telehealth-explainer-series/licensure-and-interstate-compacts (last visited Feb. 8, 2025).

questions remain about their long-term integration into the healthcare system and whether credentialing of practitioners is sufficient.[13]

Due to the lack of federal intervention, the responsibility to reform licensure will primarily rest with state legislatures, resulting in a patchwork regulatory environment that stifles telehealth growth and limits patient access to qualified practitioners.[14] Although Congress and federal agencies have recognized the need for greater licensure mobility, their attempts to mitigate cross-state licensure barriers have been inconsistent, leaving many telehealth providers confined within the constraints of state specific licensure laws.[15] One such effort, the Telemental Health Care Access Act ("THCAA"), seeks to expand licensure reciprocity for Medicare providers that are engaged in telehealth services.[16] Additionally, the Interstate Medical Licensure Compact ("IMLC") and PSYPACT receive federal support as models for regulatory streamlining; however, the processes remain state-driven, not federally controlled.[17] Despite this legislation, there is no national system that requires states to recognize each other's' licenses, making access to telehealth uneven across state lines.[18]

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[13] Edward Timmons & Conor Norris, *Potential Licensing Reforms in Light of COVID-19*, 3 HEALTH POL'Y OPEN 1, 2 (2022).
[14] Nicol Turner Lee, Jack Karsten, & Jordan Roberts, *Removing Regulatory Barriers to Telehealth Before and After COVID-19*, BROOKINGS INST. (May 2020), https://www.brookings.edu/articles/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19.
[15] James René Jolin et al., *Reforming Physician Licensure in the United States to Improve Access to Telehealth: State, Regional, and Federal Initiatives*, 102 MILBANK Q. 833, 835 (2024).
[16] AHA House Statement on Legislative Proposals to Support Patient Access to Telehealth Services, AM. HOSP. ASS'N (Apr. 10, 2024), https://www.aha.org/2024-04-10-aha-house-statement-legislative-proposals-support-patient-access-telehealth-services.
[17] *Federal Grant Awarded to Expand Interstate Medical Licensure Compact; Support License Portability for PAs*, FED'N OF STATE MED. BDS. (Aug. 27, 2019), https://www.fsmb.org/advocacy/news-releases/federal-grant-awarded-to-expand-interstate-medical-licensure-compact/; Rebecca A. Clay, *PSYPACT: 26 states have now passed laws allowing interstate practice*, AM. PSYCH. ASS'N (July 2, 2021), https://www.apaservices.org/practice/legal/technology/psypact-interstate-practice-telehealth.
[18] *Practice Therapy Or Telehealth Across State Lines: Mental Health Care Options*, BETTERHELP, https://www.betterhelp.com/advice/therapist-tools/can-i-practice-therapy-or-

Given the wide regulatory inconsistencies and the boom in digital counseling platforms, there remains a critical need for licensing standards, privacy protections, and quality control to be set.[19] Without clear guidelines or adequate oversight, platforms risk operating in a gray area: providing wide access to some, while potentially harming others through inconsistent care quality and inadequate credential verification.

III. Licensing Challenges in Digital Counseling: A Regulatory Patchwork

One of the biggest regulatory challenges in digital counseling is the patchwork of state licensure laws.[20] Many states restrict therapists from providing services across state lines unless they hold separate licenses for each jurisdiction.[21] This means therapists must stay updated on the most recent legislation to avoid operating in the gray, otherwise they run the risk of practicing in states where they are not licensed; this has only widened the confusion for both therapists and consumers.[22] This gray area leaves patients at the mercy of the ambiguous patchwork, with the potential that they receive therapy, without their knowledge, from a provider not legally allowed to treat them. Additionally, the state-by-state licensure rules further narrow the pool of therapists from whom they can seek help, particularly disadvantaging patients in rural and underserved parts of the states, where there are fewer mental health professionals in a given state.[23]

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telehealth-across-state-lines-exploring-options/ (last visited Feb. 8, 2025) ("There isn't a federal law in the US allowing therapists to practice teletherapy across state lines. Different states have different laws regarding telehealth, so certified mental health counselors are often limited to practicing therapy in the states allowed by their license.").

[19] Nicole Martinez-Martin & Karola Kreitmair, *Ethical Issues for Direct-to-Consumer Digital Psychotherapy Apps: Addressing Accountability, Data Protection, and Consent*, 5 JMIR Mental Health 1, 2–4 (2018).

[20] Jay Ostrowski & Traci P. Collins, *A Comparison of Telemental Health Terminology Used Across Mental Health State Licensure Boards*, 6 Prof. Couns. 387 (2016).

[21] *Which States Allow Telehealth Across State Lines?*, Record Retrieval Solutions (Sept. 19, 2024), https://www.recordrs.com/blog/which-states-allow-telehealth-across-state-lines/.

[22] Linda M. Richmond, *Cross-State Licensure Laws for Telehealth Evolve During Pandemic*, 57 Psychiatric News, no. 2 (Jan. 27, 2022), https://doi.org/10.1176/appi.pn.2022.2.5.

[23] Ostrowski & Collins, *supra* note 20, at 388.

This patchwork was clearly illustrated by a 2016 study led by Jay Ostrowski and Traci Collins who investigated the dangers posed by variance of health terminology for "telemental" health across different state licensure boards.[24] The term was coined in an effort to standardize the inconsistencies within practice and academia, who use terms from 'online counseling' to 'cybertherapy'.[25] The study highlights the confusion and hazards these variations can cause for practitioners seeking guidance in their practicing states.[26] Ostrowski and Collins surveyed all 50 state mental health licensure board websites and found 42 different tele-mental health terms used across 65 boards, representing 36 states.[27] Of those, only 14 states had consistent policies across all mental health professions, and just 43% of boards provided even minimal guidance on tele-mental licensure requirements.[28] This lack of definitional clarity contributes to confusion among providers trying to comply with state requirements and obstructs transparency about what services are permitted, which licenses are valid, and how to access resources.[29] As a result, both providers and patients may struggle with delayed or denied care, reduced access across state lines, and inconsistent standards of practice.[30]

Ostrowski and Collins' study findings show that serious systemic challenges exist regarding cross-state mental health licensure beyond simple bureaucratic confusion.[31] Having 42 disparate terms across 65 licensing boards highlights how fragmented and inconsistent regulatory approaches are, and how difficult it is for practitioners to confidently navigate compliance

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[24] *Id.* at 389.
[25] *Id.*
[26] *Id.* at 391–93.
[27] *Id.* at 390.
[28] *Id.* at 391.
[29] *Id.* at 392–93.
[30] *Id.* at 394.
[31] Nadine J. Kaslow et al., *Competencies Conference: Future Directions in Education and Credentialing in Professional Psychology*, 60 J. CLIN. PSYCHOL. 699, 701 (2004).

requirements for licensure when crossing state lines.[32] This lack of standardization has real-life consequences for both therapists and patients. Therapists will have greater administrative burdens, face potential legal risk, and have delayed access to new patient flows.[33] The situation is no better for patients. Fewer than half of state licensure boards provide minimal guidance on tele-mental health, suggesting that patients are receiving care from therapists who may lack qualifications or are unfamiliar with their legal standing.[34] This lack of transparency can and will undermine trust, the touchstone of therapy.

Jeffrey Barnett and Keely Kolmes articulated the same issue in their case example of Dr. Roule Breyker.[35] Dr. Breyker had a license to practice counseling in the state of Montana, and due to its rural nature, decided to expand his practice to other cities throughout the state via remote digital services.[36] The success of his expansion ushered in inquiries from potential clients in neighboring states, and beyond to Canada.[37] Excited, Dr. Breyker shared the news with his colleagues who, to his dismay, reacted with concern, and questioned how he would manage an interjurisdictional practice.[38]

What Dr. Breyker's case example highlights is the dynamic use of the internet. On the one hand, to advertise and expand tele-mental health, but on the other, the complex legal issues that accompany development.[39] All

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[32] Ostrowski & Collins, *supra* note 20, at 394; *see also* Deborah C. Baker & Lynn F. Bufka, *Preparing for the Telehealth World: Navigating Legal, Regulatory, Reimbursement, and Ethical Issues in an Electronic Age*, 42 PRO. PSYCHOL.: RES. & PRAC. 405 (2011) (noting "This lack of uniformity begins with the threshold issue of what we should call this particular area of practice. Various terms such as "telehealth," "telemedicine," "e-health," and even "m-health" are used by the provider community, legislators, policymakers, and payers.").
[33] Jolin et al., *supra* note 15, at 839.
[34] Ostrowski & Collins, *supra* note 20, at 391.
[35] Jeffrey E. Barnett & Keely Kolmes, *The practice of tele-mental health: Ethical, legal, and clinical issues for practitioners*, 1 PRAC. INNOVATIONS 53, 61 (2016).
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*; *See also* Elias Aboujaoude, *Telemental health: why the revolution has not arrived*, 17 WORLD PSYCHIATRY 277, 278 (2018) (noting "Another challenge is the confusing legal

jurisdictions require health professionals to be licensed before they can legally provide services to clients at that location.[40] For therapists hoping to expand across state lines, the lack of uniformity poses a number of challenges, both logistical and legal.[41] Some states require therapists to be fully licensed in that state, which can be a long, costly, and impractical process.[42] A few states do allow temporary licensing, which enables short-term practice of less than thirty days in a given timeframe, but such provisions differ significantly.[43] Other states make no mention of the issue, leaving therapists to navigate imprecise legal frameworks or seek guidance directly from licensing boards.[44]

Without a central licensing system, clinicians face a patchwork of varying and often discordant requirements that make compliance a convoluted process.[45] And, lacking national licensing reciprocity, mental health practitioners are compelled to either avoid working with out-of-state clients or work under the specter of legal jeopardy.[46] This gray area of legality exposes practitioners to disciplinary action from licensing boards for unauthorized practice, malpractice risks if challenged in an unlicensed jurisdiction, and legal liability if a client or third party files a complaint.[47] These risks inhibit the growth of tele-mental health services, dissuading providers from rendering care in states lacking clear guidelines.[48]

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landscape within which telepsychiatry practice occurs. Depending on the country, this may involve adhering to a complex web of federal and regional legislation.").

[40] Barnett & Kolmes, *supra* note 35, at 61.

[41] *Id.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*; *see also* U.S. DEP'T OF HEALTH & HUM. SERVS., *Barriers and Opportunities for Improving Interstate Licensure* (2023), https://aspe.hhs.gov/sites/default/files/documents/405ad876b1de337a81b4db0257666586/barriers-opportunities-improving-interstate-licensure.pdf.

[47] Barnett & Kolmes, *supra* note 35, at 61.

[48] *Id.*

IV. Expanding on Interstate Compacts: Federally Maintained Database For Interjurisdictional Practice

The inconsistency of state licensure laws prevents therapists from practicing across state lines unless they obtain separate licenses for each jurisdiction, which erodes availability of care, especially in rural and underserved communities.[49] Currently, temporary solutions exist on the small-scale state level through interstate compacts, offering some inter-state reciprocity, but not without confusion or lack of standardization.[50] Although broad federal licensure reciprocity for mental health practitioners remains politically and logistically complicated, a federally maintained practitioner database represents a more feasible and immediately actionable approach to addressing many barriers practitioners face as they seek to provide care across state lines.[51]

A federal registry of mental health professionals would function as an interjurisdictional verification system, ensuring licensure transparency and credential consistency across state lines. It would not supersede state regulations but create an improved mechanism for credentialing, offering up-to-date, publicly available data on licensed practitioners. Each entry would include the name, credentials, active licensure, states of practice, existing cross-state privileges, educational background, certifications, areas of specialization, compliance history, and any disciplinary records, of each practitioner. States opted into the database would gain access to shared practitioner records, allowing quicker approvals for out-of-state providers while retaining state-specific oversight. Thus, the system would include dual access levels: a public-facing interface for patients to verify provider credentials, and a regulatory portal for state agencies to process out-of-state licensure applications more efficiently. While participation would be voluntary, states opting in could be offered federal incentives, such as

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[49] *Id.*
[50] *Licensure and Interstate Compacts*, *supra* note 12.
[51] Jolin et al., *supra* note 15, at 844.

funding for licensing board modernization, streamlined federal reimbursement for telehealth services, and enhanced legal protections and liability frameworks for practitioners.[52] This system would balance state and federal authority by allowing states to retain control over licensure while benefiting from a streamlined, standardized credential verification process that reduces administrative burdens.

Patients seeking telehealth might use the database to validate credentials before beginning treatment. Therefore, the system would also feature a federally overseen complaint and disciplinary tracking mechanism so that providers with ethical breaches or malpractice problems are easily identifiable across state lines. Currently, there is no unified system ensuring that providers with a history of misconduct cannot move their practice across state lines undetected.[53] This database would close that loophole, making disciplinary records easily accessible across jurisdictions while ensuring compliance with federal privacy laws such as the Health Insurance Portability and Accountability Act ("HIPAA").[54] Only relevant, non-sensitive information, such as licensure status, disciplinary actions, and compliance history, would be publicly available to protect both providers and patients.

While full licensure portability remains politically challenging, existing federal legislative efforts could be expanded using this database as a foundation. The Telehealth Treatment and Technology ("3T") Act already encourages reciprocal recognition of healthcare licenses across state lines, allowing an electronic database to interact with state licensing boards for

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[52] Gold et al., *supra* note 8, at 459–60.
[53] Marian Wang, *Federal Agency Failed to Report Disciplined Providers to National Database*, PROPUBLICA (Sept. 21, 2010), https://www.propublica.org/article/federal-agency-failed-to-report-disciplined-providers-to-national-database (noting that the Center for Medicare & Medicaid Services contributed to the gaps in a federal database).
[54] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996).

timely approval of electronic licenses.[55] The CARE for Mental Health Professionals Act establishes a Mental Health Licensure Portability Program, meaning the federal database could be utilized to formalize and operationalize this effort.[56] Another, the SHARE Act, based on using FBI criminal history records to check licensure, could provide standardized background checks with mental health providers across the country.[57] This proposal aligns with current federal initiatives and modernizes and standardizes cross-state mental health licensure without eroding state control.

To further support this initiative, federal-private partnerships could be formed with existing credentialing organizations, such as the National Practitioner Data Bank, to integrate current licensure verification systems.[58] Public awareness campaigns could educate both providers and patients on the benefits of using the database for verification and transparency, increasing trust in digital mental healthcare.[59] Additionally, ongoing legislative efforts to strengthen interstate compacts, such as PSYPACT, could be reinforced by aligning them with this database to streamline cross-state licensure approval.

This solution shows a substantive reconcilable application to expand mental health access with ethical, transparent, and effective digital counseling services by merging existing compacts, federal initiatives, and platform accreditation measures. Instead of being caught in a gridlock of legislative inaction, a centralized database provides a pragmatic, politically

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[55] Record Retrieval Solutions, *supra* note 21.
[56] *Id.*
[57] *Id.*
[58] NAT'L COUNCIL OF STATE BDS. OF NURSING, *Reporting & Enforcement: National Practitioner Data Bank (NPDB)*, https://www.ncsbn.org/nursing-regulation/discipline/reporting-and-enforcement/npdb.page (last visited Mar. 7, 2025).
[59] Shane Ashley Pawluk & Monica Zolezzi, *Healthcare Professionals' Perspectives on a Mental Health Educational Campaign for the Public*, 76 HEALTH EDUC. J. 479, 486–87 (2017); Waleed Mohammed Bugshan et al., *Role of Health Awareness Campaigns in Improving Public Health: A Systematic Review*, 12 INT'L J. LIFE SCI. & PHARMA RES. 29, 30 (2022).

viable, and immediately actionable step toward ensuring that mental health practitioners can meet the needs of a growing digital healthcare landscape.

While promising, this proposal is not without challenges. One concern is that states may resist participation, fearing an erosion of their licensing authority. However, the database would not impose federal control; rather, it would function as a shared credentialing tool that preserves state autonomy while enhancing oversight and efficiency. Another likely concern is cost. Although implementation may require upfront investment, the long-term savings, through reduced administrative burdens, expanded access to care, and fewer costly emergency interventions, would outweigh initial expenses. Critics may also argue that the system fails to eliminate the need for therapists to comply with differing state requirements. Yet even without uniform licensure standards, a centralized verification process would streamline application reviews and reduce bureaucratic delays. Finally, some may raise privacy concerns about provider data. The system, however, would operate under strict federal privacy regulations, ensuring that only essential licensure and disciplinary records are shared, thereby maintaining patient trust and safeguarding provider confidentiality. Ultimately, while implementation may present challenges, the proposed database offers a balanced, state-driven approach to modernizing licensure that strengthens oversight, streamlines processes, and lays the foundation for more equitable access to mental health care nationwide.

V. Enhancing Access, Accountability, and Quality in Digital Mental Health Care

The database would immediately enhance patient safety and care quality. This result provides consumer protection by ensuring that only verified and licensed practitioners appear in the database, significantly reducing

consumer risk of unqualified or improperly credentialed therapists.[60] In addition to safety, the database would also help boost public trust in digital mental health services.[61] While use of online counseling platform services increases, concern also mounts around practitioner legitimacy and digital counseling effectiveness more generally.[62] By requiring a standardized credentialing and guaranteeing that all digital therapists would be subject to the same rigorous licensing and educational guidelines as every other doctor and therapist, it would reassure consumers that online therapy is a safe and equitable option in the mental health landscape. Enabling patients to independently verify their provider's credentials would promote accountability and a higher quality of care, ultimately empowering them to make more informed health decisions.

Further, access for patients in rural and underserved communities would be greatly improved.[63] Workforce shortages and anti-competitive licensing laws limiting cross-state practice leave many in these regions without access to qualified mental health professionals.[64] The database would be a bridge, allowing therapists to apply for out-of-state licensure more easily, while still abiding by the requirements that vary from state to state. Additionally, establishing such a system would incentivize more providers to offer telehealth across state lines by facilitating the licensure process for those wishing to become eligible for the new system of care, thereby increasing access to culturally competent, multilingual, and specialized care for diverse patient populations.[65]

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[60] Martinez-Martin & Kreitmair, *supra* note 19, at 3.
[61] *Id.* at 3–4.
[62] Julia Stoll et al., *Ethical Issues in Online Psychotherapy: A Narrative Review*, 10 FRONT. PSYCHIATRY 1, 9 (2020).
[63] Gold et al., *supra* note 8, at 459.
[64] Bridget M. Kuehn, *Clinician shortage exacerbates pandemic-fueled "mental health crisis"*, 327 JAMA 2179 (2022); Madeleine Rossi, *Breaking Barriers: Cross-State Licensing Reform for Licensed Professional Counselors*, 25 MINN. J.L. SCI. & TECH. 195, 206, 219 (2024).
[65] Gold et al., *supra* note 8, at 443.

The database's economic ramifications would be large as it would save practitioners time and money that could be spent on patient care by reducing administrative burdens related to increasingly redundant licensure processes.[66] Simplifying credentialing could also spur coverage for telehealth services among insurance providers and Medicaid programs, which would reduce the cost of therapy services and help low-income people access them. Additionally, financial incentives offered to states for getting involved with the database, like funding for updating licensing boards and streamlined payments, would help sustain the telehealth industry long-term.[67]

VI. CONCLUSION

Following the COVID-19 pandemic, digital counseling platforms have become more prevalent than ever before, leading to a transformation of mental health management. However, while these platforms have improved accessibility, they have also illuminated important regulatory gaps, quality issues, and ethical dilemmas. As the post-pandemic landscape settles, the solution rests in the institution of a federally maintained database for interjurisdictional practice that would ensure only qualified professionals provide care, patients receive transparent information, and practitioners are not only offered the opportunity, but encouraged to expand accessibility.

The impact of this solution would be substantial. Patients would be able to trust digital therapy services, knowing that practitioners had been properly vetted and licensed. Rural and marginalized populations would find fewer access barriers. Legal and ethical accountability would increase, and digital platforms could continue innovating while adhering to structured, ethical,

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[66] David M. Cutler, *Reducing Administrative Costs in U.S. Health Care*, THE HAMILTON PROJECT (Mar. 2020), https://www.hamiltonproject.org/assets/files/Cutler_PP_LO.pdf (noting "Administrative costs are estimated to account for one quarter to one-third of the total U.S. spending on health.").

[67] Gold et al., *supra* note 8, at 459–460.

and patient-centered standards. From a regulatory point of view, the database is a pragmatic way to fill gaps in oversight without imposing broad federal mandates that might run into political resistance.[68] The database would achieve the mutual goal of improving interstate mental healthcare delivery without pushing back against state sovereignty through efforts at full licensure reciprocity.[69] Ultimately, the future of digital mental health care depends on striking a balance between accessibility, innovation, and regulatory integrity. By implementing strong changes, a sustainable, equitable, and legally sound digital counseling framework that protects both consumers and providers is created.

[68] Jolin et al., *supra* note 15, at 844.
[69] *Id.* at 840.

Ensuring Autonomy in End-of-Life Care: The Case for Federal Legalization of Physician-Assisted Dying

Grant Higgins

I. INTRODUCTION TO PHYSICIAN-ASSISTED DYING

The debate over physician-assisted dying, also known as physician-assisted suicide or death with dignity, has long been contentious in the United States, generating profound legal and ethical debates. Physician-assisted dying ("PAD") involves the intentional ending of one's life using medical means or knowledge provided by a physician.[1] While individuals of strong moral conviction hold well-reasoned yet differing views on PAD, the central concern in public and professional discussions remains the same: allowing every patient to approach the end of life with minimal suffering, in a manner that honors their deepest personal beliefs.[2] Ethical arguments in favor of PAD emphasize the principles of autonomy, dignity in death, and relief from suffering, with proponents advocating for patient-centered decision-making that prioritizes individual choice.[3] Critics, however, raise concerns about coercion, the role of the physician as a healer, the sanctity of life, and the potential for abuse, particularly among vulnerable populations.[4] While the Supreme Court has addressed physician-assisted dying, the current legal

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[1] *See* AM. MED. ASS'N, *Code of Medical Ethics Opinion 1.1.7: Physician Exercise of Conscience*, https://code-medical-ethics.ama-assn.org/ethics-opinions/physician-exercise-conscience; *see also* MARK A. HALL, ET AL., HEALTH CARE LAW AND ETHICS 582 (9th Ed. 2018) ("following the recommendation of the American Public Health Association, this text will use the term 'physician aid in dying'").

[2] *Id.*

[3] *See* Washington v. Glucksberg, 521 U.S. 702, 702 (1997) (the general arguments for and against PAS were famously discussed in this 1997 Supreme Court case); *see also* Vacco v. Quill, 521 U.S. 793, 793 (1997).

[4] *Id.* at 702 (The court held that "Washington's assisted-suicide ban was rationally related to legitimate government interests in preservation of human life, preventing suicide, maintaining integrity and ethics of the medical profession, protecting vulnerable persons who might be pressured into physician-assisted suicide, and protecting disabled and terminally ill people from prejudice, negative and inaccurate stereotypes and societal indifference; thus, it did not violate due process clause.").

landscape in the United States remains fragmented, with state-specific laws leading to disparities in access and legal ambiguities.

This article examines the evolution of physician-assisted suicide, discussing the legal frameworks and statutory language in the United States, and evaluates the ethical arguments for and against this practice. The current system for PAD is failing many terminally ill patients by creating unnecessary barriers and geographic inequities. By enacting a federal law that legalizes physician-assisted dying for terminally ill, competent patients with strict safeguards, the United States can ensure a balanced approach that respects patient rights, legal principles and ethical consideration, while also improving access for all patients.

II. THE CONSTITUTIONALITY AND ETHICAL EVOLUTION OF PHYSICIAN-ASSISTED DYING

In the early 1990s, federal lawsuits were filed in Washington state[5] and New York,[6] challenging the constitutionality of state laws that criminalized assisted suicide, specifically as they applied to competent, terminally ill patients seeking assistance from a licensed physician to end their lives. After losses at the trial and appellate levels, the cases reached the U.S. Supreme Court, resulting in a consolidated 1997 decision.[7] The ruling was a setback for proponents of PAD legalization, as the Court overturned both appellate court decisions, holding that there was no federal constitutional right for a physician to prescribe a lethal dose of medication to a competent, terminally ill patient.[8] However, the Court also clarified that while states could prohibit physician-assisted dying, they were not constitutionally required to do so,

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[5] Compassion in Dying v. Washington, 850 F. Supp. 154, 1455-56 (W.D. Wash. 1994).
[6] Quill v. Koppell, 870 F. Supp. 78, 79 (S.D.N.Y. 1994).
[7] *See Vacco*, 521 U.S. at 793; *Glucksberg*, 521 U.S. at 702.
[8] *See Vacco*, 521 U.S. at 796; *Glucksberg*, 521 U.S. at 705.

leaving the door open for states to legalize the practice in the future.[9] Additionally, the Court suggested, but did not hold, that physicians could lawfully administer pain-relieving, palliative medications that might hasten death, provided that the primary intent was pain relief rather than ending the patient's life.[10] In any case, *Glucksberg* did not prevent states from enacting their own PAD laws and the Court noted that there should be time for reasonable legislative consideration, as the legislative process is better equipped to handle the matter at this stage.[11] This acknowledgement provides a compelling basis for reevaluating PAD's legal status at the federal level.

The primary obstacle to legalizing PAD is the numerous ethical arguments and state interests raised by opponents. Efforts to persuade state legislatures to pass laws legalizing physician-assisted dying have historically been unsuccessful, likely because such legislation is seen as highly controversial.[12] In *Glucksberg*, the U.S. Supreme Court summed up this perspective by stating:

> "In almost every State – indeed, in almost every western democracy – it is a crime to assist a suicide. The States' assisted suicide bans are not innovations. Rather they are longstanding expressions of the States' commitment to the protection and preservation of all human life."[13]

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[9] *See Glucksberg*, 521 U.S. at 735-36 ("we therefore hold that Wash. Rev. Code § 9A.36.060(1) (1994) does not violate the Fourteenth Amendment, either on its face or 'as applied to competent, terminally ill adults who wish to hasten their deaths by obtaining medication prescribed by their doctors.'").
[10] *Glucksberg*, 521 U.S. at 737-38 (O'Connor, J., concurring).
[11] *See Glucksberg*, 521 U.S. at 789 (Souter, J., concurring); *see also Glucksberg*, 521 U.S. at 735 ("Our holding permits this debate to continue, as it should in a democratic society.").
[12] Alan Meisel, *A History of the Law of Assisted Dying in the United States*, 73 SMU L. REV. 119, 149 (2020) (discussing the historical, cultural, and psychological context in which the practice of assisted dying must be viewed and understood).
[13] *Glucksberg*, 521 U.S. at 710.

Opponents argue that PAD allows families to coerce vulnerable members to end their lives,[14] PAD serves as a gateway to euthanasia,[15] it undermines the physician's role as a healer,[16] it is unnecessary given advances in palliative care,[17] and constitutes murder in violation of moral principles.[18] "Slippery slope" arguments against PAD also outline that if it were permitted, many people could abuse it to allow for euthanasia or use it to spare their families the substantial financial burden of end-of-life health-care costs.[19] Based on these arguments, attempts to challenge laws criminalizing PAD for terminally ill patients have been unsuccessful in several state courts including Alaska, California, Florida, Georgie, Massachusetts, Montana, New Mexico, and New York.[20] However, decades later, these concerns remain unaddressed.[21]

The Court's distinction between palliative care that unintentionally hastens death, and PAD is an arbitrary line that fails to align with the principles of medical ethics and patient autonomy. If physicians are already permitted to administer medications and sedatives to terminally ill patients – fully aware that these medications may accelerate death – then the

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[14] *Id.* at 719.
[15] *Id.* at 732.
[16] *See* AM. MED. ASS'N, *Code of Medical Ethics Opinion 5.7: Physician-Assisted Suicide*, https://code-medical-ethics.ama-assn.org/ethics-opinions/physician-assisted-suicide (describing physician-assisted suicide as "fundamentally incompatible with the physician's role as healer).
[17] Meisel, *supra* note 12, at 150.
[18] *Id.*
[19] *Glucksberg*, 521 U.S. at 732 ("we have recognized, however, the real risk of subtle coercion and undue influence in end-of-life situations.").
[20] *See* Sampson v. State, 31 P.3d 88 (Alaska 2001); Donorovich-Odonnell v. Harris, 194 Cal. Rptr. 3d 579 (Cal. Ct. App. 2015); Krischer v. McIver, 697 So. 2d 97 (Fla. 1997); Final Exit Network, Inc. v. Georgia, 722 S.E.2d 722 (Ga. 2012); Kligler v. Healy, No. SUCV2016-03254-F, 2017 WL 2803074 (Mass. Super. Ct. May 32, 2017); Baxter v. State, 224 P.4d 1211 (Mont. 2009); Morris v. Brandenburg, 376 P.3d 836 (N.M. 2016); Myers v. Schneiderman, 85 N.E.3d 57 (N.Y. 2017).
[21] Angelika Anderson, *Body, My Choice: Should Physician-Assisted Suicide be Legalized in the United States for Individuals with Chronic Mental Illness*, 10 TEX. A&M L. REV. 269, 273 (2023).

fundamental moral and medical considerations underlying PAD are already accepted in practice. The intent-based distinction suggested by the Court does not change the reality that in both cases, the physicians is acting in the patient's best interest by alleviating suffering and ensuring a dignified end-of-life experience.

III. STATUTORY LANDSCAPE OF PAD IN THE UNITED STATES

Following *Washington v. Glucksberg*, Oregon became the first state to legalize PAD with the passage of the Death with Dignity Act ("DDA") in 1997.[22] Oregon's Death With Dignity Act allows terminally ill people with a life expectancy prognosis of less than six months to end their lives by voluntarily taking lethal medications prescribed by a physician for that purpose.[23] Patients are required to make two verbal requests for the medication to their doctor with at least fifteen days between each request, in addition to submitting a written request signed in the presence of two witnesses.[24] Both the attending physician and a consulting physician must verify the patient's diagnosis and prognosis, as well as assess the patient's capacity to make healthcare decisions.[25] If either physician suspects the patient may be experiencing depression or other mental disorders, they can refer the patient for psychological evaluation.[26]

After Oregon's passage of the Death with Dignity Act, several other states enacted similar laws, either through legislative action or ballot measures.[27]

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[22] *Physician-Assisted Suicide Fast Facts*, CNN ED. ESCH., https://www.cnn.com/2014/11/26/us/physician-assisted-suicide-fast-facts (last updated May 29, 2024).
[23] *See* Or. Rev. Stat. § 127.815 and § 127.820) (1994) (discussing the various safeguards within the Oregon Death with Dignity Act).
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Physician-Assisted Suicide Fast Facts*, *supra* note 22.

As of 2025, eleven jurisdictions authorize PAD laws under specific legislative frameworks and patient criteria.[28] Most states require patients to be legal residents, mentally competent, capable of self-administering the medication, and have a terminal illness with a prognosis of six months or less.[29] However, some states have unique provisions. For example, New Mexico allows not only physicians but also nurse practitioners and physician assistants to prescribe life-ending medication.[30] Montana permits PAD through a court ruling in *Baxter v. Montana*, which allows physicians to use a patient's consent as a legal defense against homicide charges but does not explicitly establish a right to aid in dying.[31] Similarly, at least 12 states currently have bills that would legalize PAD while ten states, including Washington, D.C., already allow it, but only for their own residents.[32] Recently, however, neither Vermont nor Oregon require people to be residents of the state to use its law allowing terminally ill people to receive lethal medical and permit any qualifying American to travel to their state for the practice.[33] Patients must be at least 18 years old, within six months of death, and must be assessed to ensure they are capable of making an informed decision.[34] Furthermore, Illinois' End-of-Life Options for Terminally Ill Patients Act is moving forward in the IL General Assembly to allow

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[28] COMPASSION & CHOICES, *States Where Medical Aid in Dying is Authorized*, https://compassionandchoices.org/states-where-medical-aid-in-dying-is-authorized/ (last visited Feb. 14, 2025) (jurisdictions include California, Colorado, Hawai'i, Maine, Montana, New Jersey, New Mexico, Oregon, Vermont, Washington, and Washington, D.C.).
[29] *Id.*
[30] *See* N.M. STAT. ANN. § 24-7C-3 (West 2021).
[31] *Physician-Assisted Suicide Fast Facts*, *supra* note 22.
[32] Gene Johnson, *Oregon ends residency rule for medically assisted suicide*, AP NEWS (Mar. 28, 2022), https://apnews.com/article/business-health-oregon-lawsuits-portland-3cf31cb519d84a47e2d3cb70e8f0bce7.
[33] *Id.*
[34] Jesse Bedayn, *'I'm dying, you're not': Those terminally ill ask more states to legalize physician-assisted death*, AP NEWS (Apr. 12, 2024), https://apnews.com/article/medical-aid-dying-legal-physician-assisted-suicide-b67affd86c1d1ce99379ed34bdb2946b.

physicians to prescribe "aid-in-dying" medication to end the patient's life in a peaceful manner.[35]

Although specific laws vary by state, all jurisdictions require that patients seeking PAD meet three key criteria: (1) a terminal diagnosis of six months or less to live, (2) demonstrated competence and sound judgement, and (3) a voluntary and informed decision.[36] Despite being legal in some jurisdictions, like Oregon, for over 30 years, PAD accounts for less than 1% of deaths in those areas.[37] Across all jurisdictions, only 10,211 eligible individuals have utilized a prescription for PAD over nearly three decades.[38] A significant portion – up to 38% - of individuals who go through the rigorous process of obtaining a prescription for PAD never take sthe medication.[39] While some may die naturally before using it, others may face difficulties in accessing the medication when they need it, fear legal repercussions, or experience changes in their physical condition that make self-administration difficult.[40] For instance, patients suffering from neurological conditions like ALS – a major subgroup of PAD patients – often experience swallowing difficulties in later stages of their life.[41] The requirement to self-administer the medication

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[35] SB0009, 104th General Assembly (2025); HB1328, 104th General Assembly (2025).
[36] Joanne Lynn et al., *Physician-Assisted Death: Scanning the landscape: Proceedings of a Workshop*, § 2 Conceptual, Legal, and Ethical Consideration in Physician-Assisted Death (2017).
[37] COMPASSION & CHOICES, *Medical Aid-in-Dying Utilization Report*, (Jan. 2024), https://compassionandchoices.org/wp-content/uploads/2024/02/2025-utilization-report.pdf (This report demonstrates data points to show how medical aid in dying is being used and where there are opportunities to improve access because in all jurisdictions where medical aid in dying is legal, there are statistical reporting requirements for administrative agencies.).
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] Mara Buchbinder, *Access to Aid-in-Dying in the United States: Shifting the Debate From Rights to Justice*, 108 AM. J. PUB. HEALTH. 754, 756 (2018) (discussing rights-based ethical and legal frameworks that emphasize patients' rights of self-determination in end-of-life decision making and how terminally ill people experience such putative rights once they are legally authorized).

means that some patients choose to end their lives prematurely before they lose the physical ability to ingest the medication.[42] While self-administration has been viewed as an important safeguard in the context of PAD, it can be considered an exclusionary requirement that creates unnecessary barriers for vulnerable patients, especially those suffering from conditions like ALS.

IV. CONSEQUENCES OF THE PATCHWORK OF PAD LAWS

Since there is no fundamental constitutional right to die, states are not required to adopt a uniform approach to PAD.[43] Each state has the authority to determine whether to permit or prohibit the practice and may establish its own legal framework, including specific requirements and procedures, as long as it does not conflict with existing state or federal laws.[44] Given the Supreme Court's ruling in *Jacobson v. Massachusetts*[45], states' legalization of PAD serves to protect individuals with terminal illnesses, ensuring their well-being and autonomy in end-of-life care is protected by clear safeguards and oversight in the process. However, in states where PAD is illegal, patients suffering from unbearable and incurable illnesses are forced to make end-of-life decisions without the necessary medical guidance or assistance. As a result, some resort to extreme measures, such as refusing food, water, and medication, leading to prolonged suffering for both them and their loves ones.[46] This disconnect between patient and physician contradicts the

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[42] *Id.*
[43] *Glucksberg*, 521 U.S. at 789.
[44] *Id.*
[45] *See* Jacobson v. Massachusetts, 197 U.S. 11 (1905) (holding that a state has the authority to enact reasonable laws under its police powers to protect the public health and safety of its citizens).
[46] Jane E. Brody, *When Patients Choose to End Their Lives*, N.Y. TIMES (Apr. 5, 2021) https://www.nytimes.com/2021/04/05/well/live/aid-in-dying.html; *see also* John F. Burns, *Briton Who Fought for Assisted Suicide Is Dead*, N.Y. TIMES (Aug. 22, 2012) https://www.nytimes.com/2012/08/23/world/europe/tony-nicklinson-who-fought-for-assisted-suicide-is-dead.html (describing how the High Court rejected Mr. Nicklinson's request for assisted dying, who suffered from locked-in syndrome – an incurable condition

general approach to healthcare, where medical professionals help patients make informed decisions and receive the care they need to reduce pain. Given that modern medicine already allows for interventions that hasten death as an indirect consequence of pain relief, it is illogical to deny a patient's request to exercise greater control over their own death when faced with unbearable suffering. For terminally ill patients, the ability to choose a dignified and humane end-of-life option through PAD is a vital extension of autonomy and legalizing PAD would simply extend the same principles that justify palliative sedation but in a manner that fully respects patient autonomy and informed consent.[47]

Furthermore, the implementation of PAD in the United States is flawed, creating an unequal and often inaccessible process for terminally ill patients who wish to exercise their desire to a medically assisted death. While PAD laws were intended to offer compassionate end-of-life options, multiple barriers to access disproportionately impact low-income, rural, and less-educated patients.[48] The rate at which Asian, Black, Hawaiian, Pacific Islander, Indigenous American, Alaskan Native, Latino/a/x, Hispanic, and multiracial individuals access PAD is consistently lower than that of white populations across all years and jurisdictions.[49] This reflects an elitist system where only those with financial resources, strong social support networks, and high health literacy can successfully navigate the process.[50] Even if

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leaving him completely paralyzed but fully conscious – chose to end his life by refusing food, ultimately succumbing to pneumonia).

[47] Lynn et al., *supra* note 36, at 33.

[48] Buchbinder, *supra* note 41, at 756.

[49] COMPASSION & CHOICES, *supra* note 37, at 3 (in all jurisdictions and across all years, Asian populations have represented 3.44% of patients utilizing medical aid in dying and Latinx and Hispanic populations have comprised 2.05%. Patients from all other racial and ethnic groups accounted for less than 1% and 1.26% of patients were classified as 'other' or 'unknown.'").

[50] Buchbinder, *supra* note 41, at 758.

patients have these resources, physician participation in PAD is voluntary, and willingness among physicians is generally lower than among the general public.[51]

While safeguards exist to ensure that participation is voluntary for both patients and providers, patients seeking PAD must clear multiple procedural and regulatory hurdles which often delay or completely block access to care.[52] With the exception of Vermont and Oregon, all states that have legalized PAD through legislation include statutory provisions that restrict the practice to in-state residents.[53] The residency requirement represents the most problematic PAD safeguard because such residency restrictions act as a barrier to access rather than as a safeguard.[54] These restrictions force terminally ill patients to go through a burdensome and expensive process of establishing residency in a new state to access PAD, which can be a significant obstacle for many, especially those who are limited in mobility or those receiving regular care across state lines.[55] The residency restriction has left Americans in most states, who want the ability and option to have this treatment, without recourse. The combination of regulatory and geographic barriers creates a stratified system in which the very patients who might benefit the most from PAD – those suffering from terminal illnesses with limited resources and access to quality care – are the least likely to be able to use it.

While PAD is not federally recognized in the United States, it is legal in eleven jurisdictions for patients with terminal illnesses.[56] The majority of

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[51] *Id.*
[52] *Id.*
[53] COMPASSION & CHOICES, *Medical Aid in Dying: Residency Restrictions*, https://compassionandchoices.org/legal-advocacy/residency-restrictions/ (last visited Mar. 9, 2025).
[54] *Id.*
[55] *Id.*
[56] COMPASSION & CHOICES, *supra* note 28.

terminally ill people who utilize PAD (88%) are enrolled in hospice or palliative care services at the time of their deaths, and over 77% of people who use PAD are able to die at home.[57] These statistics reflect the perspective of patients with terminal illnesses who view these practices as critical to preserving their autonomy and enabling them to "die with dignity, to control where and when they die, and to manage their physical and mental state at the time of death."[58] The ethical debate surrounding PAD centers on the balance between individual autonomy and societal interests. Ultimately, legalizing PAD at the federal level would eliminate many of the access barriers that currently exist under state-based models and give terminally ill patients their preferential end-of-life care, regardless of the location they are in.

V. MODEL LANGUAGE IN FAVOR OF PROPOSED FEDERAL LEGALIZATION

Based on the ongoing debates for and against PAD, legislators who have not yet legalized it may question whether the argument for patient autonomy is strong enough to address the various concerns surrounding PAD – the answer is yes. Even though it is illegal in most states, a 2018 Gallup poll showed more than two-thirds of Americans support physician-assisted death.[59] A 2024 Gallup poll demonstrated that approximately 71% of Americans believe that doctors should be "allowed by law to end the patient's

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[57] COMPASSION & CHOICES, *supra* note 37.
[58] *See* Laura Trenaman-Molin, *Physician-Assisted Suicide: Should Texas Be Different?*, 33 HOYS. L. REV. 1475, 1482 (1997) (analyzing legal developments regarding physician-assisted suicide for the terminally ill and discussing arguments both for and against the issue).
[59] *See, e.g.,* Megan Brenan, *Americans' Strong Support for Euthanasia Persists*, GALLUP (May 31, 2018), https://news.gallup.com/poll/235145/americans-strong-support-euthanasia-persists.aspx.

life by some painless means if the patient and his or her family request it."[60] Studies of dying patients have shown that about half would like the option of physician-assisted dying to be available for possible future use.[61] Polls also suggest that even though efforts to identify a federal constitutional right to die have failed, a majority of Americans favor physician-assisted death.[62] However, the same medical advancements that have prolonged life can also prolong the dying process, trapping patients in a "twilight zone of suspended animation" that extends both their suffering and the emotional burden on their families.[63] As such, this perspective suggests that, as medical technology continues to advance, there is a strong ethical argument for giving patients the right to choose a peaceful and dignified death. Given the growing movement to restore humanity and dignity to the process by which Americans die, this view reflects a growing acceptance of PAD as a compassionate option for those facing terminal illnesses and unbearable suffering.

In order to responsibly advocate for the passing of a federal law that would legalize PAD across the United States, clear safeguards must be established. The following proposed PAD Act outlines a structured and comprehensive process to ensure that terminally ill patients seeking PAD are thoroughly assessed, with medical, psychological, and legal safeguards in place. Under the proposed Act, a patient diagnosed with a terminal illness that will lead to death within six months, as confirmed by qualified healthcare providers, must make a written request for a lethal dose of medication from a physician

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[60] Rachael Yi, *Most Americans Favor Legal Euthanasia*, GALLUP (August 8, 2024), https://news.gallup.com/poll/648215/americans-favor-legal-euthanasia.aspx.
[61] Paul B. Bascom & Susan W. Tolle, *Responding to Requests for Physician-Assisted Suicide*, 288 JAMA 91 (July 3, 2002).
[62] *Id.*
[63] Cruzan by Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261, 270 (1990) (Brennan, J., dissenting) ("Medical technology has effectively created a twilight zone of suspended animation where death commences while life, in some form, continues.").

signed in the presence of two witnesses. Patients must demonstrate competence by proving that they understand their diagnosis, acknowledge the chronic nature of their condition, and are free from symptoms that impair rational decision-making. Similar to Oregon's DDA, both the attending physician and a consulting physician must examine the patient to verify the patient's diagnosis and prognosis. These doctors are then tasked with ensuring the patient is fully informed, confirming the patient's illness and pain level, evaluating alternative treatments, and ultimately determining if PAD is appropriate. If either physician suspects the patient may be experiencing symptoms that impair competency, the patient will need to undergo a psychiatric evaluation to assess their mental competency and outline alternative options, ensuring that the decision is not influenced by depression, coercion, or financial distress. If the doctors unanimously approve the request and should the patient confirm their decision, the doctor will prescribe the medication. Consent must be voluntary and informed to ensure the decision is deliberate and free from coercion. To confirm that the decision is voluntary, informed and self-administered, the two doctors must be present when the patient ingests the medication. This proposed Act is designed to prioritize patient autonomy while implementing strict safeguards to prevent any potential abuse, coercion, or uninformed decisions.

Conversely, one fundamental argument against legalization centers on whether the decision to end one's life is truly voluntary. Critics argue that individuals who are seriously ill, elderly, or otherwise vulnerable may feel pressed to seek death due to pain, depressions, despair, or the fear of becoming a burden to their loved ones.[64] As a result, opponents fear that

[64] Compassion in Dying v. Washington, 79 F.3d 790 (9th Cir. 1996) (many of these arguments are discussed and refuted in this en banc opinion).

patients will be unable to make a fully autonomous choice and thus, legalizing PAD could disproportionately impact vulnerable populations to end their lives early.[65] Additionally, opponents point to advancements in palliative care and physician education, arguing that improvements in pain management and end-of-life care can address many of the factors that drive terminally ill patients to consider physician-assisted dying, thereby reducing the perceived need for legalization.[66] However, patients routinely make medical decisions with guidance from their doctors, and in all other aspects of healthcare, individuals rely on physicians for expert advice when making choices about their bodies.[67] For instance, patients who refuse treatment and opt for hospice care receive medical support and pain management throughout the dying process.[68] Americans have, exercise, and maintain the right to make decisions about the health of their own bodies, even when those choices come with negative consequences.[69] From an ethical perspective, legalizing PAD would allow individuals to maintain control over when and how they die, ensuring they have access to compassionate, medically supervised options rather than being left with potentially inhumane and unreliable alternatives. If bodily autonomy is a fundamental American value, then PAD aligns with these ideals by providing individuals with another option to determine what is best for their bodies – even if that choice is death.

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[65] *Id.* at 825-26.
[66] Meisel, *supra* note 12, at 150.
[67] Anderson, *supra* note 21, at 276.
[68] *See Hospice & Palliative Care*, ACCENTCARE, https://www.accentcare.com/our-services/hospice-palliative-care/ (last visited Feb. 14, 2025).
[69] *Cruzan*, 497 U.S. at 270 (holding that a competent person has a constitutionally protected liberty interest under the Fourteenth Amendment to refuse unwanted medical treatment); *see also Thor v. Superior Court*, 5 Cal. 4th (1993) (this case also supports the principle of patient autonomy, recognizing the patient's right of control over bodily integrity because the court noted that a competent, informed adult has the right to direct the withholding or withdrawal of life-sustaining medical treatment, even at the risk of death.).

Additionally, this law would not restrict PAD to residents of the state that they are in so patients would have access to end-of-life care, regardless of where they live. This law would address one of the biggest challenges under the current state-based PAD laws which is the residency requirement. For example, increased access to PAD has been seen in jurisdictions that have improved their laws by removing residency requirements.[70] This restriction forces terminally ill patients to establish residency in a state that allows PAD – often an insurmountable hurdle for those who are already critically ill.[71] Removing residency requirements for PAD would allow terminally ill patients to access care in states that permit the practice, much like abortion laws that enable individuals to seek services in states where abortion remains legal. Patients regularly travel to other states for the best possible healthcare, and there is no justifiable reason they shouldn't be able to do the same to access PAD, when their home state might deny them that option.

Furthermore, many U.S. states uphold the principle of autonomy by allowing individuals to preauthorize the withholding of life-sustaining treatment through advance directives and Do Not Resuscitate ("DNR") orders.[72] These documents enable competent patients to refuse medical interventions, ensuring a natural death and minimizing suffering while also permitting physicians to honor previously executed directives even when a patient is no longer capable of decision-making.[73] Congress should incorporate existing competency standards and this anticipatory planning

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[70] COMPASSION & CHOICES, *supra* note 37(this trend has been evident across years of increased access to PAD in California, Colorado, Hawaii, Oregon, and Washington, starting with the 2018 amendment to Oregon's law.).
[71] *Id.*
[72] *See, e.g.*, TEX. HEALTH & SAFETY CODE ANN. §§ 166.031 (1); *see* CAL. PROB. CODE § 4670.
[73] *Advanced Care Planning: Health Care Directives*, NAT'L INST. ON AGING, https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care (last reviewed Oct. 31, 2022).

into PAD legislation. The competence assessment for PAD should align with that of advance directives and DNR orders, requiring an adult patient to fully understand and appreciate the implications of requesting and accepting a lethal prescription (a standard known as "informed consent").[74] PAD laws should follow similar principles, requiring competence only at the time of consent and allowing prior directives to guide end-of life decisions when competence declines. Similarly, if a patient with a progressive neurological condition like ALS has clearly documented their wish to access PAD but loses the ability to self-administer, a lawfully designated physician could be authorized to assist under highly regulated conditions. PAD laws already require robust consent mechanisms, and instead of rejecting PAD for ALS patients due to concerns about self-administration and coercion, patients who have consistently and voluntarily expressed their intent through advance directives can access this option. While critics argue that self-administration can exclude certain patients, particularly those with ALS, the requirement ultimately serves as a protective measure that affirms that the patient's choice is deliberate and independent.

This federal PAD law would provide patients with the autonomy to end their suffering on their own terms rather than enduring prolonged pain, distress, or loss of dignity. As one terminally ill patient described, "[physician-assistance in dying] is not me choosing to die. I am going to die. But it is my way of having a little bit more control over what it looks like in the end."[75] A federal law ensuring access to PAD would reinforce the principle that personal autonomy extends to end-of-life decisions. While

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[74] *See* Candice T. Player, *Death with Dignity and Mental Disorder*, 60 ARIZ. L. REV. 115, 139-40 (2018) (defining competence as a combination of "(i) the ability to understand; (ii) the ability to appreciate the significance of medical information; (iii) the ability to reason; and (iv) the ability to communicate a choice.").
[75] Bedayn, *supra* note 34.

justice and individual autonomy may demand that terminally ill patients have access to PAD, this does not obligate individual physicians to provide it. Mandating physicians to provide PAD instead of focusing on equitable access across the U.S. could create a tension, posing additional challenges for healthcare providers. However, a 2019 study revealed that 60% of US physicians believe that PAD should be legalized.[76] The American Public Health Association, the American College of Legal Medicine, and the American Medical Women's Association (AMWH) support the legalization of PAD.[77] In view of the general support among physicians, this federal law would balance respecting physicians' privacy and their right to opt out with ensuring that patients can still access physicians willing to participate in PAD.[78] By adopting these safeguards, policymakers can ensure that PAD is a humane and ethical option for patients across the US.

VI. CONCLUSION

Physician-assisted dying aims to help terminally ill individuals avoid prolonged suffering and loss of dignity caused by their conditions. The current patchwork of state laws leaves many terminally ill patients without access to a dignified end-of-life option. A federal PAD law would provide a more equitable and legally consistent framework for end-of-life care in the U.S by ensuring equal access for all terminally ill patients, regardless of their

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[76] Peter T. Hetzler III et al., *A Report of Physician's Beliefs about Physician Assisted Suicide: A National Study*, 9 YALE J. BIOLOGY& MED. 575, 577 (2019) (This survey was sent to 1000 randomly chosen physicians from around the US to assess their beliefs about the national legalization of physician-assisted suicide: "49% of physicians agreed that most patients who seek PAS do so because of pain, and 58% agreed that the current safeguards in place for PAS, in general, are adequate to protect patients.").

[77] *MAID: Medical Aid in Dying*, Britannica ProCon, (last updated Mar. 25, 2025) https://www.britannica.com/procon/MAID-medical-aid-in-dying-debate ("The AMWH says '[PAD supports the right of mentally capable, terminally ill patients to advance the time of death that might otherwise be a protracted, undignified, or extremely painful death.'").

[78] Buchbinder, *supra* note 41, at 756.

state of residence. While legalizing PAD at the federal level can face, allowing states to opt in for death with dignity laws will standardize regulations to prevent inconsistencies across the states, provide compassionate options for those suffering from terminal illnesses and restore patient autonomy for all.

The Bolar Exemption: Adapting Interpretations to Accommodate for Increased Generic Prescription Drug Needs

Emily Moll

I. BACKGROUND

In the United States, many people cannot afford the prescription medications they need.[1] A way to combat this issue and promote greater access to medicine in the U.S. is to support and expedite the production and sale of generic drugs while respecting patent rights. However, generic drugs cannot enter the marketplace until their correlating brand-name drugs' patents expire.[2] Therefore, during patent terms of new medications, people who cannot afford the high prices of brand-name drugs are out of luck until generic drugs can enter the market at lower costs. To allow generics to enter the marketplace and provide more affordable solutions as soon as patent terms expire, generic companies opt to start the regulatory review process during the patent period without fear of being sued for patent infringement, a feat made possible by the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.[3]

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[1] Krishnamurthy & Parikh, *Drug Prices and Shortages Jeopardize Patient Access to Quality Hospital Care*, AM. HOSPITAL ASSOC. (May 22, 2024, 8:27 AM), https://www.aha.org/news/blog/2024-05-22-drug-prices-and-shortages-jeopardize-patient-access-quality-hospital-care (stating "nearly 30% of Americans say they haven't taken their medication as prescribed due to high drug prices, and it is estimated that more than 1.1 million Medicare patients alone could die over the next decade because they cannot afford to pay for their prescribed medications").

[2] Aaron S. Kesselheim et al., *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658, 1658 (2017).

[3] *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act, PUB. L. NO. 98-417, 98 STAT. 1585 (1984) [hereinafter Hatch-Waxman Act].

This article explores the history of the regulatory review exemption (Bolar exemption) in the U.S. and how expansion of its interpretation can aid generics in entering the marketplace sooner. First, it explains the overlap and boundaries between patented brand-name drugs and their generic counterparts in the context of gaining regulatory approval and entering the market. Secondly, it discusses the statutory origin of the Bolar exemption and how it is reflected in a provision of the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement. Next, this article explains the U.S.' current judicial interpretation of the Bolar exemption, which has provided constraints as to which activities are protected from patent infringement.

This article then addresses a possible solution to increasing access to medicine by enabling generic drugs to enter the marketplace more easily after patent expiry. This solution includes amending the Hatch-Waxman Act in the U.S. to resemble the EU's most recent proposal of the Bolar exemption. Such an amendment would extend the scope of the Bolar exemption to include pricing and reimbursement, post-approval activities that currently are not protected under the Bolar exemption from patent infringement in the U.S. Then, this article will discuss how the U.S. can incorporate limitations to what is considered a protected pricing and reimbursement activity to stay within the bounds of the TRIPS Agreement.

By adopting the EU's proposal within certain limitations, the U.S. can help its generic drug companies enter the market more seamlessly upon patent expiry due to the broadened scope of what pre-market activities are not considered patent infringement. With the checks and balances provided by the TRIPS Agreement, such that there is minimal risk of impeding innovation, this adoption will result in increased access to more affordable medicine for U.S. citizens.

II. PRESCRIPTION DRUGS AND THE ORIGIN OF GENERICS IN THE WAKE OF PATENT EXCLUSIVITY

U.S. patent law grants inventors the right to exclude others from using their works for a limited amount of time, typically twenty years from the date of filing the patent application.[4] Because high costs for innovation, research, and development are necessary to produce and market pharmaceutical prescription drugs, most pharmaceutical companies elect to patent their medications.[5] These companies are able to list their brand-name drugs at higher prices that many consumers cannot afford because their products are the only ones on the market for that particular medication, leaving them with little to no competition.[6] Exclusivity terms for pharmaceutical drug patents typically range between twelve (12) and sixteen (16) years due to prescription drugs and medications also requiring regulatory approval by the U.S. Food and Drug Administration ("FDA"), such that this is essentially the period of time these brand-name drug companies can sell their drugs on the market at high prices with very minimal competition, if any.[7]

In an effort to reap the benefits on the tails of successful pharmaceutical drug companies, other companies produce generic drugs to enter the market after the corresponding brand-name medications' patents expire. Generic drugs are those that have the same intended effect on patients as their brand-name counterparts, such that they are bioequivalent.[8] To establish bioequivalence, a necessary step for obtaining FDA approval,[9] generic drugs

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[4] *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFF. (2014), https://www.uspto.gov/sites/default/files/inventors/edu-inf/BasicPatentGuide.pdf.
[5] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 849 (2002).
[6] Kesselheim et al., *supra* note 2.
[7] *Id.*
[8] *Generic Drugs: Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1 (last visited Feb. 21, 2025).
[9] Hatch-Waxman Act, *supra* note 3.

must have a persuasive combination of the same route of administration, use, safety, quality, strength, dosage form, or performance characteristics as the brand-name drugs.[10] While generic drugs may not be identical to their brand-name counterparts, the differences are almost negligible because their active ingredients are the same.[11]

Many Americans prefer generic drugs because they are substantially cheaper than the brand-name medications.[12] Generic drugs are cheaper than brand-name drugs for several reasons. First, generic companies do not have to conduct their own clinical trials to show safety and effectiveness when seeking FDA approval, such that their development costs are much less expensive than that of the brand-name drugs.[13] Because it costs less to create the generic drugs, the generic drug companies are able to sell their medications on the market at lower prices.[14] Generic drugs estimate on the market for 80% to 85% less than their brand-name counterparts.[15] Furthermore, once a brand-name drug's patent expires, that company is no longer able to exclusively sell its drug on the market, such that many generic drug companies may enter the market and compete.[16] Because there are more options available, these generic drug companies tend to list their products at lower prices.[17] One survey evaluating consumer preferences and perceptions of generic drugs found that 91.8% of its participants believed that generic drugs were less expensive than their brand-name counterparts.[18] While only 52.2% of those in the study preferred to take the generic drugs over the brand-

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[10] *Generic Drugs: Questions and Answers*, *supra* note 8.
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] S. Jain et al., *PRM132 – Brand name or generic drugs: A national survey of patient perception and preferences*, 16 VALUE IN HEALTH (2013).

name drugs,[19] these lower prices allow for increased access to medicine for Americans who could not previously afford the exorbitant costs of the brand-name medications.

III. DECREASING THE TIME FROM BRAND-NAME EXCLUSIVITY TO GENERICS: THE HATCH-WAXMAN ACT

As mentioned above, prescription drugs, including generics, must obtain FDA approval before being sold in the U.S.[20] Before 1984, generic drug companies encountered the issue of having to wait extended periods of time to obtain FDA approval after brand-name patented drugs expired.[21] This delay was due to them not being able to start the regulatory approval process during the patent term without committing patent infringement.[22] This system essentially provided the owners of the name-brand medications an unofficial, longer market exclusivity term for their higher cost drugs.[23]

To help alleviate this issue in an attempt to bring more affordable medications to market sooner after patent expiry, Congress passed the Hatch-Waxman Act in 1984.[24] The Hatch-Waxman Act states that a person will not infringe a patent if he or she uses the patented invention for a purpose "reasonably related to" obtaining regulatory approval.[25] Thus, generic drug companies can file an abbreviated new drug application ("ANDA") prior to FDA approval under this statute before the brand-name drug's patent expires

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[19] *Id.*
[20] *Prescription Drugs and the Approval Process*, NAT'L CONF. OF STATE LEGISLATORS (2022), https://www.ncsl.org/health/prescription-drugs-and-the-approval-process#.
[21] Jocelyn Ulrich, *40 Years of Hatch-Waxman: What is the Hatch-Waxman Act?* PHRMA (2024), https://phrma.org/blog/40-years-of-hatch-waxman-what-is-the-hatch-waxman-act#.
[22] *Id.*
[23] Dmytro Doubinsky, *Application of the Bolar Exception: Different Approaches in the EU*, S. CTR.: RSCH. PAPER 214 (2025).
[24] *Id*. at 10; *see* Hatch-Waxman Act, *supra* note 3, at 1585.
[25] Hatch-Waxman Act, *supra* note 3, at 1603 ("It shall not be an act of infringement to make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.").

without fear of being sued for patent infringement.[26] This enables generic drug companies to enter their products into the market as close to the patent term's expiration date as possible.[27] However, there are still restrictions to what is considered permissible use under this exception. For example, a generic company cannot use the patented drug commercially during the patent term.[28]

The Hatch-Waxman Act created the first statutory regulatory review exemption to patent infringement in the U.S., colloquially called a "Bolar exemption" after a landmark case, that occurred before the statute's adoption.[29] In that case, Roche Products, Inc. ("Roche") filed a complaint against Bolar Pharmaceutical Co. ("Bolar") for patent infringement after Bolar utilized a generic equivalent to Roche's product "Dalmane" to seek FDA approval before the patent expiry.[30] The U.S. District Court for the Eastern District of New York originally held that Bolar's use of Dalmane's generic equivalent to acquire FDA approval was *de minimis* and therefore did not infringe Roche's patent.[31] However, the U.S. Court of Appeals for the Federal Circuit reversed the district court's decision, finding that Bolar's use did infringe Roche's patent.[32] While this case itself didn't establish the Bolar exemption, the exemption was coined as such when the Hatch-Waxman Act was enacted shortly after the conclusion of the case.[33]

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[26] *Patents and Exclusivity*, FDA/CDER SBIA CHRONS. (2015), https://www.fda.gov/media/92548/download#.
[27] Doubinsky, *supra* note 23.
[28] Hatch-Waxman Act, *supra* note 3, at 1603 ("It shall be an act of infringement . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.").
[29] Carlos Correa, *The Bolar Exception: Legislative Models and Drafting Options*, S. CTR.: RSCH. PAPER 66 (2016); *see* Roche Prods. Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858 (1984).
[30] Correa, *supra* note 29.
[31] *Id.*
[32] *Id.*
[33] *Id.*

IV. INTERNATIONAL IMPLICATIONS: THE TRIPS AGREEMENT

Because the U.S. is a member of the World Trade Organization ("WTO"), its patent laws must comply with the terms of the international Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement, enacted in 1994.[34] The Agreement lays out the minimum requirements that WTO member states must follow to protect and enforce intellectual property ("IP") rights, which includes patents.[35] The Doha Ministerial Declaration, which arose seven years after the TRIPS Agreement was enacted to help shed light on interpreting the vague provisions of the Agreement, emphasized that the TRIPS Agreement should be interpreted in a light favorable to promoting public health.[36]

Within the TRIPS Agreement, Section 30 creates a limited Bolar exemption from patent infringement on the international stage.[37] Three conditions to establish Bolar exemptions are in Section 30's arguably vague language: 1) the exceptions must be limited, 2) they must not conflict with the normal exploitation of the patent, and 3) they must not unreasonably prejudice the interests of patent owners, also accounting for third party interests.[38] Because this section of the TRIPS Agreement provides for a broadly defined Bolar exemption, the U.S. did not have to amend the Hatch-Waxman Act, such that it remains good law to this day. The remaining issue

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[34] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].
[35] Doubinsky, *supra* note 23.
[36] Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, GENEVA: WORLD HEALTH ORG., ESSENTIAL DRUGS & MED. POL'Y (2002); *see* World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 I.L.M 746 (2002).
[37] Doubinsky, *supra* note 23; *see* TRIPS Agreement, *supra* note 34.
[38] Doubinsky, *supra* note 23, at 11.

was what regulatory approval activities actually are protected under the Hatch-Waxman Act and in light of the TRIPS Agreement.

V. INTERPRETING THE BOLAR EXEMPTION IN THE U.S. AND PROMOTING ACCESS TO MEDICINE

Because every WTO member state is free to enact its own IP laws under Article 8 of the TRIPS Agreement, so long as those laws do not violate the TRIPS Agreement,[39] every country's interpretation of Section 30 and the Bolar exemption differs in scope. In the U.S., the Supreme Court and Federal Circuit have held that activities that occur before and after FDA approval (pre- and post-approval activities) can be "reasonably related" to obtaining regulatory approval, such that they do not invalidate the Hatch-Waxman Act.[40] The Federal Circuit has since held that the Bolar exemption only protects very limited types of post-approval activities, like new drug applications and post-approval research results.[41] Thus, many important activities that are necessary for generic drugs to enter the marketplace immediately upon patent expiration are not protected from patent infringement as a Bolar exemption, since they occur between FDA approval and the patent term expiring.

In 2023, the EU proposed a new interpretation of the Bolar exemption, which included expanding the scope of protected regulatory approval activities for generic drugs.[42] Currently, the EU statute that allows for a Bolar

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[39] *See* Trips Agreement, *supra* note 34 ("Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Agreement.").
[40] Lisa Mueller, *Understanding Bolar and Bolar-Like Exceptions in U.S. and Abroad – Part 1*, 15 THE NAT. L. REV. (2017); *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).
[41] *Id*.; *see also* Momenta Pharms., Inc. v. Teva Pharms. USA Inc., 809 F.3d 610 (Fed. Cir. 2015), *cert. denied sub nom.* Amphastar Pharms., Inc. v. Momenta Pharms., Inc., 137 S. Ct. 68 (2016).
[42] Robin Blaney & Roderick Dirkzwager, *EU Pharma Legislation Review Series: Bolar Exemption Under Patent Rights*, COVINGTON & BURLING LLP: INSIDE EU LIFE SCIS. (2023),

exemption is similar to that of the U.S., such that certain pre-market activities that enable a generic prescription drug to enter the market after its corresponding brand-name drug's patent period expires are permissible.[43] The EU's proposal added the following provision to what is not considered infringing patent rights: "studies, trials and other activities conducted to generate data for an application for . . . pricing and reimbursement."[44] The main rationale for the EU seeking to expand the scope of the Bolar exemption in this manner is to better enable generic drugs to enter the market "on day one of loss of the patent."[45] Pricing is set by how much suppliers, typically pharmacies, will charge for providing that prescription drug to consumers.[46] Reimbursement, on the other hand, is how much groups like insurance companies will pay back the drug owners for providing the product.[47] Therefore, these two activities work hand in hand.

VI. LOOKING ACROSS THE OCEAN: ADOPTING THE EU'S RECENTLY PROPOSED BOLAR EXEMPTION

While the EU proposal has not yet been adopted, it provides a basis for what the U.S. can do to expand the scope of its Bolar exemption laws while still protecting the rights of patent owners. Because pricing and reimbursement of drugs are not considered permissible post-approval activities by the Federal Circuit, they are not currently protected as a Bolar exemption in the U.S. Thus, amending the Hatch-Waxman Act to include

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https://www.insideeulifesciences.com/2023/05/02/eu-pharma-legislation-review-series-bolar-exemption-under-patent-rights/?utm_source.

[43] *Id.* (referencing Article 10(6) of Directive 2001/83/EC, which states that "conducting the necessary studies and trials . . . and the consequential practical requirements shall not be regarded as contrary to patent rights").

[44] *Id.*

[45] *Id.*

[46] Louis P. Garrison Jr. & Adrian Towse, *Value-Based Pricing and Reimbursement in Personalized Healthcare: Introduction to the Basic Health Economics*, 7 J. PERS. MED. (2017).

[47] *Id.*

pricing and reimbursement would expand the scope of the Bolar exemption in the U.S. Allowing for pricing and reimbursement to occur for generic drugs before the corresponding brand-name drug patents expire would likely greatly decrease the time between patent expiry and the generic drug entering the market. The sooner generic prescription drugs can enter the market, the sooner they become more affordable for American citizens, such that amending the Hatch-Waxman Act to include pricing and reimbursement within Bolar exemption scope would increase access to medicine.

There may be downsides to this proposal, as critics of the EU proposal argue that its amendment, if enacted, would violate the TRIPS Agreement.[48] They are concerned that there are no safeguards or restrictions in place with the EU's proposed amendment, such that adding pricing and reimbursement to its Bolar exemption will infringe patent rights.[49] Because the TRIPS Agreement was enacted to promote IP rights, any encroachment of those rights would be a violation of the Agreement.

In the U.S., the Hatch-Waxman Act allows for use of a patented product that is "reasonably related to" obtaining regulatory approval, and it must not be used for commercial purposes.[50] Thus, authors of an amendment should thread the needle between these two requirements. A possible solution to creating a valid amendment to the Hatch-Waxman Act under TRIPS would be to explicitly list "pricing and reimbursement" as a permissible post-approval activity and list specific examples that would fall under this provision. To be more specific, the Hatch-Waxman Act could be amended to include the EU's proposed terminology among the list of what is considered a non-infringing activity: "studies, trials and other activities conducted to

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[48] Maarten Meulenbelt et al., *Are the Revisions to the EU's 'Bolar' System Compatible with TRIPS?*, WORLDTRADELAW.NET (2024), https://www.worldtradelaw.net/document.php?id=articles/ProposedEUBolarProvisionTrips.pdf.
[49] *Id.*
[50] Hatch-Waxman Act, *supra* note 3, at 1603.

generate data for an application for pricing and reimbursement."[51] This terminology would provide guardrails for the amendment, reducing the risk of having commercial activities, that violate patent rights, falling into the scope of protection. For example, an activity that could reasonably relate to regulatory approval includes conducting surveys of potential suppliers and buyers using a combination of the data gathered from the patented brand-name drug and the generic drug. Because the generic drug will have been approved by the FDA at this point, there should be data on the expected costs, intended supply, and other factors that go into setting pricing and reimbursement. Such an amendment is also arguably commercial, such that this should be included as a very limited exception to that provision of the Hatch-Waxman Act.

However, to ensure the proper limits of the amendment, the results of those surveys should be required to be kept confidential until the corresponding patent terms expire. Language to incorporate such a limit could include, "any studies, trials, and other activities conducted to generate data for an application for pricing and reimbursement should be kept confidential between only necessary parties until the correlating patented drug's expiry." Thus, there would be no potential impact on the patented brand-name drug's success in the market. If there is no impact on the patented drug and there is some reasonable relation to regulatory approval, this amendment should not impede a patent owner's rights. It also will provide generic drug owners with the necessary data and game plans for conducting more blatant commercial activity once the patented brand-name drugs expire, aiding them in entering the market more quickly.

To further effectuate limitations to the proposed pricing and reimbursement exception, there should be a timeline that restricts these

[51] Blaney & Dirkzwager, *supra* note 42.

activities from being performed except for within a specific time period. This is because conducting such activities long before the patent expiry may not be deemed reasonably related to regulatory approval and lean more towards commercial activity.[52] Additional language to the amendment could read: "pricing and reimbursement approvals are not permissible until after regulatory approval is granted, and such activity must not occur until six months or less before the patent expiration date." Adding these additional guard rails to this proposed exception would likely soothe the minds of patent owners thinking their patents are being exploited because generic drug companies would be limited in the amount of time they can initiate pricing and reimbursement activities before their patents expire.

In order to track generic drugs used for the pricing and reimbursement exception, Congress could further amend the Hatch-Waxman Act to include the language: "all products created by generic companies for the sole purpose of pricing and reimbursement must be labeled as such." If this language were enacted, the patented drugs' parent companies would be able to discern if their name-branded pharmaceuticals were being replicated illegally before the patent expiration date. Specifically labeling the drugs in a format that makes it clear they are for pricing and reimbursement only steers this exception away from being exclusively commercial and more so along the lines of being reasonably related to regulatory review.

Such an amendment, with the proposed limitations provided above, would likely coincide with the TRIPS Agreement. Because the application of pricing and reimbursement in the form of private surveys for generic drugs is limited, it would not conflict with the exploitation of the patent and does not impede on the rights of patent owners or third parties, such that it would not be in violation of Article 30. Furthermore, this expansion of the Bolar

[52] Meulenbelt et al., *supra* note 48.

exemption would not violate Article 7 of the TRIPS Agreement because it would not impede in the enforcement and protection of IP rights due to having adequate limitations. Lastly, this proposed amendment would further the intention of the TRIPS Agreement, as clarified in the Doha Ministerial Declaration, because it would help promote public health initiatives.

The U.S. remains a member of the WTO, though the government has recently paused its promised 2024 and 2025 funding to the Organization.[53] Regardless of any future decisions about WTO membership, the proposed amendment to the Hatch-Waxman Act remains a sound policy choice. While changes in WTO status could have implications for international patent protections, they would not affect the amendment's purpose of effectiveness within the U.S. Lawmakers should adopt this proposed amendment because it promotes access to affordable medications for U.S. citizens while preserving domestic patent rights and fostering innovation. The proposal strikes a careful balance between encouraging pharmaceutical advancements and ensuring timely market entry for generic drugs after patent expiry. That balance—and the amendment's value—remains unchanged regardless of the U.S.' WTO membership status.

VII. CONCLUSION

In conclusion, the lack of affordable medicine in the U.S. calls for a need to assist the increase of generic drugs to market. Patents and the rights that come with them are vital to the healthcare industry because they promote innovation, such that the world would not have nearly as many lifesaving medications as it does without their existence. However, there must be a balance between promoting innovation and providing necessary prescription

[53] Emma Farge, *Exclusive: US pauses financial contributions to WTO, trade sources say*, REUTERS (Mar. 28, 2025), https://www.reuters.com/world/us-suspends-financial-contributions-wto-trade-sources-say-2025-03-27/.

drugs at affordable prices, such that the U.S. should broaden the scope of the Bolar exemption to enable generic drugs to enter the marketplace more easily. With the proper restrictions, like limiting pricing and reimbursement to conducting surveys, these proposed amendments should not hinder patent rights, such that the patent owners will still enjoy their rights to exclude anyone from suing their products during the patent terms.

Should the U.S. be inspired by the EU's proposal and amend the Hatch-Waxman Act to include price and reimbursement to the Bolar exemption with the necessary restrictions and limitations, it will likely be valid under the TRIPS Agreement. This solution will assist generic drug companies, such that once their drugs' correlating patent terms expire, they can immediately enter the marketplace and provide affordable alternatives to U.S. citizens while still promoting patent rights.

Raising the Shield: Protecting Access to Gender Affirming Care

Andrew Pichette

I. GENDER-AFFIRMING CARE FOR TRANSGENDER YOUTH

Gender-affirming care for transgender youth is a crucial component of treating gender dysphoria, the dissonance that accompanies having differing gender identity than assigned sex.[1] Gender-affirming medical care is most typically performed through pharmaceutical intervention and surgical care generally referred to as "sex reassignment" or "gender confirmation" surgery.[2] Despite heated politicization of the topic, there is a universal consensus among major medical associations and global health authorities regarding the therapeutic value of pharmaceutical-based gender-affirming care.[3] Research has shown that transgender and nonbinary youth are disproportionately at risk for negative mental health conditions, "including depression, anxiety, and suicidal ideation and attempts."[4] Studies have repeatedly found that access to pharmaceutical and surgical gender-affirming care reduce rates of several negative mental health outcomes as well as instances of suicidal ideation.[5]

First, this article will discuss restrictions on gender-affirming care in the United States and current legislative trends. Secondly, it will discuss the federal regulatory landscape with a focus on the Employee Retirement Income Security Act of 1974 ("ERISA"). Lastly, the article will discuss ways states can utilize a public option insurance plan to evade ERISA preemption and provide coverage for gender-affirming care.

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[1] Lewis A. Grossman, *Criminalizing Transgender Care*, 110 IOWA L. REV. 281, 283 (2024).
[2] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY & METABOLISM 3869, 3872, 3894 (2017).
[3] Grossman, *supra* note 1, at 283.
[4] Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, JAMA NETWORK OPEN, 2022, at 2.
[5] *Id.*

II. THE ACCESS ISSUE: RESTRICTIONS ON GENDER-AFFIRMING CARE

Restrictions are not unheard of in western nations, which often require certain steps to qualify for pharmaceutical-based gender-affirming care, but notably no other western country besides the United States has outright bans in place on pharmaceutical treatment of gender dysphoria in minors.[6] In spite of the medical benefits associated with gender-affirming treatment for youth, there are numerous restrictions in place around the country.[7] There are twenty-six states that have prohibited gender-affirming care for youths, defined as persons between the ages of thirteen and seventeen by the Movement Advancement Project's research.[8] These legal restrictions, despite lacking substantive scientific support, have proliferated since 2021.[9] Alarmingly, the Trump administration has signaled its hostility towards the transgender community, publishing executive orders that refer to gender-affirming care as "chemical and surgical mutilation."[10] H.R. 1399, introduced by Representative Greene in the 118th Congress, is currently working its way through committees as of February 2025. If passed, H.R. 1399 will make it a felony to provide any gender-affirming care to a minor anywhere in the country if passed and not blocked by the courts.[11]

At the time of writing, it is uncertain exactly what policies and regulations the federal government will adopt to restrict gender-affirming care. The executive order entitled "Protecting Children From Chemical and Surgical Mutilation," has authorized the Secretary of Health & Human Services to

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[6] Grossman, *supra* note 1, at 287.
[7] MOVEMENT ADVANCEMENT PROJECT, *Transgender Healthcare "Shield" Laws*, https://www.lgbtmap.org/equality-maps/healthcare/trans_shield_laws (last visited Feb. 9, 2025).
[8] *Id.*
[9] Gillian Branstetter, *The Supreme Court Case on Trans Health Care, Explained.* ACLU OF N.H., (Dec. 2, 2024, 3:00 PM), https://www.aclu-nh.org/en/news/supreme-court-case-trans-health-care-explained.
[10] Exec. Order No. 14187 90 F.R. (2025).
[11] H.R. 1399, 118th Cong. § 2260B(a) (2024).

take regulatory action to modify Medicare or Medicaid participation conditions, clinical-abuse or inappropriate-use assessments, and section 1557 of the Patient Protection and Affordable Care Act ("ACA").[12] While it is unclear what exact form these changes will take, it seems likely that federal funding that supports gender-affirming care will be cut, and any program dependent on ACA compliance or federal funding is endangered by the Trump administration's position.[13]

III. FEDERAL RESTRICTIONS AND ERISA

Based on the Trump administration's executive orders and the spread of state-level restrictions, gender-affirming care is at risk. While state-level "shield laws" can hamper the ability of restrictive states to reach across state borders for information to pursue cases[14], they only restrain the capacity of other states, not the federal government.[15] Given the crisis at hand, states that value the lives of transgender youth must take proactive steps to protect access to gender-affirming care, and doing so will require avoiding the use of federally funded or supported programs, like Medicaid, that the Trump administration has already threatened.[16] It also requires navigating preemptive laws, like the Employee Retirement Income Security Act of 1974 ("ERISA").

ERISA is a federal law that regulates employer-provided benefit plans.[17] In situations where federal statutes conflict with state statutes, the preemption doctrine typically prioritizes federal law.[18] Three clauses contain the

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[12] Exec. Order No. 14187 90 F.R, *supra* note 10.
[13] *Id.*
[14] MOVEMENT ADVANCEMENT PROJECT, *supra* note 7.
[15] *See generally* UCLA WILLIAMS INST., https://williamsinstitute.law.ucla.edu/wp-content/uploads/Shield-Law-IL-Sep-2024.pdf, (last visited Feb. 9, 2025) (discussing Illinois' various shield laws and how they impact other states).
[16] Exec. Order No. 14187 90 F.R, *supra* note 10.
[17] Erin C. Fuse Brown and Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. 389, 392 (2020).
[18] *See, e.g.,* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 226 n.3 (2000).

extremely broad scope of ERISA.[19] ERISA preempts all state laws "as they may now or hereafter relate to any employee benefit plan,"[20] not just those that conflict.[21] ERISA does, however, permit states to regulate the "business of insurance," though it also prohibits characterizing self-insured plans as being in the "business of insurance."[22] In effect, ERISA allows states to regulate individually purchased plans in the market by mandating coverage for plans not subject to ERISA, but they cannot do the same for employee benefit plans.[23] A law may survive ERISA preemption if it regulates a conventional insurance plan that an employer purchases, but if the law is applied to a self-funded employer-based plan, it is preempted because ERISA's "deemer" clause precludes that plan from being treated as insurance subject to state regulation.[24] Unhelpfully, federal courts have been inconsistent in their application of ERISA, making any attempt at state-level health care reform subject to a high risk of litigation.[25] However, the Supreme Court has held that state rate regulations that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage" are not preempted.[26]

Accordingly, if a state wants to compel employer-based insurance plans to cover gender-affirming care, it will run afoul of ERISA, as it would "relate to any employee benefit plan" and be subject to preemption.[27] Instead, states must pursue other options in order to expand coverage of gender-affirming care. There are several categories of people that efforts to improve access to

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[19] Brown & McCuskey, *supra* note 17, at 392.
[20] 29 U.S.C. § 1144(a) (2022).
[21] Brown & McCuskey, *supra* note 17, at 392.
[22] Peter D. Jacobson, *The Role of ERISA Preemption in Health Reform: Opportunities and Limits,* O'NEILL INST. PAPERS, Apr. 27, 2009, at 1.
[23] *Id.* at 3.
[24] *Id.* at 1.
[25] Brown & McCuskey, *supra* note 17, at 392-94.
[26] Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474, 478 (2020).
[27] 29 U.S.C. § 1144(a) (2022).

gender-affirming care for youths must reach. The first is minors covered by their parents' self-funded employer-based insurance; those plans which are subject to ERISA.[28] The second is minors covered by insurance provided directly by groups subject to state law such as insurers and state governments, which are broadly not subject to ERISA.[29] The third is Medicaid or Medicare beneficiaries who may see coverage of gender-affirming care procedures disappear in response to the withdrawal of federal support, which may prompt states to stop including gender-affirming care coverage in Medicaid programs they administer. The fourth is insurance purchasers in the individual marketplace, and, lastly, the uninsured.

The second group, made up of minors covered by insurers solely regulated by the state, is much easier to target for measures improving access to gender affirming care. ERISA does not preempt state laws that regulate insurance provided by the state in the form of a governmental plan.[30] Accordingly, states wanting to mandate coverage of gender-affirming care for beneficiaries of government-provided plans and plans provided directly by insurers need only find the political will to legislate mandated coverage and, for government plans, finance it in an ERISA-compliant manner. Minors covered by insurance governed by state law are the easiest target population to provide gender-affirming care insurance coverage because ERISA specifically does not concern plans provided by state governments[31] or a state's ability to regulate businesses considered insurers.[32]

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[28] *See* 29 U.S.C. § 514 (2022) ("the provisions of this title and title IV shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 4(a) and not exempt under section 4(b).").

[29] 29 U.S.C. § 1003 (2022) (stating that the provisions do not apply to governmental employee benefit plans).

[30] *Id.*

[31] *Id.*

[32] 29 U.S.C. § 514(b)(2)(A) (2022) ("Except as provided in subparagraph (B), nothing in this title shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.")

In 2023, 48.6% of the population of the United States was covered by employer-based plans.[33] Among those covered by employer-based plans, 65% are covered by self-funded plans.[34] Because employer-provided insurance covers more people than any other provider form, any effort to incentivize the provision of gender-affirming care should target this group.[35] Minors covered by their parents' self-funded employer-based plans are difficult to reach with regulations without triggering ERISA preemption, as those plans are the primary subject of ERISA's preemption clauses.[36] This demographic can be reached with an alternative competitive insurance plan is provided that drives voluntary plan switching by employers. One way states can accomplish that goal is to intervene directly by legislatively providing for a public health insurance option with mandatory coverage for gender affirming care, emulating states that already have implemented, or are implementing, public health options of varying scopes.[37]

IV. AVOIDING FEDERAL RESTRICTIONS WITH A PUBLIC OPTION

States are highly constrained in their ability to simply extend existing public programs like Medicaid by federal laws like the ACA.[38] Accordingly, any solution being brought forward at the state level must walk a thin line to

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[33] KFF, *Health Insurance Coverage of the Total Population*, https://www.kff.org/other/state-indicator/total-population (last visited May 2, 2025).
[34] KFF, *2023 Employer Health Benefits Survey*, (Oct. 18, 2023) https://www.kff.org/report-section/ehbs-2023-section-10-plan-funding.
[35] KFF, *supra* note 33.
[36] *See* 29 U.S.C. § 514 (2022) ("the provisions . . . shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 4(a) and not exempt under section 4(b).").
[37] Christine Monahan et al., *State Public Option Plans Are Making Progress on Reducing Consumer Costs*, THE COMMONWEALTH FUND (Nov. 7, 2023), https://www.commonwealthfund.org/blog/2023/state-public-option-plans-are-making-progress-reducing-consumer-costs.
[38] Jaime S. King et al., *Are State Public Health Options Worth it?* 59 HARVARD J. OF LEGIS. 145, 190 (2022).

either cooperate with the federal system or exist beyond its reach, and public options are one way to accomplish that. "Public options" are health insurance programs and plans run or created by the government.[39] Instead of a single-payer system, public options are insurance plans placed in the market alongside private insurance options by governments.[40] Besides being created by statute and administrative action, they are otherwise largely identical.[41] States are able to administer public options themselves but can also arrange to have them administered by private companies, an approach that has been done already in Colorado and Washington.[42]

While public options have begun to emerge in the United States, there are concerns that public option plans may reduce the revenue of health care providers, thus adoption has been slow.[43] However, there is positive evidence from Washington's recently adopted "Cascade Care" program, emerging from a study of the first enrollment period of Washington's public option plan. This study indicates that, out of new enrollees on Washington's exchange, 40% chose to enroll in the public option over competing private plans on the market.[44] Additionally, evidence from the first year enrollment period indicated that, without direct rate setting, expected reductions in premiums are difficult to achieve without mandating provider participation.[45] However, subsequent studies have also indicated that Washington and Colorado's public options are generating reduced rates of premium increases compared to other states, suggesting that as these programs have matured

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[39] HEALTHINSURANCE.ORG, *public option*, https://www.healthinsurance.org/glossary/public-option/ (last visited Feb. 14, 2025).
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] Aditi P. Sen et al., *Participation, Pricing, and Enrollment in a Health Insurance "Public Option": Evidence from Washington State's Cascade Care Program*, 100 THE MILBANK Q. 190, 207 (2022).
[45] *Id.* at 212.

they are achieving greater financial stability than private competitors while passing savings along to consumers.[46]

Implementing public health insurance options presents an opportunity to reach some of the groups that may want to purchase insurance that provides coverage for gender-affirming care. Thus far, states that have developed public options have done so by collaborating with private insurers to provide public option plans that meet certain requirements set by the state.[47] For example, in Colorado, the passage of the Colorado Standardized Health Benefit Plan Act has created a tiered set of health insurance plans that are required to include certain benefits, with each tier costing more but providing greater benefits.[48] Other states seeking to provide an ERISA-exempt public option plan could choose to do the same and provide coverage for gender-affirming care. Modeling prospective plans on the Colorado and Washington public option statutes, which have thus far survived federal scrutiny, is a strong place for public option advocates to start.

Creating a public option plan can be done by statute. For example, Colorado's statute creating its standardized health public option plan includes that it must cover, "at a minimum, pediatric and other essential health benefits."[49] A public option intended to guarantee coverage for gender-affirming care could utilize the same language as Colorado's statute and simply append "gender-affirming care" to the minimum coverage requirements built into the statute. Defining "gender-affirming care" would ultimately fall to legislative or administrative discretion depending on the statute, but guidance on determining what is medically appropriate gender-affirming care is available through numerous advocacy groups and medical

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[46] Monahan et al., *supra* note 37.
[47] *Id.*
[48] Colorado Standardized Health Benefit Plan Act, 10 C.R.S. § 1304 (Lexis 2025).
[49] Colorado Standardized Health Benefit Plan Act, 10 C.R.S. § 1302 (Lexis 2025).

associations' publications.[50] Colorado's Standardized Health Benefit Plan Act similarly contains language regarding the creation of advisory committees to provide input on the plan,[51] rate management goals,[52] and reimbursement rate increases for hospitals supporting areas with small numbers of licensed hospital beds.[53] States seeking guidance on statutory construction could draw heavily from the Colorado Standardized Health Benefit Plan Act and for guidance on implementation from Colorado and Washington, which each have a few years of experience operating a public option plan.[54] Additionally, Maine, Nevada, Minnesota, and New Mexico have passed legislation related to plans for future public option plans which could similarly provide inspiration for state legislatures looking to provide a public option.[55]

A public option like those adopted by other states could mandate coverage of gender-affirming care at all tiers, and, importantly, escape ERISA preemption if correctly structured.[56] While ERISA would preempt any attempt to mandate that employers participate in the public option, it would not preclude the existence of a public option or the ability of employers to opt-in voluntarily.[57] Constructing a public option plan with a tier that can compete with certain self-funded plans provides a way to potentially reach employers and persuade them to buy into a state regulated insurer that has mandatory coverage for gender-affirming care, and offering that plan as a

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[50] Hembree et al., *supra* note 2, at 3869; *see also* WORLD HEALTH ORG., https://www.who.int/standards/classifications/frequently-asked-questions/gender-incongruence-and-transgender-health-in-the-icd/ (last visited Mar. 31, 2025); E. Coleman et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*, 23 INT'L J. OF TRANSGENDER HEALTH, S1, S254 (2022).
[51] Colorado Standardized Health Benefit Plan Act, 10 C.R.S. § 1307 (Lexis 2025).
[52] Colorado Standardized Health Benefit Plan Act, 10 C.R.S. § 1305 (Lexis 2025).
[53] Colorado Standardized Health Benefit Plan Act, 10 C.R.S. § 1306 (Lexis 2025).
[54] Monahan et al., *supra* note 37.
[55] *Id.*
[56] King et al., *supra* note 38, at 216.
[57] *Id.*

voluntary option likely protects the public option plan from ERISA preemption.[58] Certain funding mechanisms, like compulsory employer contributions to the public option, would likely implicate ERISA.[59] However, payroll taxes that do not compel participation in the public health option plan, but are mandatory to pay, appear to be a viable funding mechanism that does not create a risk of ERISA preemption.[60]

A public option could also cover other groups that may need to be covered to improve general access to gender-affirming care. State government employees, for example, could be permitted to enroll in the public option plans by including group health coverage as part of their benefits package.[61] Medicaid beneficiaries would have to begin paying premiums when they did not otherwise, but, for those seeking gender-affirming care, it may be the only way to access it if the Trump administration is successful in withholding funding.[62] Another group that the public health option also may struggle to provide coverage for is individual purchasers in the marketplace, and, by extension, the undocumented.[63] Undocumented individuals constitute one of the largest sections of the uninsured population, in part because the ACA prohibits marketplace insurance plans from providing coverage to undocumented individuals.[64] However, this is only a potential barrier unless the government successfully amends the ACA to prohibit ACA-compliant plans from including coverage for gender-affirming care. Until the ACA is amended, a public option plan covering it could likely be offered on the marketplace without jeopardizing access to ACA-linked federal funding.

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[58] *Id.*, at 191.
[59] *Id.*
[60] *Id.*, at 192.
[61] Kaye Pestaina et al., *The Regulation of Private Health Insurance*, KFF, https://www.kff.org/health-policy-101-the-regulation-of-private-health-insurance.
[62] Exec. Order No. 14187 90 F.R, *supra* note 10.
[63] King et al., *supra* note 38, at 149.
[64] *Id.*

Participation in the marketplace provided for by the ACA is contingent on the satisfaction of the ACA's requirements for health plans.[65] As of the first quarter of 2023, only 2.5 million of the 18.2 million enrollees in the individual market were enrolled in off-marketplace plans, and enrollment rates in off-marketplace plans have been dropping.[66] The preference for marketplace plans appears to be largely driven by subsidies.[67] A public option plan providing for gender affirming care for youths is not likely to survive federal scrutiny under the Trump administration because of the administration's stated intent to interpret the ACA to restrict gender-affirming care for youths as much as possible,[68] which might prohibit states from placing a public option plan on the marketplace if it provides for that care.[69]

The preference for marketplace plans could potentially cause a public option plan to suffer from low enrollment through the individual market if it is not affordable compared to on-marketplace plans, and would likely require subsidies comparable to those on the marketplace.[70] Additionally, the ACA prohibits marketplace plans from covering undocumented individuals, who are a large portion of the uninsured population.[71] Conditions for the marketplace, and the Trump administration's present outlook, indicate that a public option plan would probably have to be off the marketplace, especially if the plan sought to provide coverage for undocumented individuals.[72] If the Trump administration is successful in blocking federal subsidies to marketplace plans that provide for gender-affirming care coverage, such a

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[65] *Id.*
[66] Jared Ortaliza et al., *As ACA Marketplace Enrollment Reaches Record High, Fewer Are Buying Individual Market Coverage Elsewhere*, KFF, (Sept. 7, 2023), https://www.kff.org/private-insurance/issue-brief/as-aca-marketplace-enrollment-reaches-record-high-fewer-are-buying-individual-market-coverage-elsewhere.
[67] *Id.*
[68] Exec. Order No. 14187 90 F.R, *supra* note 10.
[69] King et al., *supra* note 38, at 149.
[70] Ortaliza et al., *supra* note 66.
[71] King et al., *supra* note 38, at 149.
[72] *Id.*

public option would have to be placed off-marketplace where it would not be supported by federal subsidies, making it more costly for states to subsidize themselves.[73]

While there is currently a trend towards use of on-marketplace plans due to subsidies,[74] this trend is not necessarily a death sentence for an off-marketplace public option plan. Given that the trend towards marketplace plans appears to be driven by subsidies,[75] it stands to reason that subsidies for the public option plan could similarly drive enrollment. Subsidies for marketplace plans have been found to reduce out-of-pocket spending in low-income populations, a result that could possibly be replicated with similar cost management measures.[76] Because risk pooling is key to maintaining the financial stability of insurance plans, states pursuing a public option need to make sure to adequately subsidize the plan well enough to maintain a risk pool of roughly average health,[77] which could also be supported by enrolling state government employees in the public option plan in order to broaden the risk pool. Insurance risk pools with skewed risk can result in cost increases that prompt healthy beneficiaries to seek out cheaper plans, raising costs further for those who remain.[78] However, if the risk pool's equilibrium is maintained with a sufficient number of healthy beneficiaries, a public option plan could avoid adverse selection issues.[79]

A public option which provides gender affirming care would be able to draw employers away from self-funded plans within ERISA's scope to the

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[73] Pestaina et al., *supra* note 61.
[74] Ortaliza et al., *supra* note 66.
[75] *Id.*
[76] Charles Liu et al., *The Affordable Care Act's Insurance Marketplace Subsidies Were Associated With Reduced Financial Burden for US Adults*, 40 HEALTH AFFS. 496, 499 (2021).
[77] Pestaina et al., *supra* note 61.
[78] *Id.*
[79] Bernadette Fernandez & Namrata K. Uberoi, *Health Insurance: A Primer,* PRIVATE-SECTOR HEALTH INSURANCE: A PRIMER 19, 22 (Stephen Maxwell Mathis ed., 2015).

public option, expanding access to coverage.[80] It could also reach state government employees and their dependents.[81] Given that a large section of the insured population receives insurance through employers, a public option plan that targets those two groups could have a significant impact on increasing coverage for gender-affirming care, and it should not be dismissed despite some of its shortcomings in providing all-encompassing coverage.[82] While states have a difficult path ahead in creating public option plans because of federal statutes,[83] an off-marketplace public option presents a viable option for states looking to create a comprehensive insurance option that can guarantee coverage for gender-affirming care for transgender persons below eighteen years of age.

V. CONCLUSION

In summary, the Trump administration's current efforts to restrict gender affirming care, if not blocked by the courts, are likely to severely inhibit the ability of states to provide affordable access to gender-affirming care with federal funds. A public health option crafted to evade ERISA preemption can reach employers who are seeking to provide gender-affirming care coverage to employees.[84] While participation in the marketplace excludes coverage for undocumented individuals, offering the plan outside the marketplace can potentially reach that population as well.[85] Accordingly, states seeking to create a public option need to focus on ways to support an off-market plan and advertise it sufficiently to reach those are seeking reliable coverage for gender-affirming care. Cost concerns are inseparable from health care and insurance, but there is evidence from existing public option plans that they

[80] King et al., *supra* note 38, at 190.
[81] Pestaina et al., *supra* note 61.
[82] KFF, *supra* note 33.
[83] King et al., *supra* note 38, at 217.
[84] King et al., *supra* note 38, at 191.
[85] King et al., *supra* note 38, at 149.

can effectively manage costs and operate in competitive insurance marketplaces.[86]

Gender-affirming care saves lives,[87] and in the face of federal interference and growing state restrictions, states should pursue all means necessary to continue providing access to gender-affirming care. States looking to provide gender-affirming care should consider creating a public option plan while continuing to monitor developments at the federal level, which remain unpredictable. For states committed to protecting transgender individuals and their access to care, adoption of off-marketplace public option plans is a worthwhile approach to consider. A public option plan is able to avoid ERISA preemption while also avoiding other restrictions that might be placed by the federal government through modifications to the ACA or Medicaid conditions of participation.

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[86] Monahan et al., *supra* note 37.
[87] Tordoff et al., *supra* note 4, at 2.

Regulating Telemedicine in the United States: The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 Proposed Amendment

Natalie Purko

I. THE IMPACT OF TELEMEDICINE AND ACCESS TO HEALTHCARE

Telemedicine has transformed healthcare in the United States, especially among populations in underserved communities and rural areas. Through the use of technology, individualized healthcare that is centered around increased access and improved outcomes has created new capabilities for patients and providers, leading to the expansion of telehealth.[1] Telehealth is crucial in rural areas, and this paper will propose an amendment to legislation protecting access to telehealth in the availability of controlled substances in rural areas.

Telemedicine is critical in rural communities because it supports patients in seeking immediate care without being forced to travel or disrupt their day-to-day lives to receive care.[2] Additionally, in regard to financial benefits, the use of telemedicine can prevent unnecessary hospital visits and travel, as well as allow for more accurate diagnosis and treatment to be determined and provided more efficiently.[3] When tests or consultations can be completed virtually, the next steps for the patient's needs can be established faster. In addition to accessibility and financial benefits, various types of care notably improve through telemedicine.[4]

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[1] Hyder, M. A. & Razzak, J., *Telemedicine in the United States: An Introduction for Students and Residents*, 22 J. MED. INTERNET RES. 1, 2 (2020), https://doi.org/10.2196/20839.
[2] G.B. Colbert, A.V. Venegas-Vera & E.V. Lerma, *Utility of Telemedicine in the COVID-19 Era*, 21 REV. CARDIOVASC. MED. 583, 585 (2020), https://doi.org/10.31083/j.rcm.2020.04.188.
[3] T.S. Nesbitt, *The Evolution of Telehealth: Where Have We Been and Where are We Going?*, NAT'L CTR. BIOTECHNOLOGY INFO. 1, 2-3 (2012), https://www.ncbi.nlm.nih.gov/books/NBK207141/?report=printable.
[4] *Id.* at 2.

In these rural communities, there are generally greater health care needs with more limited opportunities to receive healthcare.[5] With twenty percent of people living in rural and frontier areas of the United States, it is pivotal that there is access to healthcare there.[6] There are unique health challenges to communities in rural areas.[7] According to the Centers for Disease Control and Prevention ("CDC"), rural communities are often comprised of older and more immunocompromised individuals in comparison to individuals living in urban and suburban areas.[8] Furthermore, individuals in rural communities are more likely to suffer from chronic conditions such as heart disease, cancer, stroke, and chronic lower respiratory disease.[9] The absence of accessible healthcare amplifies these conditions and creates severe health disparities in rural areas.[10] The obstacles to access to healthcare in these areas include insufficient local clinics, too few providers, lack of medical technology, and significant travel barriers to adequate care.[11]

Not only will there be significant benefits to patients through expanded access to telemedicine, but there will also be benefits for providers that will improve health across our nation, not just in rural communities. Through telemedicine, there are healthcare opportunities that are not always possible with in-person care, and these opportunities can support more efficient and effective care.[12] When patients can be seen at their convenience, they can

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[5] *Introduction to Rural Telehealth*, TELEHEALTH FOR RURAL AREAS, https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-rural-areas.
[6] *Id.*
[7] *Get Started with Rural Telehealth,* TELEHEALTH RURAL AREAS, https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-rural-areas/getting-started.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] Brian William Hasselfeld, M.D., *Benefits of Telemedicine*, JOHNS HOPKINS MED., 1,1 https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/benefits-of-telemedicine.

better protect themselves and others from infectious diseases.[13] Additionally, patients can be seen in environments they feel comfortable and safe in.[14] Furthermore, patients can have the opportunity to see providers at the time most convenient for them, avoiding harmful waiting periods due to backlogs in care.[15] With regard to access to controlled substances, patient access is consequential to preventing abuse, misuse, and dependence on controlled substances.[16] This paper will argue for the expansion of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to include an amendment that allows the use of telemedicine for care, specifically necessary access to controlled substances, in rural areas for the purpose of increasing access to healthcare.

II. H.R. 6353 - RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2008

Prior to COVID-19, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 ("the Act") originally amended the Controlled Substances Act ("CSA") to provide for more regulated dispensing of medications through technology.[17] With the amendment, the Act limited healthcare providers from prescribing medications without assessing patients in person first, in an effort to prevent unnecessary use and abuse of prescribed substances.[18] However, with the crisis of COVID-19, many states stretched

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] World Health Organization, *Controlled Substances*, ACCESS TO MED. & HEALTH PRODS., https://www.who.int/our-work/access-to-medicines-and-health-products/controlled-substances.
[17] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 Fed. Reg. 91253 (Nov. 19, 2024) (to be codified at 21 C.F.R. pt. 1307.41).
[18] Shlyn Watkins et al., *DEA, HHS Extend Telemedicine Flexibilities for Controlled Substance Prescriptions Through 2025*, HOLLAND & KNIGHT, 1, 2 (2024), https://www.hklaw.com/en/insights/publications/2024/11/dea-hhs-extend-telemedicine-flexibilities-for-controlled-substance.

their telemedicine laws, and the Act included a temporary exception to ensure medication management could be accessible for all, including without in-person evaluations.[19] Telemedicine has had a remarkable impact on healthcare, and for healthcare systems to continue to improve access, costs, and quality for patients, telemedicine must be utilized and accessible for all.

The original extension of the Act was implemented in 2020 and has been extended for the third time, with the adjustments effective through 2025.[20] The extension of the Act consists of four requirements for obtaining a prescription through telemedicine.[21] There must be a valid, reasonable medical purpose for the prescription, the prescription must be obtained through telemedicine programming, the prescribing healthcare provider must be authorized to prescribe the controlled substance or be exempt from obtaining a registration to prescribe through telemedicine, and the rest of the requirements of the Act must be met.[22] The Act extension has been renewed three times in an effort to find an effective final edit to the Act that addresses the evolving needs of society, especially post-COVID-19.[23] It is essential to incorporate telemedicine in the final adjustments of the Act to ensure that healthcare, specifically necessary access to controlled substances, is accessible and effective for all, no matter the location of the patient.

III. THE PITFALLS OF THE RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2008

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 is centered around utilizing technology to facilitate a more efficient and effective healthcare system. While the Drug Enforcement Administration

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[19] *Id.*
[20] *Id.* at 14.
[21] *Id.*
[22] *Id.*
[23] *Id.*

("DEA") and the Department of Health and Human Services ("HHS") have agreed to extend the flexibilities in the Act for the third time, this extension is only through December 31, 2025.[24] The agencies have stated they are working on developing an appropriate final amendment to the Act, however, they have not stated whether that includes a permanent update to allow access to telemedicine healthcare without an initial in-person visit.[25] The purpose of the extension of the Act was initially to ease out of COVID-19 pandemic healthcare systems to ensure that no access to healthcare was lost that had been established.[26] The agencies' initial goals for the extension were to prevent loss of access to care, to prevent significant backlogs for in-person healthcare visits, and to address exceptional public health needs.[27] While COVID-19 has become more controlled, the access to healthcare issues that existed before and during the pandemic have persisted.

It is crucial to acknowledge the purpose of the Act and the number of extensions there have been. The initial flexibilities were implemented in 2020, with the purpose of filling access gaps and ensuring that healthcare was available for all, despite much of the world experiencing unexpected shutdowns.[28] In 2023, the flexibilities were extended, as the DEA reported seeking a final solution to continue increasing access to care but had not yet reached a final plan.[29] With the current flexibilities expiring at the end of 2025, it is paramount that the importance of the flexibilities is acknowledged. The DEA's latest proposal discarded the flexibilities and re-established the

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[24] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 Fed. Reg. 91253.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] Rachel Stauffer, *DEA Extends Telehealth Responsibilities for Controlled Substance Prescribing Through December 31, 2025*, MCDERMOTT WILL & EMERY, 1, 2 (Nov. 2024) https://www.mcdermottplus.com/insights/dea-extends-telemedicine-flexibilities-for-controlled-substance-prescribing-through-december-31-2025/.
[29] *Id.*

requirements of in-person provider visits for half of a provider's prescriptions of controlled substances.[30] While HHS did not agree with the proposal at the time, and lawmakers encouraged inclusion of more flexibilities, the DEA has not presented a new plan with flexibilities included.[31] In fact, the DEA has stated that the current extension will allow both patients and providers to prepare for in-person requirements coming back, as well as ensure that regulations can be understood and followed.[32]

While there are concerns regarding the Act and the extension of flexibilities, the concerns are insignificant in comparison to the damage that would be caused should the flexibilities of the Act be abandoned. With the flexibilities of the Act, there has been immense growth in access to care, especially in rural areas. Data illustrates that prescription accuracy improved due to telemedicine and the exceptions to the Act created, with 19 percent of prescription errors being corrected by remote pharmacists.[33] Additionally, telemedicine contributed to quicker healthcare outcomes, with over 25,000 miles travelled by patients prevented due to the opportunity to visit remote pharmacies.[34] It is critical to acknowledge the improvements that would continue with the extension becoming a permanent amendment to the Act.

Residents in rural communities face greater risks of death due to the inaccessibility of healthcare resources and environmental factors.[35] An influential first step to combatting this would be increasing access to healthcare resources to ensure that every individual has the opportunity for effective and efficient healthcare. Amending the Ryan Haight Online

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[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] Nesbitt, *supra* note 3.
[34] Nesbitt, *supra* note 3.
[35] *Id.*

Pharmacy Consumer Protection Act of 2008 to permanently include the telemedicine flexibilities will increase access to healthcare in rural areas.

In a recent study executed by Harvard Medical School and Yale School of Medicine, it was discovered that health outcomes were equally successful and effective through telemedicine as in-person visits.[36] The study explored the effectiveness of palliative care through telemedicine in comparison to in-person visits, and there were identical outcomes between the two groups.[37] There was no substantial variation in quality of life among the groups.[38] Similar to healthcare access in rural areas, palliative care is only accessible to ten percent of the population that needs care, and there are immense healthcare disparities due to geography.[39] Because telemedicine is so effective in palliative care, as the study determined that the quality of life was the essentially the same between in-person care and telemedicine, in addition to more independence for patients, it is essential to look at other areas of healthcare in which telemedicine could be as successful, if not more, in patient outcomes. However, if the flexibilities to the Act are not continued after the extension deadline in December of 2025, geographic disparities will continue to increase, and the lack of access to care in rural areas will continue to harm individual health and societal health overall.

IV. PROPOSAL TO IMPLEMENT THE AMENDMENT TO MAKE HEALTHCARE MORE ACCESSIBLE FOR ALL

Creating an amendment that permanently includes the flexibilities to the Act will allow the access that has been gained to continue to grow, increasing

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[36] Isabella Backman, *Telehealth is Just as Effective as In-person case, Study Finds*, YALE SCH. MED., 1, 3, (2024), https://medicine.yale.edu/news-article/telehealth-is-just-as-effective-as-in-person-care-new-study-finds/.
[37] *Id.*
[38] *Id.*
[39] *Id.*

comfort with using telemedicine among patients and providers, and an expansion of the possibilities of telemedicine.

The current Act, H.R. 6353, reads as follows:[40]

> "(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—
> (1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.
> (2) As used in this subsection:
> (A) The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—
> (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
> (ii) a covering practitioner.
> (B)(i) The term 'in-person medical evaluation' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.
> (ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice."

Within the text of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, there should be an amendment to include the flexibilities that have been extended over the past five years to provide greater healthcare access:[41]

> "(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—
> ''(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.
> (2) As used in this subsection:

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[40] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, H.R. 6353. 110th Cong. (2008), https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf.
[41] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FED. REG. 91253, *supra* note 17.

> ''(A) The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—
>
> (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
>
> (ii) a covering practitioner.
>
> (B)(i) The term 'in-person medical evaluation' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.
>
> (ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.
>
> (3) A prescription can be obtained through telemedicine through meeting the following requirements:
>
> (i) Prescribed for a valid, medical purpose,
>
> (ii) Through a certified telemedicine program,
>
> (iii) By a provider who is authorized to prescribe controlled substances or otherwise exempt from obtaining a registration to prescribe, and
>
> (iv) All other requirements for the Act are met."[42]

The DEA and HHS have granted each of the temporary extensions of the flexibilities.[43] These regulations were implemented by DEA's Assistant Administrator and Deputy Assistant Administrator signing letters indicating the exceptions in 2020.[44] Additionally, in 2023, the DEA and HHS implemented two notices of proposed rulemakings in the Federal Register to expand the scope of telemedicine and patient access.[45] Through all these temporary extensions to ensure access to care through telemedicine, the DEA and HHS have remained supportive of telemedicine and increasing access to care. However, it is imperative that the commitment to access to healthcare

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[42] 21 U.S.C. § 829 (2025).
[43] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FED. REG. 91253, *supra* note 17.
[44] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FED. REG. 91253, *supra* note 17.
[45] Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 89 FED. REG. 91253, *supra* note 17.

for all is not just temporary. Through implementing an additional regulation that amends the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, access to healthcare can continue to improve by supporting those who face barriers to receiving in-person care.

As this country faces a crisis in regard to access to healthcare, it is essential to utilize the tools that are available, such as telemedicine, to combat access inequalities and healthcare disparities. A potential negative consequence of making telehealth more accessible without the requirement of an in-person meeting could be drug abuse and misuse. While this could be possible, this proposal argues that if the addition to the Act includes a requirement of addiction awareness to patients and even a test by providers when there are warning signs, abuse and misuse of drugs could be mitigated.[46] This test could comprise of questions relating to risk factors for addiction, and the prescribing physician and pharmacy could establish warning signs and intervention measures if risks are present. Examples of these questions could include screening assessments regarding medical history, family history, and health tendencies. Access to healthcare and the inclusion of substance use disorder treatment and mental health services in traditional healthcare have beneficial effects on healthcare and outcomes.[47] In fact, evidence has indicated that this integration promotes effective and efficient care.[48] Because evidence has shown that providers in substance use disorder treatment are unable to meet the overwhelming need for care, including these services in telemedicine appointments would be extraordinarily impactful

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[46] Jennifer McNeely, et al., *Substance Use Screening, Risk Assessment, and Use Disorder Diagnosis in Adults*, NAT'L. LIBR. MED., 1, (May 30, 2024) https://www.ncbi.nlm.nih.gov/books/NBK565474/?report=printable.
[47] Office of the Surgeon General, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, NAT'L. LIBR. MED., 1, (Nov. 2016) https://www.ncbi.nlm.nih.gov/books/NBK424848/.
[48] *Id.*

and effective at reaching more individuals faster.[49] Requiring conversations regarding addiction awareness and individual circumstances creates opportunities for providers to discuss substance use, potential abuse, interventions, and even treatments through telemedicine.[50] Not only does this promote safe and effective prescription use, but this also creates an opportunity for the patient to understand their substance use and health.

Some could argue that through implementing this proposal and no longer requiring an in-person visit to have access to healthcare and a provider, health outcomes will decrease. However, studies have shown that telehealth has supported patient health outcomes.[51] Through the use of telemedicine, geographical obstacles have been overcome, and patient access has grown substantially.[52] Additionally, cost savings were found to have improved with telemedicine, increasing access to healthcare financially as well.[53] Although the studies were done regarding chronic disease management, it must be acknowledged that these outcomes could have the same impacts on other areas of healthcare.

Telemedicine has changed healthcare for the better in many areas, and it is necessary to acknowledge this and the possibilities of the Act in changing healthcare in prescription access. There are notable positive consequences of making healthcare more accessible and not requiring an in-person meeting for prescription access. More specifically, the broadened use of telehealth can assist healthcare systems in battling overwhelming backlogs in appointment scheduling. Significant care backlogging can prevent patients

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[49] *Id.* at 2.
[50] McNeely, et al., *supra* note 4646.
[51] Victor C. Ezeamii, et al., *Revolutionizing Healthcare: How Telemedicine is Improving Patient Outcomes and Expanding Access to Care*, CUREUS, 1, 2 (2024) https://pmc.ncbi.nlm.nih.gov/articles/PMC11298029/.
[52] *Id*.
[53] *Id.*

from receiving care that is necessary to enhance their lives and improve their health.[54] Moreso, care backlogging can also prohibit patients from receiving essential care for treatment, and even survival.[55] Because care backlogging has been shown to be harmful to health and even create more severe negative health consequences for patients, it is imperative to acknowledge the positive impact telehealth can have on improving backlogging and ensuring care is rendered to patients at their needs. Implementing the flexibilities to the Act as an amendment will allow the access to care that has been gained to continue to grow, while also improving healthcare efficiency and effectiveness.

Telehealth is instrumental in providing care to patients who otherwise would not have access due to geographic location, as well as providing an additional level of privacy and opportunity for continued treatment.[56] Due to the online format, there is an additional sense of privacy in that one does not need to leave the comfort of their home to receive care, and they do not need to face the challenges of going in public to receive this care. Furthermore, through the use of telemedicine, it can be easier to meet consistently with providers, as scheduling and traveling barriers are nonexistent. Through the addition to the amendment of the Act, drug use and misuse can be monitored and minimized, ensuring that the impacts of telehealth are positive.

V. CONCLUSION

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[54] Van Ginneken E, et al., *Addressing Backlogs and managing Waiting Lists During and Beyond the COVID-19 Pandemic*, NAT'L. LIBR. MED., 1, 1 (2022) https://www.ncbi.nlm.nih.gov/books/NBK589256/.
[55] *Id.*
[56] *Tele-treatment for Substance Use Disorders*, TELEHEALTH FOR BEHAV. HEALTHCARE, https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-behavioral-health/tele-treatment-for-substance-use-disorders.

The lack of access to healthcare in the rural communities of the United States is in a vicious relationship with generally worse healthcare outcomes.[57] With twenty percent of the population living in rural and frontier areas, it is essential that there are opportunities for effective and efficient healthcare for all, regardless of geographic location.[58] Despite current disadvantages in rural communities, telemedicine has contributed to bridging the healthcare gap by providing opportunities for individuals to receive the care they need at their convenience.

Flexibilities to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, implemented in 2020, have created new access to care that was not possible before with the restrictions of in-person visits to receive care. These flexibilities have positively impacted healthcare so much that they have been extended three times by the DEA and HHS.[59] With the latest extensions to the Act expiring in December 2025, it is essential that the DEA and HHS act now to preserve access to healthcare through telemedicine and no longer require an in-person visit to receive care in the prescription of controlled substances. Rural communities deserve access to healthcare, and the proposed amendment to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 would improve and protect that access.

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[57] Hyder & Razzak, *supra* note 1.
[58] *Introduction to Rural Telehealth*, *supra* note 5.
[59] *Id.*

Addressing Inequities to Maternal and Fetal Health Outcomes for Native American Women

Anna Rossio

I. INTRODUCTION

The Native American population in the U.S. has faced a long history of abuse, neglect, and discrimination.[1] Native women, specifically, experienced traumatic and ineffective health care for decades, particularly regarding forced sterilization that took place during the 1960s and 1970s.[2] Repercussions from this maltreatment persist today with high physician distrust and inequities in health outcomes such as high cervical cancer prevalence, high suicide rates, and little to no abortion care access.[3] Negative health outcomes are compounded by challenges Native mothers face, such as inadequate access to care and support, high poverty rates, and underlying health challenges[4], including increased alcoholism rates, diabetes rates, and cardiovascular disease rates.[5] These issues cause adverse health outcomes not only for the mother, but the fetus as well.[6] Providing Native women the prenatal care they desperately need will help lower the disparate health

[1] Mary G. Findling et al., *Discrimination in the U.S.: Experiences of Native Americans,* 54 HEALTH SERV. RES. 1431, 1432 (2019).
[2] Jane Lawrence, *The Indian Health Serv. and the Sterilization of Native Am. Women*, 24 AM. INDIAN Q. 400, 400 (2000).
[3] Keely K. Ulmer, *Disparities in Healthcare: A Focus on Native Am. Women's Health and the Sys. That Is Failing Them*, 9(3) PROCEEDINGS IN OBSTETRICS AND GYNECOLOGY 1, 6 (2020), https://pubs.lib.uiowa.edu/pog/article/3483/galley/112389/view/.
[4] Micaela Simpson, *The Marshall Factor: How Forced Sterilization of Native Am. Women Birthed Generational Reprod. Injustice*, 49 S.U. L. REV. 65, 67-8 (2021).
[5] *See* U.S. Comm'n on Civil Rights, *Nature, Scope, and Effect of Native Am. Health Disparities,* in BROKEN PROMISES: EVALUATING THE NATIVE AMERICAN HEALTH CARE SYSTEM (2004).
[6] Arambula Solomon et al., *What's Killing Our Children? Child and Infant Mortality Among Am. Indian and Alaskan Natives*, National Academy of Medicine (2017), https://nam.edu/wp-content/uploads/2017/03/Whats-Killing-Our-Children-Child-and-Infant-Mortality-among-American-Indians-and-Alaska-Natives.pdf.

outcomes they, and their babies, face.[7] To do so, the government must uphold the promises it made to Native tribes decades ago.[8]

First, this article will address Native women's historical experiences with the healthcare system and the organizations proving that care. Specifically, this article will discuss the history of forced sterilizations of Native women. Next, this article will discuss the healthcare challenges Native women face that cause disparate health outcomes for mothers and children. Finally, this article will propose amending the Indian Health Care Improvement Act to increase funding for the Indian Health Service ("IHS") to expand access to pregnancy-related care.

II. TRAUMATIC HISTORY OF NATIVE WOMEN HEALTH CARE

Native Americans are the only minority in the United States who have legal rights to federal health care services.[9] The federal government collaborates with the Indian Health Service ("IHS") and tribal leaders to provide health services to the Native population.[10] A fundamental aspect behind the government's obligation to provide health services is the trust relationship between tribes and the federal government.[11] The trust relationship aims to create a balance between tribal sovereignty and the government's responsibility for providing resources and support to uplift the Native population to levels comparable to non-Native groups.[12] However, that trust fragmented when the IHS and federal government violated and traumatized Native women starting in the 1960s.[13]

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[7] Jessica D. Hanson, *Understanding Prenatal Health Care for Am. Indian Women in a N. Plains Tribe,* 23 J. TRANSCULTURAL NURSING 29, 30 (2012).
[8] Donald Warne & Linda Bane Frizzell, *Am. Indian Health Pol'y: Hist. Trends and Contemp. Issues*, 104 AM. J. OF PUB. HEALTH S263, S263 (2014).
[9] Nat'l Academies of Sci., Engineering, and Med., *Communities in Action: Pathways to Health Equity* 509 (James N. Weinstein et al. eds., 2017).
[10] *Id.* at 510-11.
[11] Holly E. Cerasano, *The Indian Health Serv.: Barriers to Health Care and Strategies for Improvement*, 34 GEO. J. POVERTY LAW & POL'Y 421, 425 (2017).
[12] *Id.*
[13] Lawrence, *supra* note 2, at 400.

During the 1960s and 1970s, the IHS and its physicians performed forced or coerced sterilizations on Native women.[14] The surface motivation behind the family planning services for Native women in 1965 was greater education, but the true motivation was targeting Native women because of their high birth rate.[15] Between 1970 and 1976, IHS sterilized between twenty-five to fifty percent of Native women.[16] Within the same time frame, IHS performed over 3,000 sterilizations.[17] Girls as young as fifteen years old were included in this group.[18]

Native women went to IHS medical facilities to give birth or have an unrelated procedure but leave unable to have children in the future.[19] Tactics used include giving Native women "vitamins," that were actually birth control pills, and manipulating women to think certain symptoms they experienced were from pregnancy fears, which sterilizations could fix.[20] Further, many Native women reported learning about the sterilization only after the procedure's completion or facing threats from doctors and social workers to consent to the procedure.[21] Doctors attempted to use signed consent forms as a defense for accusations of forced or coerced sterilizations, but these consent forms did not meet necessary standards.[22] For example, basic elements, such as information regarding right to withdraw consent or a summary of the oral presentation were either written in English so that the patient could not understand what they were signing, or were completely absent from the forms.[23] If the form did contain the necessary information

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[14] *Id.* at 406.
[15] *Id.* at. 402
[16] *Id.* at 410.
[17] *Id.* at 407.
[18] *Id.* at 400.
[19] Myla Vicenti Carpio, *The Lost Generation: Am. Indian Women and Sterilization Abuse,* 31 SOC. JUST. 40, 46 (2004), https://www.jstor.org/stable/29768273.
[20] *Id.*
[21] Simpson, *supra* note 4, at 77.
[22] Carpio, *supra* note 19, at 44.
[23] Brint Dillingham, *Indian Women and IHS Sterilization Practices,* 3 AM. INDIAN J. 27, 27 (1977).

and was readable to the patient, they were often signed while the patient was anesthetized or in labor pains.[24] Thus, doctors by and large failed to actually obtain consent from their Native patients to perform these irreversible, life-altering procedures.[25]

Family is highly valued in Native tribes, and especially so in some, such as the Cree people; if a family does not have many children, the Cree believe the family is being punished for a past wrong.[26] With the high value native Women and their communities place on family, removing their child-bearing ability dramatically impacted their mental health;[27] in one study, Native women reporting sterilization were nearly 2.5 times more likely to report mental health issues than their non-sterilized counterparts.[28] Sterilized Native women also dealt with social ostracization as well as higher rates of alcoholism, drug abuse, shame, and guilt due to forced sterilization.[29]

As a result of the violation Native women felt from forced sterilizations, they developed a deep distrust for doctors and IHS.[30] Doctors making decisions about Native women's ability to have children based on stereotypes severely damages the necessary trust for a doctor-patient relationship.[31] Sterilized Native women were violated during a time of vulnerability and dependency on people whom they thought they could trust.[32] A study

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[24] Carpio, *supra* note 19, at 49.
[25] *Id.* at 45.
[26] *Id*. at 50.
[27] Christina J.J. Cackler et. al, *Female Sterilization and Poor Mental Health: Rates and Relatedness among Am. Indian and Alaska Native Women*, 26 WOMEN'S HEALTH ISSUES 168, 175 (2016); Emily Marie Owen, "Their Decision, it Didn't Take Place": The Forced Sterilization of Native Am. Women in the U.S. (April 2017) (Undergraduate honors thesis, Louisiana State University) (on file with LSU Scholarly Repository).
[28] Cackler et. al, *supra* note 27, at 171.
[29] Lawrence, *supra* note 2, at 410.
[30] Kiara Tanta-Quidgeon, *Understanding how the U.S. Healthcare System can Better Serve Indigenous People Through the Lived-Experiences of Five Indigenous Women*, U.S. OF CARE https://unitedstatesofcare.org/wp-content/uploads/2023/06/Understanding-how-the-U.S.-Healthcare-System-can-Better-Serve-Indigenous-People-Through-the-Lived-Experiences-of-Five-Indigenous-Women-1.pdf (last visited Feb. 13, 2025).
[31] TRIBAL HEALTH, *Indigenous Midwifery: Reinventing Native Pregnancy and Birth*, https://tribalhealth.com/ midwifery/ (last visited Apr. 5, 2025).
[32] Simpson, *supra* note 4, at 81.

conducted by Ashleigh Guadagnolo, an assistant professor in the department of Radiation Oncology at the University of Texas, demonstrates that Native Americans are less likely to trust health care providers and hospitals than non-Hispanic Whites when presenting for cancer treatment.[33] Therefore, distrust among Native Americans directly impacts health outcomes as it makes this demographic hesitant to seek care.[34]

III. LIMITATIONS: ELIGIBILITY AND MINIMAL FACILITIES

To better understand the crisis Native mothers faced, it is important to know the process Native Americans go through to access health care. First and foremost, one must be eligible for services from the IHS and IHS facilities.[35] To be eligible, an individual must be part of a federally recognized American Indian or Alaska Native tribe.[36] However, simply being part of Native American descent does not automatically mean an individual has tribal membership.[37] Native Americans wishing to be part of one of the 574 federally recognized tribes must meet various criteria established by the specific tribe.[38] Common requirements include lineal descendancy from the original member list as designated in a tribal constitution, meeting the "blood quantum" (whether an individual has enough "Indian blood" to "count" as Native),[39] and tribal residency.[40] Within those requirements, different tribes vary on how much blood quantum an individual must have to gain

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[33] Ashleigh Guadagnolo et al., *Med. Mistrust and Less Satisfaction with Health Care Among Native Am. Presenting for Cancer Treatment*, 20 J. OF HEALTH CARE FOR THE POOR & UNDERSERVED 210, 211 (2009).
[34] Tanta-Quidgeon, *supra* note 30.
[35] INDIAN HEALTH SERV., *Indian Health Manual*, https://www.ihs.gov/IHM/pc/#2-1.2 (last visited Feb. 21, 2025) [hereinafter *Indian Health Manual*].
[36] *Id.*
[37] *See* Russell Thornton, *Tribal Membership Requirements and the Demography of "Old" and "New" Native Ams.*, in CHANGING NUMBERS, CHANGING NEEDS: AM. INDIAN DEMOGRAPHY & PUB. HEALTH (1996).
[38] *Id.*
[39] *Id.*
[40] U.S. DEP'T OF INTERIOR, *Tribal Enrollment Process*, https://www.doi.gov/tribes/enrollment (last visited Feb. 14, 2025).

membership.[41] Being within IHS's health care program's scope requires the completion of an entire process in proving your native heritage.[42]

Contrary to popular belief, IHS is not a health insurance program but, rather, a federally-funded service providing health care services for eligible Native Americans.[43] If Native Americans visit an IHS facility, they typically do not pay premiums and are not usually charged for services at said facilities.[44] Tribes can also contract with federal government to take control of managing health care delivery, which can potentially increase the number of facilities available.[45] On the surface, these implementations appear to greatly increase health care access for Natives; however, only 44 Indian hospitals and 570 Indian health centers, clinics, and health stations exist.[46]

Even if a woman has access to a facility, the closest facility may not provide the necessary care for her pregnancy.[47] There are three major hospitals located in Alaska, New Mexico, and Arizona, which provide obstetric care, but most IHS hospitals do not provide obstetric services.[48] Therefore, Native women who live outside those three locations have limited options for obstetric care.[49] Women can see if their tribe has a clinic that provides prenatal care if the tribe took control over from IHS, or have the tribe apply for a Contract Health Services program, where IHS will purchase primary and specialty health services for eligible Native Americans.[50] However, Contract Health Services programs also have eligibility

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[41] Thornton, *supra* note 37.
[42] *Indian Health Manual*, *supra* note 35 (last visited Feb. 21, 2025).
[43] *See* U.S. COMM'N ON CIV. RTS., *Structural Barriers Limiting Native American Access to Health Care and Contributing Health Disparities,* in BROKEN PROMISES: EVALUATING THE NATIVE AMERICAN HEALTH CARE SYSTEM (2004).
[44] CTR. FOR MEDICARE & MEDICAID SERVS., *Health Coverage Options for Am. Indians and Alaska Natives,* 1, 3 (May 2024), https://www.cms.gov/marketplace/technical-assistance-resources/aian-health-coverage-options.pdf.
[45] U.S. COMM'N ON CIV. RTS., *supra* note 43, at 55.
[46] *Id.*
[47] Cerasano, *supra* note 11, at 431.
[48] U.S. COMM'N ON CIV. RTS., *supra* note 43, at 51-52.
[49] *Id.* at 52
[50] *Id.* at 62.

requirements, one being that an individual receiving care must live on a reservation within a Contract Health Service Delivery Area or live within the area and be a member of the tribe location on that reservation.[51] Consequently, Native women have limited options for obtaining prenatal and obstetric care that are covered by IHS.[52]

IV. MATERNAL AND FETAL CRISIS

There is currently a maternal health crisis in the United States, which is higher for Native women as maternal morbidity and mortality are twice as high among them compared to white women.[53] Those living in rural communities have the highest maternal morbidity and mortality occurrence,[54] which is especially concerning given that large populations of Native women live in rural communities.[55] Sadly, most of these maternal deaths are preventable[56] by providing access to prenatal care which allows doctors to identify high-risk patients and alleviate risk for negative birth outcomes.[57] Prenatal appointments give women an opportunity to receive information and counseling about their pregnancy and any potential complications.[58] Recently, Native mothers are almost three times more likely to receive late or no prenatal care than white mothers.[59] Having information about their

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[51] *Id.*
[52] Hanson, *supra* note 7, at 30.
[53] Katy B. Kozhimannil et al., *Severe Maternal Morbidity and Mortality Among Indigenous Women in the U.S.*, 135 OBSTETRICS & GYNECOLOGY 294, 297 (2020).
[54] *Id.*
[55] Sarah Dewees & Benjamin Marks, *Rsch. Note - Twice Invisible: Understanding Rural Native Am.,* https://www.usetinc.org/wp-content/uploads/bvenuti/WWS/2017/May%202017/May%208/Twice%20Invisible%20-%20Research%20Note.pdf (last visited Apr. 5, 2025).
[56] Archived Page on the Wayback Machine, INTERNET ARCHIVE, https://web.archive.org/web/20250328141747/ https://minorityhealth.hhs.gov/infant-mortality-and-american-indiansalaska-natives (enter following hyperlink [https://minorityhealth.hhs.gov/infant-mortality-and-american-indiansalaska-natives] in starting point field, then select second snapshot from Mar. 28, 2025) [hereinafter Archived Page].
[57] Hanson, *supra* note 7, at 30.
[58] *Id.*
[59] Archived Page, *supra* note 56.

pregnancy and receiving screens for complications can improve birth outcomes for both the baby and the mother.[60]

In addition to mothers, infants are also facing negative health outcomes.[61] In 2022, Native American infant mortality rate was more than two times the rate for non-Hispanic whites.[62] Native infants under one year old are fifty percent more likely to die from complications from short pregnancies and low birth weight.[63] Additionally, Native infants are more than three times more likely to experience sudden infant death syndrome than any other group.[64] Low birth weight itself is another negative health outcome for Native infants.[65] The very low birth weight rate for Native infants has increased since 1990, and currently accounts for about nine percent of live Native infant births.[66] The increase incidence of pregnancy and birth complications means a higher portion of Native infants are admitted to the NICU.[67] Thus, Native mothers having limited access to necessary care leads to increased death rates for both them and their infants.

V. IHS FUNDING INCREASE AND PRIORITIZING MOTHERS

A major contributing factor the lack of prenatal and maternal care is the limited funding IHS and its facilities receive.[68] The continuous underfunding creates serious limitations for access and quality of care to the point IHS funding must double to match level of care provided to federal prisoners.[69] Further, poor funding means that IHS has not updated some facilities in

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[60] Hanson, *supra* note 7, at 30.
[61] Archived Page, *supra* note 56.
[62] *Id*.
[63] Rosalina James et al., *Assessing Soc. Determinants of Health in a Prenatal and Perinatal Cultural Intervention for Am. Indians and Alaska Natives*, 18 INT'L J. OF ENV'T RSCH. AND PUB. HEALTH 1, 2 (2021).
[64] Archived Page*, supra* note 56.
[65] MARCH OF DIMES, https://www.marchofdimes.org/peristats/data (last visited Apr. 5, 2025).
[66] *Id.*
[67] James et al., *supra* note 63, at 2.
[68] Ailish Burns et al., *The Maternal Health of Am. Indian and Alaska Native People: A Scoping Rev.*, 317 SOC. SCI. & MED. 1, 2 (2023).
[69] Mary Smith, *Native Ams.: A Crisis in Health Equity*, 43 HUM. RTS. 14, 14 (2018).

decades and staff retention remains low.[70] Thus, to properly address Native women's health disparities, the federal government must increase IHS funding.

IHS is the only major federal health care provider solely funded through regular annual appropriations.[71] A consequence to funding via annual appropriations is that, if the regular appropriations are not provided at the fiscal years start, then it will receiving interim funding through a continuing resolution.[72] This interim funding can create challenges for IHS because they cannot make up-front purchases since reimbursement is not guaranteed.[73] The inconsistent funding also makes it harder to regularly make payments to collaborators that work with IHS.[74] Annual appropriations fundings creates more consequences than just insufficient funding because lapses in payment can harm business relationships, consistent services, and even cause shutdowns.[75] A potential solution could be to request advance appropriations which would allow IHS to receive the funds in advance of the obligation.[76] However, most federal programs paying for health services are not funded through annual appropriations or receive these advance appropriations.[77] Therefore, to properly address the IHS funding issue, it must be removed from the annual appropriations process.

IHS funding must be recategorized from discretionary spending to mandatory spending.[78] Discretionary spending means Congress possess the discretion to allocate money among programs and is usually paid via annual appropriations.[79] Additionally, discretionary categorization means IHS must

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[70] Cerasano, *supra* note 11, at 431.
[71] ELAYNE J. HEISLER & KATE P. MCCLANAHAN, CONG. RSCH. SERV., R46265, ADVANCE APPROPRIATIONS FOR THE INDIAN HEALTH SERV.: ISSUES AND OPTIONS FOR CONGRESS (2020).
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] Cerasano, *supra* note 11, at 431.
[79] *Id*. at 435.

compete with other programs with the same designation to receive funding.[80] If, on the other hand, IHS funding is categorized as mandatory spending, then the money promised would be provided when needed.[81] Reclassifying IHS as a mandatory spending program would remove the competition barrier between IHS and other federal agencies and increase the likelihood that IHS actually receives promised funds.

Initially, it seems amending the Indian Health Care Improvement Ace to reclassify IHS funding as mandatory would not increase the funding amount. However, if it remains discretionary, IHS' funding can be revoked or decreased with no legal consequences.[82] The IHS funding system can lead to lapses in funding due to irregular financing.[83] Therefore, reclassifying to mandatory funding will increase IHS funding because IHS would be guaranteed to receive the money promised and, not having it unexpectedly reduced or ceased, suffer no lapses in funding as a result. Mandatory status will also create more stability in IHS funding and increase their financing because IHS will receive the anticipated money instead of receiving only partial payments that lapse when money runs out. Within the mandatory funding, there should be proposed mandatory funding for maternal and fetal care so that Native women are guaranteed access to prenatal care and midwives. Proposed mandatory funding is possible as evidenced by IHS' budget for fiscal year 2025, which included a proposed mandatory funding for special diabetes program.[84]

Some argue that increased funding does not guarantee that IHS will address the maternal and fetal health crisis due to IHS' mismanagement

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[80] *Id*.
[81] *Id*.
[82] Timothy Westmoreland & Kathryn R. Watson, *Redeeming Hollow Promises: The Case for Mandatory Spending on Health Care for Am. Indians and Alaska Natives*, 96 AM. J. PUB. HEALTH 600, 601 (2006).
[83] Heisler & McClanahan, *supra* note 71.
[84] Press Release from IHS Director Roselyn Tso, Statement from IHS Director Roselyn Tso on the President's Fiscal Year 2025 Budget, (March 11, 2024) (on file with the Indian Health Serv. website).

history.[85] To ensure money goes towards Native women, the Indian Health Care Improvement Act should be further amended by adding a specific provision under Subtitle B, Health Services, to set goals for addressing maternal and infant mortality rates. One goal to include is opening several Medicaid and IHS clinics and requiring at least two midwives to be staffed at each clinic. Requiring midwives will bolster the resources for Native women in their pre- and postpartum care and help reduce the health crises Native women face. Additionally, connecting IHS funding to tangible foals for maternal health will likely increase the chance that changes are implemented. This would further drive tribes to increase maternal health prioritization and put funding toward Native mothers' health concerns.

Another way to obtain more funding for expanding obstetric and prenatal care is to have more tribes apply for Title I contracts and Title V compacts under the Indian Self-Determination and Education Assistance Act. Under Title I, a tribe may contract with IHS to conduct and administer portions of their health programs that IHS previously controlled.[86] Under Title V compact, the tribe can exercise more independence by taking over control of the entire program.[87] Giving tribes more control over their health programs allows them to tailor said programs to their communities' specific needs.[88] More control also means tribes can better ensure that the care they are providing is culturally competent, which will help address the persistent distrust for doctors. Utilizing these contracting options allows tribes to expand their clinics, giving Native women easier access to maternal healthcare.

Beyond funding, the IHS must increase access to prenatal care and other maternal care for pregnant women. Currently, there are large geographical

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[85] U.S. GOV'T ACCOUNTABILITY OFF., *Indian Health Serv.: IHS Mismanagement Led to Millions of Dollars in Lost or Stolen Property*, https://www.gao.gov/products/gao-08-727 (last visited Apr. 5, 2025).
[86] Cerasano, *supra* note 11, at 423-24.
[87] *Id*. at 424.
[88] *Id*.

gaps in access to service in hospitals and clinics, as most are concentrated on the country's west side.[89] The South and East Coast geographic regions of the U.S. have two hospitals within their IHS region which are not guaranteed to provide obstetric care.[90] With the goals specified in the proposed amendments to the Indian Health Care Improvement Act, the IHS should use the funding to open more clinics and hospitals with obstetric care on the South and East Coast regions to fill the gaps in access.

IHS can also create and apply for a program specifically tailored to addressing the maternal health crisis like the Special Diabetes Program for Indians. Within the program there will be specific measures to attain, such as lowering the maternal morbidity rate and the low-birth-weight rate for infants. Specific goals will keep the program accountable and ensure money is spent toward achieving the goals, thus avoiding financial abuse like IHS has fallen victim to in the past. Creating and applying for such a program ensures money is set aside specifically for the maternal health crisis. The program will allow the IHS to fund more midwives who can make home visits to Native mothers and implement more clinics that provide obstetric services. The IHS having its own program like an organization such as Family Spirit[91] will make it more accessible to tribes, and eventually the program will move beyond requiring a grant and become the new standard.

Once changes are made to the Indian Health Care Improvement Act and IHS receives increased funding, the first step is to develop the special program addressing the maternal and fetal health crisis. Doing so includes setting up a committee within the IHS Maternal Child Health[92] program that will collaborate with tribal leaders to best address the various communities'

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[89] U.S. DEP'T OF HEALTH & HUM. SERVS., HP-2022-21, HOW INCREASED FUNDING CAN ADVANCE THE MISSION OF THE INDIAN HEALTH SERVICE TO IMPROVE HEALTH OUTCOMES FOR AMERICAN INDIANS AND ALASKAN NATIVES (2022).
[90] *Id*.
[91] FAMILY SPIRIT, https://familyspiritprogram.org/about/#provenimpact (last visited Apr. 5, 2025).
[92] INDIAN HEALTH SERV., *Maternal and Child Health*, https://www.ihs.gov/mch/ (last visited Apr. 5, 2025).

needs. The committee will make specific recommendations to IHS on broad priorities as well as how funds should be distributed within the program. Instead of requiring tribes to apply for grant money from the special program, the committee should focus funds towards regions experiencing the greatest lack in care and highest negative health outcomes. As the program develops funds can be expanded to regions that already have at least some accesses to maternal and fetal care.

A priority recommendation is building and developing maternal health clinics in the East Coast region to address the large gap in Native health care facilities. Tribal leaders can assist in determining which areas within the East Coast will be best served by having a maternal care clinic as well as where clinics will have the greatest impact. Another option is to build more IHS hospitals within the region that provide obstetric services, but this could take up too much of the already limited funding. Building more clinics throughout the region specifically for maternal and fetal health could better address the issue the program is created to tackle.

IHS and the tribal committee can coordinate with community health partners to train the medical providers providing care to the Native women. These community health partners can train the medical providers on culturally-competent care and potentially provide extra resources during initial development stages. Additionally, the community health partners can articulate community needs, so the new resources are utilized in the most efficient manner. They could implement training programs and help build a sustainable clinical program that will have a lasting impact on the communities. Utilizing community health partners also increases staff and resources, which means clinics can implement home visits to Native women. Home visits will make it easier for Native women to get the necessary pregnancy education without dealing with travel complications. Partnering with those already aiding the community allows for a more expansive and sustainable program.

A funding recommendation the committee can make is putting funding toward implementing a telehealth system for Native mothers. Increasing telehealth networks makes it easier for clinics to reach mothers in their locale. Telehealth also helps fill any gaps that may occur because of limited community health partners or limitations on transportation for Native mothers. Utilizing telehealth for educational visits will put less strain on the mother as she can remain in the comfort of her home during the appointment. Further, if home visits are limited due to issues with staffing, then telehealth can play a role in filling that gap by expanding access without requiring the mother to go to the clinic. Clinic resources can then be saved for visits that must be in person allowing for better utilization of resources.

The Maternal Child Health program committee should also establish a team that records data pertaining to the program's success. A team to oversee key measures the program hopes to address will assist in ensuring the funding and program are meeting stated goals. Continued evaluation allows the tribal committee to spot shortcomings in the program early and remedy them sooner. Additionally, the tribal committee could discover areas needing more funding and better allocate necessary resources. Evaluation also helps track the benefits on maternal and fetal outcomes when access to obstetric care is increased. Having data to support the program's mission could support petitions for more funding in the future.

VI. CONCLUSION

Addressing the health inequities faced by Native mothers and their babies is imperative to minimizing the maternal and fetal health crisis. Native mothers faced a traumatic history with the healthcare system, causing long lasting consequences for their overall health and care access. The federal government continues to fail to fulfill its promise of providing them high quality care and the resources necessary to accomplish that quality level. To begin to rectify the damage done, Congress must reclassify the IHS as a

mandatory spending program so that tribes are guaranteed to receive the money promised. Said money should additionally be tailored to addressing the maternal health crisis by creating a program designed for obstetric and maternal care in addition to expanding hospitals and clinics for mothers. Without these changes to improve access to care, Native mothers and infants will continue to face deadly consequences.

The Changing Face of Healthcare Antitrust Enforcement and Its Impact on Access to Care

Katelyn Sears

I. ANTITRUST AND HEALTHCARE: A CHANGING LANDSCAPE

The role of antitrust in healthcare is far-reaching and impacts not only access to medicine and affordability of care, but also healthcare employees through their wages, benefits, and working conditions.[1] Antitrust laws have played a crucial role in preserving competition in the healthcare marketplace, which can in turn reduce prices, improve quality of care, and prevent monopolistic behavior among providers and pharmaceutical companies. As an example, studies have shown that hospital mergers can lead to price increases of up to 20% for patients without corresponding improvements in quality of care.[2] The Federal Trade Commission ("FTC") specifically has intervened through actions such as blocking hospital mergers or investigating pharmaceutical pricing. The FTC's interventions demonstrate how antitrust enforcement can promote patient welfare and economic fairness across the healthcare system. Given the FTC's significant role in antitrust enforcement, the identity and leadership style of its chair are equally critical considerations. The chair of the FTC is appointed by the President and oversees the board of commissioners.[3] Thus, with each change in administration comes a change in philosophy and execution of antitrust enforcement in all sectors, including healthcare, making leadership especially consequential in this space.

This article will examine the historical approaches and enforcement strategies to identify how the FTC's actions have positively or negatively

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[1] DEPT. OF JUST., *Healthy Competition*, https://www.justice.gov/atr/HealthyCompetition.
[2] Mariah Taylor, *Health system mergers increase prices by 5.2%: Study*, BECKER'S HOSP. REV. https://www.beckershospitalreview.com/finance/health-system-mergers-increase-prices-by-5-2-study/
[3] 15 U.S.C. § 41.

impacted healthcare. Next, this article will weigh the pros and cons of each administration's approach, regarding short and long-term impacts such as litigation costs and stifled innovation. Finally, this article will suggest legislation to create statutory guidance that balances both access to healthcare and promotes innovation to create more stability for mergers in the healthcare industry.

II. AGGRESSIVE HEALTHCARE ANTITRUST UNDER THE BIDEN ADMINISTRATION

Under the Biden Administration, Lina Khan was named as the chair of the FTC.[4] Former Chairwoman Khan's philosophy was aimed toward improving access to healthcare by preventing consolidation to improve competition and lower costs.[5] Her aggressive antitrust enforcement has been emphasized by the FTC's oversight of mergers, drug pricing, and non-compete clauses that aim to maintain a competitive and fair market.[6] During her tenure, she cracked down on not only horizontal integration but also vertical integration, which she claims can still have significant consequences and distort competition.[7] Horizonal integration occurs when there is consolidation of direct competitors at a similar stage in the supply chain, whereas vertical integration occurs when there is the incorporation of more stages of a product or service's supply chain into the organization's own processes and

[4] FED. TRADE COMM'N, *Lina M. Khan Sworn in as Chair of the FTC*, https://www.ftc.gov/news-events/news/press-releases/2021/06/lina-m-khan-sworn-chair-ftc.
[5] Lina Khan, Chair, FTC, Remarks by Chair Lina M. Khan As Prepared for Delivery American Medical Association National Advocacy Conference (Feb. 14, 2024).
[6] FENWICK, *Heart of Healthcare Podcast: FTC Chair Lina Khan on Healthcare, Antitrust, and the Future of Competition*, https://www.fenwick.com/insights/publications/heart-of-healthcare-podcast-ftc-chair-lina-khan-on-healthcare-antitrust-and-the-future-of-competition.
[7] *Id*; HARV. LAW SCH. CTR. ON THE LEGAL PRO., *Vertical and Horizontal Integration*, https://clp.law.harvard.edu/knowledge-hub/magazine/issues/integration-in-legal-services/vertical-and-horizontal-integration/.

management.[8] Generally, it is much more difficult to enforce antitrust laws against vertical integration as opposed to horizontal integration. Further, her philosophy deviates from the traditional "consumer welfare standard," emphasizing potential harms to competition and innovation and market structure instead of price effects.[9] Her advocacy of this deviation has led the FTC to challenge mergers based on theories that are generally not accepted by courts, which has seen rejections from the courts due to a lack of supporting precedent.[10] Further, the effect of her leadership can be observed through key cases during her time as the chair of the FTC, such as the case of Illumina, Inc., v. FTC.

III. LAISSEZ-FAIRE HEALTHCARE ANTITRUST UNDER THE TRUMP ADMINISTRATION

Under the 2025 Trump Administration, Andrew Ferguson has been named as the chair of the FTC.[11] Chairman Ferguson's philosophy has been considered "pro-business," which promotes the idea that consolidation

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[8] *Id*. (providing an example of horizontal integration as Disney acquiring a competing entertainment company such as Pixar Animation Studios. Contrastingly, an example of vertical integration was provided of Apple designing both the software and hardware of their products, which allows Apple to manage all aspects of its product).

[9] Issue Lapowsky, *Lina Khan Has Unfinished Business*, COMPILER, https://www.compiler.news/lina-khan-has-unfinished-business/. The "consumer welfare standard" directs antitrust enforcers to consider whether the merger in question will negatively impact the consumer in any way, using economic tools and data such as whether the merger will raise prices, reduce output, or stifle innovation. Fred Ashton, *Why the Consumer Welfare Standard is the Backbone of Antitrust Policy*, AM. ACTION F. (Oct. 26, 2022) https://www.americanactionforum.org/insight/why-the-consumer-welfare-standard-is-the-backbone-of-antitrust-policy/.

[10] FTC v. U.S. Anesthesia Partners, No. 4:23-CV-03560, 2024 WL 2137649, at *8 (S.D. Tex. May 13, 2024). The court rejected the FTC's suit against a private equity firm by pointing out that "the mere capability to do something does not meet the requirement that the thing is likely to recur." They held that the private equity firm being capable of to becoming a controlling investor in anesthesia partnership was insufficient to prove that they had actually engaged in anticompetitive practices to monopolize the local anesthesiology.

[11] FED. TRADE COMM'N, *Andrew N. Ferguson Takes Over as FTC Chairman*, https://www.ftc.gov/news-events/news/press-releases/2025/01/andrew-n-ferguson-takes-over-ftc-chairman.

instead could drive innovation, reduce administrative costs, and expand access through economies of scale.[12] Unlike Former Chairwoman Khan's philosophy of aggressive enforcement, the previous Trump administration's FTC was largely confined to the "consumer welfare standard" used by federal courts coupled with a more lax approach.[13] This approach was seen through their failure to deny any bank mergers or food and agriculture sectors, their promotion of consolidation in the defense industry, and the allowance of Essilor and Luxottica, two of the largest companies in the optical industry, which hiked prices 1000% within the year.[14] As many of these sectors, including food and agriculture, are social determinants of healthcare, the consolidation of these industries are critical to access to care. Further, Chairman Ferguson's own FTC voting record unveils insight as to what antitrust enforcement will look like under his leadership. He has vehemently dissented to many of the decisions issued under Former Chairwoman Khan, often arguing the FTC is exceeding its Congressional authority or applying novel legal theories that he claims judges won't decide.[15] Keeping his voting record in mind, as well as how Trump's early days in office in 2025 have displayed, many anticipate a lack of enforcement in these areas under

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[12] Donald J. Trump (@realDonaldTrump), TRUTH SOCIAL (Dec. 10, 2024, 4:58 PM), https://truthsocial.com/@realDonaldTrump/posts/113631003888738065 ("Andrew will be the most America First, and pro-innovation FTC Chair in our Country's History.").
[13] Laurel Kilgour & Matt Stoller, *Competition at a Crossroads: A Comparative Guide to Recent White House Records on Antimonopoly Policy*, AM. ECON. LIBERTIES PROJECT (2024).
[14] AM. MED. ASS'N, *CVS-Aetna Merger*, https://www.ama-assn.org/health-care-advocacy/access-care/cvs-aetna-merger.
[15] Justin Wise, *Trump's FTC Pick Will Go From Frequent Dissenter to Running Show*, BLOOMBERG L., https://news.bloomberglaw.com/antitrust/trumps-ftc-pick-will-go-from-frequent-dissenter-to-running-show. Ferguson's voting record reflects a dissent on the FTC's proposed rule to prohibit noncompete agreements nationwide, opposition to initiatives aimed at simplifying subscription cancellations ("Click-to-Cancel"), and a dissent against a lawsuit over alleged illegal price discrimination under the Robinson-Patman Act, claiming that he would rather target larger retailers with more buying power. The former dissent and opposition were based on Ferguson's view that the FTC has much narrower authority than Khan believes it does, and that these actions lacked clear authority for the FTC's regulation.

Chairman Ferguson.[16] This historically hands-off approach, as demonstrated through his past voting record and mergers the FTC has challenged, such as CVS Health and Aetna, is anticipated to continue through Andrew Ferguson as he begins his tenure as the FTC chair.

IV. CASE STUDIES IN DIFFERING ANTITRUST PHILOSOPHIES

A. Illumina, Inc. v. FTC

The 2021 case against Illumina demonstrated the FTC's antitrust enforcement of a vertical merger decision.[17] Illumina was the sole provider of DNA sequencing for multi-cancer early detection ("MCED") tests in the United States.[18] Illumina proposed a $7.1 billion acquisition of Grail, which

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[16] Since taking office in 2025, President Trump fired two Democratic commissioners of the FTC without cause. While this is being challenged in the courts, it does again display the pro-business philosophy that his Administration holds. Melissa Bredbenner, *President Trump's Power to Remove FTC Commissioners*, THE REGUL. REV., https://www.theregreview.org/2025/03/27/bredbenner-president-trumps-power-to-remove-ftc-commissioners/. Further, as Ferguson is set to begin a blockbuster anti-monopoly trial against Meta, he also went on the record that he would, "obey lawful orders," if the President requested that he drop the suit. This further shows how the Trump-era FTC is focused generally on being pro-business. Lauren Feiner, *FTC Chair says he'd 'obey lawful orders' if Trump asked to drop an antitrust case like Meta's*, THE VERGE, https://www.theverge.com/news/642068/ftc-chair-andrew-ferguson-trump-drop-meta-lawsuit-hypothetical. Lastly, the Trump Administration has supported the artificial intelligence infrastructure project "Stargate," which although involved a joint venture with OpenAI, Oracle, SoftBank, and MGX to invest up to $500 billion, has the potential to create 100,000 jobs and promises better medical diagnostics, personalized medicine, remote monitoring, drug repurposing, and many other healthcare advances. Once again, these actions demonstrate the pro-business mentality that is expected to be seen from Ferguson's time as the FTC chair. Chuck Buck, *New Stargate Project Creates Hope for Advances for Healthcare*, RAC MONITOR, https://racmonitor.medlearn.com/new-stargate-project-creates-hope-for-advances-for-healthcare/.

[17] CROWELL, *Fifth Circuit Largely Upholds FTC's Order In Illumina/Grail Case, Giving FTC a Victory in Litigated Vertical Merger – But Providing Merging Parties an Easier Path to "Litigate-the-Fix"*, https://www.crowell.com/en/insights/client-alerts/fifth-circuit-largely-upholds-ftcs-order-in-illuminagrail-case-giving-ftc-a-victory-in-litigated-vertical-merger-but-providing-merging-parties-an-easier-path-to-litigate-the-fix.

[18] FED. TRADE COMM'N, *Illumina, Inc., and GRAIL, Inc.*, https://www.ftc.gov/legal-library/browse/cases-proceedings/illumina-inc-grail-inc.

was one of several competitors competing to develop the MCED tests.[19] Shortly after this was announced, the FTC filed an administrative complaint and authorized a federal lawsuit to block this acquisition that it violated Section 7 of the Clayton Act and Section 5 of the FTC Act, 15 U.S.C. §§ 18, 45 on the grounds that as Illumina is the sole provider of the DNA sequencing required for these tests.[20] The FTC argued that Illumina had the potential to, "[R]aise prices charged to Grail competitors for NGS [DNA sequencing] instruments and consumables; impede Grail competitors' research and development efforts; or refuse or delay executing license agreements that all MCED test developers need to distribute their tests to third-party laboratories."[21]

In order to meet its burden of proof, the FTC must establish a *prima facie* case of anticompetitive effects, and the FTC in this case used the ability-and-incentive test and *Brown Shoe* to meet its burden here.[22] Initially, an administrative law judge disagreed with the FTC, claiming it presented insufficient evidence that this acquisition would cause competitive concerns, a decision that ended up being appealed to the Fifth Circuit.[23] The Fifth Circuit reversed this decision and held that the FTC met its burden under either the ability-and-incentive test or the *Brown Shoe* test.[24] Whereas the ability-and-incentive test focuses on whether a company has the ability to foreclose competition among competitors and that the merger substantially increases its incentive to do so, the *Brown Shoe* test includes a variety of

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[19] FED. TRADE COMM'N, *FTC Challenges Illumina's Proposed Acquisition of Cancer Detection Test Maker Grail*, https://www.ftc.gov/news-events/news/press-releases/2021/03/ftc-challenges-illuminas-proposed-acquisition-cancer-detection-test-maker-grail.
[20] *Id.*
[21] *Id.*
[22] Illumina, Inc; Grail, Inc. v. Federal Trade Commission, BRIEF OF THE FED. TRADE COMM'N (PUBLIC VERSION), No. 9401, at 31 (F.T.C. Aug. 4, 2023).
[23] CROWELL, *supra* note 17.
[24] *Id.*

factors that have a greater reliance on anecdotal evidence and market dynamics to demonstrate anticompetitive effects.[25] The implications of this decision are far-reaching, as it was the first time in decades that a vertical merger was successfully found to be competitively harmful. This decision further demonstrates Lina Khan's philosophy that mergers in healthcare, whether horizontal or vertical, impede access to healthcare and are in violation of antitrust principles. Additionally, the blocking of this merger likely prompted companies to align more closely with the Trump Administration's pro-business stance, anticipating a continuation of its lenient regulatory enforcement.

B. FTC v. CVS Health/Aetna

In 2018, the FTC reviewed CVS Health's $69 billion acquisition of Aetna, one of the largest health insurance companies in the United States.[26] As a horizontal and vertical merger, the FTC's primary concern was that the merger could harm competition in the Medicare Part D prescription drug market, where both companies had significant operations and were significant competitors.[27]

Aetna was a major provider of Medicare Part D plans, which helps individuals afford prescription medications.[28] CVS, as a pharmacy benefit

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[25] Illumina v. FTC, supra note 22, at 31; SIMPSON THACHER, *Fifth Circuit Decision in Illumina/Grail Provides Much-Needed Boost to Biden Antitrust Agenda But Comes With Some Silver Linings for Merging Parties*, https://www.stblaw.com/about-us/publications/view/2023/12/22/fifth-circuit-decision-in-illumina-grail-provides-much-needed-boost-to-biden-antitrust-agenda-but-comes-with-some-silver-linings-for-merging-parties.

[26] U.S. DEPT. OF JUST. ARCHIVES, *Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger*, https://www.justice.gov/archives/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d.

[27] *Id.*

[28] FED. TRADE COMM'N, *Your Guide to Medicare Drug Coverage*, https://www.medicare.gov/publications/11109-your-guide-to-medicare-prescription-drug-coverage.pdf.

manager ("PBM") and retail pharmacy chain, had significant influence over drug pricing and distribution.[29] The FTC worried that allowing CVS to own Aetna's Medicare Part D business could lead to higher prices and reduced choices for consumers, and further could injure competition in health insurance, pharmacy benefit management, retail pharmacy, and specialty pharmacy.[30]

To address these concerns, the FTC required CVS to divest Aetna's Medicare Part D business to WellCare Health Plans before approving the merger.[31] According to the FTC, this divestiture ensured that competition in the Medicare Part D market remained intact.[32] With this condition met, the merger was approved, allowing CVS to integrate Aetna's insurance operations with its pharmacy and healthcare services, furthering CVS's strategy of becoming a vertically integrated healthcare provider.[33] By opting for a divestiture remedy instead of blocking the merger entirely, the FTC illustrated the comparatively relaxed enforcement associated with the Trump Administration Commission.

Overall, these cases demonstrate Former Chairwoman Khan's and Chairman Ferguson's overall philosophy and impact under each of their respective administrations. These differences can be highlighted through the American Economic Liberties Project's report comparing antitrust policies and enforcement under the previous Trump administration and Biden administration, which concluded that under the Biden administration, there were four times as many billion-dollar merger challenges brought to trial as the Trump administration.[34] Moreover, this report also found that there were

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[29] U.S. DEPT. OF JUST. ARCHIVES, *supra* note 26.
[30] AM. MED. ASS'N., *supra* note 14.
[31] U.S. DEPT. OF JUST. ARCHIVES, *supra* note 26.
[32] *Id.*
[33] AM. MED. ASS'N, *supra* note 14.
[34] Kilgour & Stoller, *supra* note 13.

two and a half times as many monopolization claims filed under the Biden administration.[35] As previously mentioned, with the new Trump administration and Chairman Ferguson's appointment beginning, many anticipate a decline in antitrust enforcement and an increase in billion-dollar mergers.[36] However, these frequent changes in antitrust enforcement from one administration to the next have led to an unstable and unpredictable legal landscape, highlighting the pressing need for a clear and concise legislative direction.

V. LEGISLATIVE PROPOSAL FOR A NEW LAW TO MEDIATE INCONSISTENCIES BETWEEN ADMINISTRATIONS WHILE BALANCING PATIENT'S ACCESS TO HEALTHCARE

This Article proposes the following legislative proposal, entitled the Healthcare Market Innovation and Competition Act ("HMICA"), which includes a combination of philosophies from both the Khan-Biden administration FTC and the previous Trump administration and works to codify a framework that adapts antitrust enforcement narrowed to the evolving healthcare landscape. Again, as amendments to the Clayton and FTC Acts have historically been unsuccessful, this proposal seeks to implement a new law that regulates the FTC's actions in the healthcare sector specifically. This legislative proposal includes a provision to introduce structural separation, adopt an adaptive merger review framework, and include an innovation and access assessment mandate over the common law consumer welfare standard. This proposed Act reads as follows:

Proposed Act: Healthcare Market Innovation and Competition Act.

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[35] *Id.*

[36] Andrew Ross Sorkin, et al., *The F.T.C.'s Next, More Deal-Friendly Leader*, THE NEW YORK TIMES (Dec. 11, 2024), https://www.nytimes.com/2024/12/11/business/dealbook/ftc-trump-ferguson-khan.html.

> (1) IN GENERAL – This Act, regulating the Federal Trade Commission's actions, creates and requires structural separation in the healthcare sector, by requiring companies to file post-merger assessments with the Federal Trade Commission and the Antitrust Division of the Justice Department for certain acquisitions.
> (2) CRITERIA – The post-merger assessments must include, but are not limited to, objective criteria, such as changes in pricing, service availability, and quality metrics.
> (3) EXPANSION OF CONSUMER WELFARE STANDARD – This Act also requires that when reviewing these assessments, the FTC and federal courts must expand their current review under the consumer welfare standard to consider criteria of geographic access to care, potential for technological innovation and care integration, and impact on health equity and outcomes for marginalized populations.

This Act would be implemented by Congress and enforced by the FTC in healthcare industries. If companies failed to meet these criteria, the FTC or DOJ would enforce this law by requiring divestitures or the unwinding of the merger, depending on the level of failure of compliance of the company.

A. Structural Separation

Structural separation can play a crucial role in promoting fair competition in the healthcare industry. Unlike remedies that require constant oversight, structural separation offers a more permanent solution by removing underlying incentives for anti-competitive behavior. In the healthcare industry, where consolidation has been shown to reduce competition, increase prices, and limit choices for patients, this is especially important. A remedy such as this would also help to foster innovation and create space for competition in the market, which would allow for a more dynamic and accessible healthcare marketplace. For example, in 1933, the Glass-Steagall Act was passed to prevent commercial banks from investing in the stock market.[37] This Act was a result of congressional concern that commercial

[37] Julia Maues, *Banking Act of 1933(Glass-Steagall)*, FRED. RSRV. HIST., https://www.federalreservehistory.org/essays/glass-steagall-act.

banking operations and the payments systems were incurring losses from volatile equity markets, and the enactment of this legislation led to the broad belief that this would lead to a healthier financial system.[38] This Act was repealed by the Gramm-Leach-Bliley Act of 1999, which many economists argue led to speculative and risky activities that ultimately led to the 2008 financial crisis.[39]

Similarly, the HMCIA proposes that a similar structural separation should be enforced in the healthcare sector. Similar to what the Glass-Steagall Act did for the banking industry in the 1930s, the HMCIA would suggest the separation of healthcare companies from owning multiple parts of the same system. The benefits derived from such structural separation would include increased competition and thus lowered healthcare costs and more choices for services for patients, as well as increased transparency in healthcare pricing and options. This Article argues that such legislation could be enacted by, for example, separating health insurers from medical providers, insurers from pharmacies, and limiting pharmacy benefit managers. A majority of this structural separation is pointed toward health insurance companies. This strategy is because, by targeting insurers, this Act aims to prevent insurers from favoring their own hospitals or pharmacies. In reducing this risk of insurer bias, this Act would encourage fair competition, which could potentially lower drug prices, care costs, and increase service for patients.

For example, UnitedHealth Groups ("UHG") owns both Optum Health, which is a provider network, and OptumRx, which is a pharmacy benefit manager.[40] While their website claims that these complementary businesses

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[38] *Id.*
[39] Reem Heakal, *Glass-Steagall Act of 1933: Definition, Effects, and Repeal*, INVESTOPEDIA, https://www.investopedia.com/articles/03/071603.asp.
[40] UNITEDHEALTH GROUP, *Our business: Innovating, collaborating, discovering*, https://www.unitedhealthgroup.com/uhg/businesses.html.

function to create a "modern, high-performing health system," this also has the potential for UHG to steer patients and prescriptions toward their affiliated entities, which could obscure true pricing and limit external competition.[41] A regulatory tool that the HMCIA could use to remedy this situation and accomplish structural separation could be to include statutory ownership thresholds or prohibit ownership of both provider and payer entities.

B. Adoption of Adaptive Merger Review

Another provision of this Act instills an adoption of an adaptive merger review framework, which would mandate the FTC to conduct post-merger assessments at three, five, and ten years after major healthcare mergers, followed by whenever they see fit. This assessment could include objective criteria, such as changes in pricing, service availability, and quality metrics. Further, as will be later discussed in this Article, this could also ensure that companies are adhering to what will be replaced by the consumer welfare standard, granting the FTC and federal courts a more holistic approach as to whether this merger benefits patients' access to medicine.

This Act suggests this implementation in accordance with the Trump administration's retrospective review of Big Tech mergers.[42] During the first Trump administration FTC, the retrospective review of 616 transactions that were over $1 million found that more than 75% of the transactions included noncompete clauses, ninety-four exceeded the transaction threshold, and at least 39.3% of the acquired company's age at the time of the consummation

[41] *Id.*
[42] Kilgour & Stoller, *supra* note 13.

of the transaction was less than five years old.[43] This review was completed under the tenure of Former Chairwoman Khan, who stated that,

> While the Commission's enforcement actions have already focused on how digital platforms can buy their way out of competing, this study highlights the systemic nature of their acquisition strategies… It captures the extent to which these firms have devoted tremendous resources to acquiring start-ups, patent portfolios, and entire teams of technologists—and how they were able to do so largely outside of our purview.[44]

This approach of retrospective reviews is supported by both administrations and codifying it into legislation would serve to benefit the healthcare sector in ensuring the companies do not take advantage of mergers to drive up prices and impede patients' access to healthcare.

To ensure enforcement of this provision, this Act suggests that the FTC could grant conditional approvals pending continuous meetings of such criteria. If a company fails to meet such criteria, the FTC could impose fines on the companies to pay or force divestitures of sections of the company that are inhibiting patients' access to healthcare. Examples of criteria to consider would be compliance with nondiscrimination regulations, price controls, licensing, behavioral remedies, and data protection. For example, when Google acquired Motorola Mobility, as a condition for merger approval, Google was required to license the Motorola patents to competitors on fair, reasonable, and nondiscriminatory terms.[45] This could be statutorily implemented by the Adaptive Merger framework, allowing the FTC to follow up on the company's compliance with the condition on the merger. As

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[43] FED. TRADE COMM'N, *FTC Staff Presents Report on Nearly a Decade of Unreported Acquisitions by the Biggest Technology Companies*, https://www.ftc.gov/news-events/news/press-releases/2021/09/ftc-staff-presents-report-nearly-decade-unreported-acquisitions-biggest-technology-companies.

[44] *Id.*

[45] FED. TRADE COMM'N, *FTC Finalizes Settlement in Google Motorola Mobility Case*, https://www.ftc.gov/news-events/news/press-releases/2013/07/ftc-finalizes-settlement-google-motorola-mobility-case.

another example, if the merger brings concerns about the confidentiality and security of data, which would be extremely relevant in the healthcare sector, then the FTC could require the company to implement data protection measures, such as encryption, multifactor authentication, and timely security updates. Again, utilizing the Adaptive Merger framework would allow the FTC to re-evaluate whether the company successfully adhered to the conditions, and would allow for the FTC to enforce penalties if the company has not.

C. Innovation and Access Assessment Standard Replacing the Consumer Welfare Standard

Currently, the FTC and federal courts review antitrust under the consumer welfare standard. This standard is judicially made and adopted by the Supreme Court, but has never been codified by the legislature.[46] However, this is a short-sighted and limited perspective that has narrowed antitrust down to one principle: price. The HMCIA proposes what it entitles the Innovation and Access Assessment Standard, in which the FTC and federal courts would expand their review criteria to consider non-price factors such as geographic access to care, potential for technological innovation and care integration, and impact on health equity and outcomes for marginalized populations.

Research has shown that hospital mergers have seen price increases such as 20%, without an increase in hospital quality.[47] Further, other studies have shown that in areas where there are more concentrated healthcare markets, patient health outcomes are significantly worse, likely due to hospitals facing

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[46] *See* Reiter v. Sonotone Corp. et al., 442 U.S. (1979) (adopting the consumer welfare standard to guide federal antitrust enforcement).

[47] Zack Cooper & Martin Gaynor, *Addressing Hospital Concentration and Rising Consolidation in the United States*, 1% STEPS, https://onepercentsteps.com/policy-briefs/addressing-hospital-concentration-and-rising-consolidation-in-the-united-states/.

less competition.[48] Based on this research, it would be incredibly beneficial to include changes in pricing, service availability, quality metrics, geographic access to care, potential for technological innovation and care integration, and impact on health equity and outcomes for marginalized populations as criteria that the FTC must review when examining healthcare mergers. Analyzing more than mere "consumer welfare," in combination with retrospective reviews, has the potential to prevent mergers with these results and instead strengthen patients' access to healthcare, lower the cost of medicine and service, increase competition, and affordability of care.

Moreover, each of these elements need not be dispositive, but instead enforced as a balancing test that weighs the competitive harms against pro-innovation benefits. This would allow for some subjectivity to arise and could vary between administrations and changes in the FTC chair. While this proposed section establishes formal guidelines for the Commission to follow and criteria they must consider and address, the FTC would still have some discretion in enforcement by assessing whether a particular merger harms competition or public interest. For example, while this section proposes time periods for companies to meet the criteria, if a company needed longer than the suggested time to meet these criteria, the FTC could use their discretion to again grant a conditional approval that would cause the company to divest or be subjected to a fine if they failed to do so.

However, despite the stability that legislation such as the HMCIA could provide, there are a variety of possible criticisms to the proposal. First, challengers may argue that an act such as this one would create a need for every individual industry to enact a new law for antitrust enforcement. However, healthcare is an industry that directly impacts individuals' everyday life and well-being. Further, the complexity and urgency of

[48] *Id.*

healthcare over other markets demonstrate the necessity for regulatory certainty specific to this industry. Additionally, another argument that challengers may bring forth is a loss of efficiency that would lead to fragmented healthcare. This argument may center around the belief that vertically integrated healthcare systems promote better care coordination and improve patient outcomes through streamlined services. While the fragmentation of healthcare is a genuine concern, this concern does not amount to much if patient costs are so high that individuals are not able to receive care in the first place. While access to healthcare and efficient services is ideal, anticompetitive behaviors that bar patients from accessing care far outweigh the concern that patients may have to navigate seeing multiple providers for differing reasons.

VI. CONCLUSION

Overall, the inconsistency in antitrust enforcement across administrations has created an unsustainable legal landscape, making the need for clear legislative guidance more urgent than ever. The Healthcare Market Innovation and Competition Act proposes provisions that have the potential to mediate these inconsistencies while simultaneously balancing the promotion of innovation with patients' access to healthcare.

Chilling Care: The Legal Risks Facing Texas Healthcare Providers Under Abortion Bans

Lindsay Vaughn

I. INTRODUCTION

Over the past two decades, Texas has persistently limited abortion access, culminating in restrictive laws that took effect after the Supreme Court overturned *Roe v. Wade* in 2022.[1] The conservative majority in the Supreme Court strengthened during President Trump's first term, further fueled Texas's legislative momentum,[2] resulting in stricter state abortion laws being passed in 2021, such as Senate Bill 8 ("S.B. 8") and House Bill 1280 (H.B. 1280).[3] These bills raised significant concerns for healthcare providers, especially regarding their professional responsibilities and legal risks.[4] Clarifying Texas laws to protect physicians and genetic counselors is vital to ensure these professionals can provide comprehensive medical care without fear of legal retaliation.[5]

This article will first outline the history and implications of Texas abortion laws, focusing on Senate Bill 8 ("S.B. 8") and House Bill 1280 ("H.B.

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[1] ACLU Texas, *A Recent History of Restrictive Abortion Laws in Texas*, (last visited Feb. 10, 2025), https://www.aclutx.org/en/recent-history-restrictive-abortion-laws-texas; Lauren Mascarehnas, *The Supreme Court Overturned Roe v. Wade 2 Years Ago. Here's What's Happened Since*, CNN (June 22, 2024), https://www.cnn.com/2024/06/22/us/roe-v-wade-overturned-2-years/index.html.

[2] Nina Totenberg, *The Supreme Court is the Most Conservative in 90 Years*, NPR (July 5, 2022), https://www.npr.org/2022/07/05/1109444617/the-supreme-court-conservative.

[3] *After Roe Fell: Abortion Laws by State > Texas*, CTR. FOR REPROD. RTS. (last visited Feb. 10, 2025), https://reproductiverights.org/maps/state/texas/.

[4] Mabel Felix, et al., *Criminal Penalties for Physicians in State Abortion Bans*, KFF HEALTH NEWS (Mar. 4, 2025), https://www.kff.org/womens-health-policy/issue-brief/criminal-penalties-for-physicians-in-state-abortion-bans/ (detailing the significant challenges for physicians providing pregnancy-related care in states with abortion bans).

[5] *See* Pooja Salhotra & Eleanor Klibanoff, *Amid Support From Doctors Group, Bill to Clarify Texas' Abortion Ban Does Little to Save Lives, Critics Say*, TEX. TRIB. (Mar. 27, 2025), https://www.texastribune.org/2025/03/27/texas-abortion-bill-senate-31/ ("Doctors and health care professionals are leaving the state in droves because they are afraid. There is a maternal health care crisis taking place and pregnant people will continue to die . . . the blood is on your hands because of these bans and because of these bills."); *See also Center Sues Texas on Behalf of Women Denied Abortions After Facing Dangerous Pregnancy Complications*, CTR. FOR REPROD. RTS. (Mar. 07, 2025), https://reproductiverights.org/texas-lawsuit-medical-emergency-exceptions-abortion/ (detailing the experiences of the physician plaintiffs in *Zurawksi v. Texas*, "We need clarity on what kinds of patients we can help without losing our license or ending up in jail.").

1280"), including their impact on healthcare providers and the chilling effect they have had on physician-patient communication. It then presents a comprehensive policy proposal recommending amendments to these laws that would protect healthcare professionals from legal risks, while still aligning with Texas' restrictive abortion stance. The paper concludes by stressing the importance of these amendments to safeguard healthcare providers, promote ethical medical practices, and ultimately improve patient care in Texas.

II. PRE-DOBBS TEXAS BILLS AND TRIGGER LAW

A. *Senate Bill 8 (2021)*

The first Texas bill that indicated a marked increase in Texas' attempts at undermining *Roe* was Senate Bill 25 ("S.B. 25"), which stated that a "cause of action may not arise . . . based on the claim that but for the act or omission of another, a person would not have been permitted to have been born alive but would have been aborted," effectively prohibiting wrongful birth torts as a cause of action.[6] Although S.B. 25 purportedly maintained physician accountability under other laws, critics argued that the ambiguous language enabled providers to withhold information without facing legal consequences.[7] Since the physician would be shielded from a lawsuit under a wrongful birth cause of action, the patient would have to prove gross negligence, leaving the burden on the patient to prove that the doctor should not have lied.[8] The chilling effect created by S.B. 25 discouraged full transparency in physician-patient interactions.[9]

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[6] S.B. 25, 2017 Leg., 85th Sess. (Tx. 2017).
[7] Craig Klugman, *Texas Considers Letting Doctors Lie to Patients*, BIOETHICS TODAY (Mar. 22, 2017), https://bioethicstoday.org/blog/texas-considers-letting-doctors-lie-to-patients/.
[8] *Id.*
[9] *Id.*

In 2021, S.B. 8, widely known as the Texas Heartbeat Act, was instated, prohibiting a physician from performing or inducing an abortion after a "fetal heartbeat," typically around six weeks of gestation.[10] However, the bill lacked clarity regarding the standard of testing required to determine this heartbeat.[11] Furthermore, S.B. 8 created a civil cause of action against anyone who performs or induces an abortion in violation of the law or knowingly "aids or abets" performing or inducing an abortion in violation of the law.[12] The enforcement of S.B. 8 was left to the populace at large, as any private citizen can file a lawsuit against those who perform or assist in an abortion.[13] This reality created a chilling effect on healthcare providers, genetic counselors, and other medical professionals who feared lawsuits for simply advising patients.[14] The law's broad language discouraged healthcare providers from discussing termination option, even when a patient's health was at serious risk.[15]

B. *House Bill 1280 (2021)*

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[10] *What Does Senate Bill 8 Say About Abortions*, TX. STATE L. LIBR. (last updated May 16, 2024), https://www.sll.texas.gov/faqs/abortion-senate-bill-8/.
[11] *Id.*
[12] S.B. 8, 2021 Leg., 87th Sess. (Tx. 2021).
[13] TEX. STATE L. LIBR., *supra* note 10.
[14] HUM. RTS. WATCH, *Human Rights Crisis, Abortion in the United States After Dobbs* (Apr. 18, 2023), https://www.hrw.org/news/2023/04/18/human-rights-crisis-abortion-united-states-after-dobbs ("The chilling effect of anti-abortion legislation may also cause physicians to withhold information from patients for fear that their medical advice could violate their state's anti-abortion statutes.") (citing Jessica Glenza, "A Severe Chilling Effect': Abortion Bans Will Inhibit Doctors' Advice to Patients, Experts Fear," THE GUARDIAN (6 May 2022), https://www.theguardian.com/world/2022/may/06/abortion-bans-patient-doctor-medical-advice).
[15] Whitney Arey, et al., *Abortion Access and Medically Complex Pregnancies Before and After Texas Senate Bill 8*, 141 OBSTETRICS & GYNECOLOGY 995, 1000 (2023) ("My counseling has become very limited. We received guidance from our overarching medical organization about what we can tell patients and what we cannot say. I say there is the option of ending the pregnancy. It's not an option to you in Texas, and I can't discuss it further.").

Two months prior to the passage of S.B. 8, Texas passed H.B. 1280, a "trigger ban" that makes abortion illegal at any point of gestation and penalizes anyone who provides or attempts to provide an abortion with a first- or second-degree felony, as well as civil penalties of no less than a $100,000 fine per violation.[16] Furthermore, H.B. 1280 invokes administrative penalties that revoke the licensure, registration, certification, or other authority of the healthcare professional who performed or attempted to perform an abortion.[17] However, this law does not only prosecute physicians—rather, anyone could be subject to criminal penalties for providing a medication abortion pill to another person.[18] The only exception to H.B. 1280's total ban on abortion is if the pregnant person's life is in danger or at "serious risk of substantial and irreversible impairment of a major bodily function."[19] However, critics of H.B. 1280 have pointed out the lack clarity in the sections indicating exceptions to the bill, leading to concern, particularly from physicians, that they will be unable to use their own discretion when treating patients for fear of legal retaliation.[20]

III. POST-DOBBS IMPACT

On June 24, 2022, the Supreme Court held in *Dobbs v. Jackson Women's Health Organization* that the federal constitution does not provide a right to

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[16] H.B. 1280, 2021 Leg., 87th Sess. (Tx. 2021).
[17] *Id.*
[18] Scott Simon, *New Texas Trigger Law Makes Abortion a Felony*, NPR (Aug. 27, 2022), https://www.npr.org/2022/08/27/1119795665/new-texas-trigger-law-makes-abortion-a-felony.
[19] Elizabeth Nash & Isabel Guarnieri, *13 States Have Abortion Trigger Bans – Here's What Happens When Roe is Overturned*, GUTTMACHER INST. (June 6, 2022), https://www.guttmacher.org/article/2022/06/13-states-have-abortion-trigger-bans-heres-what-happens-when-roe-overturned.
[20] Selena Simmons-Duffin, *3 Abortion Bans in Texas Leave Doctors 'Talking in Code' to Pregnant Patients*, NPR (Mar. 1, 2023), https://www.npr.org/sections/health-shots/2023/03/01/1158364163/3-abortion-bans-in-texas-leave-doctors-talking-in-code-to-pregnant-patients.

abortion, and authority to regulate abortion must be returned to the people and their elected representatives, overruling *Roe v. Wade*.[21] At the time of this ruling, thirteen states, including Texas, had abortion trigger bans that had been lying in wait for this exact moment to take effect automatically or by quick state action once *Roe* was overruled.[22] "Abortion-rights advocates and legal experts agree that this was the final step in making access to abortion impossible in Texas except under the rarest of circumstances"—when the pregnancy or the birth is going to threaten the life of the pregnant person or cause major bodily harm.[23]

The Biden administration responded by invoking the Emergency Medical Treatment and Labor Act ("EMTALA"), a 1986 federal law that requires hospitals to provide medical screenings and stabilizing care if a patient is suffering an emergency medical condition.[24] However, a U.S. District Court Judge was quick to grant a preliminary injunction on behalf of the state of Texas, arguing that the guidance is not only wrong, but harms the sovereign interests of the state of Texas.[25] Furthermore, the Judge stated that there is nothing on record suggesting that EMTALA "has ever been interpreted and applied to supersede state laws governing the permissibility of abortions in

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[21] *Dobbs v. Jackson Women's Health Organization,* 597 U.S. 215, 302 (2022).
[22] Nash & Guarnieri, *supra* note 19.
[23] Julian Aguilar & Joseph Leahy, *Texas Republicans' Long-Sought 'Trigger Law' on Abortion Now in Effect*, HOUSTON PUB. MEDIA (Aug. 25, 2022), https://www.houstonpublicmedia.org/articles/news/texas/2022/08/25/431599/texas-republicans-long-sought-trigger-law-on-abortion-now-in-effect/.
[24] Kirk McDaniel, *Texas Judge Blocks Enforcement of Biden Emergency Abortion Guidance*, COURTHOUSE NEWS SERV. (Aug. 24, 2022), https://www.courthousenews.com/texas-judge-blocks-enforcement-of-biden-emergency-abortion-guidance/; *Following President Biden's Executive Order to Protect Access to Reproductive Health Care, HHS Announces Guidance to Clarify That Emergency Medical Care Includes Abortion Services,* DEPT. OF HEALTH & HUM. SERVS. (July 11, 2022), https://public3.pagefreezer.com/browse/HHS.gov/01-01-2023T06:35/https://www.hhs.gov/about/news/2022/07/11/following-president-bidens-executive-order-protect-access-reproductive-health-care-hhs-announces-guidance-clarify-that-emergency-medical-care-includes-abortion-services.html.
[25] *Id.*

medical emergencies."[26] The 5th Circuit Court of Appeals agreed with the federal district judge, upholding the injunction in January of 2024.[27]

IV. Implications for Physicians' and Patients' Rights

A. *Increasing Birth Rates by Race and Ethnicity*

A study done at the University of Houston between April and December 2022 estimated that the S.B. 8 policy was associated with 9,799 additional births, with increases ranging from 1.7% to 5.1% depending on the month.[28] The study compared these results to their placebo, the forty-nine other states and the District of Columbia.[29] No other state during this time enacted such a strict abortion law that the courts allowed to remain in effect and results indicated that this pattern was unique in Texas.[30] While the Texas fertility rate rose two percent overall during this time, when analyzed by race and ethnicity, there is an even sharper contrast.[31] There was an increase of 5.1% among Hispanic women, 0.9% rise among non-Hispanic Asian women, -0.6% decline among non-Hispanic Black women, and a negative two percent decline among non-Hispanic white women.[32] When taking age into account, there was an eight percent increase in fertility rates for Hispanic women twenty-five years and older.[33] For many women, travelling to other states for

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[26] *Id.*
[27] Eleanor Klibanoff, *Emergency Rooms Not Required to Perform Life-Saving Abortions, Federal Appeals Court Rules*, The Tex. Trib. (Jan. 2, 2024), https://www.texastribune.org/2024/01/02/texas-abortion-fifth-circuit/.
[28] *Texas & Harris County Reproductive Health Update: 2022 Fertility Rates, Post 2021 Six-Week Abortion Ban* at 2, Univ. of Hous. (Jan. 2024), https://www.uh.edu/class/ws/irwgs/_docs/2024/56999-ws-abortion-ban-report-v5.pdf.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.* at 1.

medical care requires money, time off work, and childcare.[34] Specifically, women twenty-five and older are more likely to have young children at home, so there is increased difficulty for them in finding care and being less able to leave their jobs for long periods of time, all of which can factor into the sharp increase in this age demographic.[35] In order for a pregnant Texan to terminate their pregnancy, they have to have funding to travel either out of the state, or in many cases, to Mexico for their abortion care.[36]

B. *The Legal Landscape for Healthcare Providers*

S.B. 8 created a serious risks for physicians, genetic counselors, and other healthcare works, who could be sued for "aiding and abetting" abortion services.[37] The statute defines aiding and abetting to include "paying for or reimbursing the costs of an abortion through insurance or otherwise . . . regardless of whether the person knew or should have known that the abortion would be performed or induced."[38] Legal scholars suggest that "aiding and abetting" applies only to abortion providers practicing under a license issued in the state, but other experts believe that many other professionals are put at risk as well, such as: nonprofit funding groups and

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[34] *See* Amir Masoud Forati, et al., *The Economic Case for Investing in Maternal Health* at 19, HEARTLAND FORWARD (May 2024) (averaging the non-medical cost for perinatal care across to U.S. to $876.59, culminating in a cumulative cost of $3 billion).
[35] UNIV. OF HOUS., *supra* note 28, at 2; Joan R. Kahn, et al., *The Motherhood Penalty at Midlife: Long-Term Effects of Children on Women's Careers*, 76 J. MARRIAGE FAM. 1, 2 (2015) ("Studies have generally found average wage penalties ranging from 5% to 10% per child among women in their 20s and 30s.").
[36] Madeleine M. Plasencia, *Assemblages and Actor Networks in the Borderlands-the Apposition of Reproductive Rights Along the Mexican-American Border*, 24 J. L. SOC'Y 115, 132–133 (2024) ("Mexican medical providers are now anticipating the arrival of patients traveling from Texas to México City for medical services and safe abortion."); Kari White, et al., *Out-of-State Travel for Abortion Following Implementation of Texas Senate Bill 8* at 1, UNIV. OF TEX. AT AUSTIN (Mar. 2022) ("SB 8 has forced nearly 1,400 Texans out of state for abortion care each month.").
[37] *Id.* at 117 ("The operation of S.B. 8 is uniquely punitive for the medical providers sued under this law.").
[38] S.B. 8, 2021 Leg., 87th Sess. (Tx. 2021).

their donors, employers who help pregnant workers travel for abortions, clinics and their employees, and people who assist in self-managed abortions.[39] The uncertain language in the statute and sharp rhetoric surrounding abortion laws that impose civil and criminal penalties make it difficult to know the true bounds of their enforcement until tested in a court.[40]

This uncertainty regarding the legal ramifications of these statutes has already had an effect on genetic testing and genetic counselors who are not willing to test the waters of legality when discussing options with pregnant patients.[41] One study of genetic counselors in states with varying levels of abortion bans, including Texas, found that they were more likely to "encourage genetic testing and anatomy scans earlier than recommended to ensure that their patients had time to obtain an abortion if anomalies were detected."[42] However, testing earlier than recommended can result in missed or misleading information and lead patients to obtain abortions without waiting for confirmatory testing, therefore risking the termination of a healthy pregnancy.[43]

More so, with the passage of H.B. 1280, even positive genetic testing for serious fetal abnormalities does not constitute necessity for an abortion.[44] In these situations, healthcare practitioners feel that their hands are tied in educating patients on all their options, including abortions.[45] Many doctors in Texas will not say the word "abortion" in an exam room or speak publicly about abortions out of fear of legal repercussions or worry that they are being

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[39] Sonia Suter & Laura Hercher, *Reproductive Genetic Medicine in A Post-Dobbs World: Will It Make Life Harder for People with Genetic Disease?*, 51 J.L. MED. & ETHICS 511, 513 (2023).
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] Simmons-Duffin, *supra* note 20.
[45] *Id.*

set up by someone posing as a patient or family member looking to bait them into talking about abortion and then sue.[46] Genetic counselors post-*Dobbs* have also indicated that they hesitate to even document out-of-state abortion procedures in patients' charts, as well as miscarriages.[47] The medical term for a miscarriage is a "spontaneous abortion," which is "generally impossible to distinguish from a medically induced abortion."[48] This lack of guidance leads healthcare providers into silence, jeopardizing their ethical and professional obligations to give patients complete information about their diagnoses and options.[49]

C. Legal Battles in Texas Post-Dobbs

There have been two lawsuits to come out of Texas since the *Dobbs* decision in June 2022, both focused on the restrictiveness of H.B. 1280 in allowing physician discretion when using their "good faith judgment" when advising a patient to end their pregnancy.[50]

Zurawski v. State of Texas was filed in March of 2023 by twenty women and two physicians who argued Texas's abortion ban prevented doctors from fulfilling their professional obligations.[51] In August 2023, a Texas judge

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[46] *Id.*
[47] *Id.*
[48] Suter & Hercher, *supra* note 39 at 514.
[49] I*d.* ("Fears about legal liability may also lead to self-censorship. Genetic counselors expressed concerns about what they can say about abortion, even when laws do not explicitly prohibit discussions of abortion . . . Genetic counselors may silence themselves in the face of laws that target aiding and abetting.").
[50] Paul J. Weber, *A Judge Has Ruled Texas' Abortion Ban is Too Restrictive for Women with Pregnancy Complications*, AP NEWS (Aug. 5, 2023), https://apnews.com/article/abortion-texas-lawsuit-ban-exceptions-women-denied-pregnancy-d90f3bce68d86e5eafe3ba4ba5939188.
[51] Yamiche Alcindor, *Woman Suing Texas Over its Abortion Ban Plans to Move Her Embryos Out of State*, NBC NEWS (February 22, 2024), https://www.nbcnews.com/politics/woman-suing-texas-abortion-ban-plans-move-embryos-state-rcna140134; *Zurawski v. State of Texas*, CTR. FOR REPROD. RTS. (last visited Feb. 10, 2025), https://reproductiverights.org/case/zurawski-v-texas-abortion-emergency-exceptions/zurawski-v-texas/.

issued an injunction blocking Texas's multiple abortion bans, as they apply to dangerous pregnancy complications, clarifying that doctors can use their own medical judgment to determine when to provide abortion care in emergency situations.[52] The State of Texas immediately appealed the ruling to the Texas Supreme Court, blocking the injunction from taking effect.[53] In May of 2024, the Texas Supreme Court denied the claims brought by the plaintiffs and refused to provide clarity on exceptions to the state's abortion bans.[54]

In *Cox v. State of Texas*, Kate Cox sued for the right to terminate her pregnancy after her fetus was diagnosed with Trisomy 18.[55] Despite her physician warning that continuing the pregnancy risked Cox's future fertility and health, Texas' ambiguous medical exception language discouraged providers from offering abortion care.[56] The Texas Supreme Court blocked Cox's request for an emergency abortion, forcing her to travel out of state.[57] Cox's case highlights the obstacles faced by patients who seek care in Texas and underscores the pressure on healthcare providers navigating unclear legal guidelines.

V. NECESSARY POLICY CHANGES

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[52] *Zurawski v. State of Texas*, CTR. FOR REPROD. RTS. (last visited Feb. 10, 2025), https://reproductiverights.org/case/zurawski-v-texas-abortion-emergency-exceptions/zurawski-v-texas/.
[53] *Id.*
[54] *See generally Texas Supreme Court Rules Against Women Denied Abortion Care Despite Dangerous Pregnancy Complications*, CTR. FOR REPROD. RTS. (May 31, 2024), https://reproductiverights.org/zurawski-v-texas-ruling-texas-supreme-court/.
[55] *Cox v. Texas: The Case in Depth*, CTR. FOR REPROD. RTS. (last updated Dec. 12, 2023) https://reproductiverights.org/case/cox-v-texas/cox-v-texas-case-in-depth/.
[56] *Id.*
[57] Eleanor Klibanoff, *Texas Supreme Court Blocks Order Allowing Abortion; Woman Who Sought it Leaves State*, THE TEX. TRIB. (Dec. 11, 2023), https://www.texastribune.org/2023/12/11/texas-abortion-lawsuit-kate-cox/.

In order to address the growing concerns of healthcare providers who face legal risks under S.B. 8 and H.B. 1280, amendments must be introduced to protect medical professionals who offer accurate medical advice and care. These changes will ensure that providers can fulfill their ethical duties without fear of criminal or civil liability.

The following proposed amendments aim to provide specific protections for healthcare providers, including clarifying the ambiguous "aiding and abetting" language in S.B. 8 and refining the medical judgment criteria in H.B. 1280. The amendments also expand legal protections for genetic counselors and ensure that providers who act in good faith and document medically necessary interventions are shielded from liability. These policy adjustments are divided into key focus areas, beginning with protections for healthcare providers.

> Proposed Amendment: Section 171.208—*Civil Liability for Violations; Exception*
> *(j) A licensed healthcare provider, including but not limited to physicians, genetic counselors, and nurses, shall not be held civilly liable for providing medically accurate information regarding abortion services that are legal in other states or countries. This provision shall also apply to:*
> *(1) Providing referrals to out-of-state providers when, in the healthcare provider's reasonable medical judgment, the patient's health or well-being may be at risk.*
> *(2) Offering guidance on medically indicated terminations based on genetic testing or fetal anomalies.*
> *(3) Documenting miscarriage treatment, spontaneous abortion, or counseling regarding lawful out-of-state medical services.*
> *(4) Recommending early genetic testing or anatomy scans to provide patients with sufficient time to explore their medical options.*
> *(k) Nothing in this section shall be construed to prevent healthcare providers from fulfilling their ethical and professional obligations in providing medical advice, counseling, or referrals in accordance with accepted medical standards*.
>
> Proposed Amendment: Section 170A.002—*Prohibited Abortion; Exceptions*

(d) A licensed physician who, in their good faith medical judgment, determines that a patient faces a serious risk of substantial and irreversible impairment of a major bodily function may provide appropriate medical intervention without being subject to criminal or civil penalties. For the purposes of this section, "good faith medical judgment" shall include:
(1) Treating medical emergencies such as ectopic pregnancy, sepsis, or severe hemorrhaging.
(2) Determining the need for immediate intervention when the patient's condition jeopardizes their life or future fertility.
(3) Documenting such cases in the patient's medical records without risk of criminal or civil liability.
(e) Genetic counselors acting within the scope of their professional duties shall be permitted to:
(1) Provide medically accurate information regarding fetal anomalies, their implications, and available options, including termination of pregnancy if lawful in other jurisdictions.
(2) Offer referrals to healthcare providers in other states or countries where the procedure is legal.
(3) Document counseling, test results, or referrals in medical records without risk of criminal or civil liability.
(f) Nothing in this section shall be construed to limit the right of a healthcare provider to offer medically accurate information, guidance, or referrals that align with accepted medical standards.

A. *Protections for Health Care Providers*

S.B. 8 (Section 171.208) and H.B. 1280 (Section 170A.002) should first be amended to include language protecting healthcare providers who act in accordance with medical ethics.[58] Physicians, nurses, and genetic counselors should be immune from civil and criminal liability for providing factual

[58] *See* Olivia Nail-Beatty, et al., *Physicians' Rights and Patients' Safety: Protecting Miscarriage Access in Texas* at 25–26, BAKER INST. (Aug. 7, 2024), https://www.bakerinstitute.org/research/physicians-rights-and-patients-safety-protecting-miscarriage-care-access-texas ("Total abortion restriction laws have dire consequences for women's and pregnant individuals' health care overall. They compromise physicians' ability to provide the best standard of care for their patients . . . These laws create barriers in the physician-patient relationship, with doctors being forced to worry about their livelihood instead of their pregnant patient's best interests. For the safety of pregnant patients in Texas, it is critical to transcend political boundaries and ensure access to timely and life-saving care.").

information about reproductive healthcare options.[59] The amendments should specify that counseling patients about legal medical care outside Texas, including lawful abortion services in other states, does not constitute medical malpractice or unethical conduct under Texas law.[60] This provision will ensure that medical professionals are free to provide complete and accurate information while protecting themselves from unjustified legal action.[61]

Furthermore, Section 170A.002 should be amended to provide explicit legal protections for genetic counselors. The revised language should clarify that genetic counselors acting within their professional scope may explain fetal anomalies, their implications, and potential outcomes without facing criminal or civil penalties.[62] Furthermore, the amendment should permit

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[59] *Id.* at 42; *Genetic Testing for Reproductive Decision Making*, AM. MED. ASS'N CODE OF MED. ETHICS (2025) (detailing the principles of medical ethics that physician who provide reproductive health care should follow, including "avoid[ing] imposing their personal moral values or judgement on the patient", "inform[ing] the [patient] about any abnormal finding for the test", "respect[ing] an individual's decision to terminate or continue a pregnancy", and "refer[ring] the individual to another qualified physician when personal moral values prohibit the physician from providing lawful abortion services when this is a service that the person desires.").

[60] *See* AM. MED. ASS'N CODE OF MED. ETHICS, *supra* note 59; Salhotra & Klibanoff, *supra* note 5 (detailing the bipartisan work of 2025 Texas Senate Bill 31, the Life of the Mother Act, to better define when doctors can intervene to perform medical necessary abortions. However, critics argue that it does not go far enough in its protections).

[61] Salhotra & Klibanoff, *supra* note 5.

[62] *See* Shelby Koenig, et al., *Exploring Prenatal Genetic Counselors' Perceptions of Abortion Laws in Restrictive States*, J. GENETIC COUNSELING 790, 798 (Aug. 2019) (reviewing a study of genetic counselors in states with restrictive abortion laws finding that genetic counselors in states with restrictive abortion laws were inconsistent in their interpretations of the laws. This "could be a result of the a lack of clarity in the laws" and due to "institutions within their state [that do] no all interpret the laws the same way, resulting in inconsistent abortion policies at different institutions in the same state."); *See also* Anne C. Heuerman, et al., *Experiences of Reproductive Genetic Counselors with Abortion Regulations in Ohio*, J. GENETIC COUNSELING 641, 648 (June 2022) (stating that "due to current prenatal imaging standards, identification of suspected fetal anomalies typically occur between 18-20 weeks' gestation, and return of diagnostic testing results can take several weeks." While this study was done in Ohio, this demonstrates that the time that it takes for diagnostic genetic test results versus the approximately six-week abortion bans in Texas limits genetic counselors in their prescribed role).

genetic counselors to provide information about abortion services that are lawful in other states if such information is relevant to the patient's healthcare options.[63] To protect genetic counselors from ambiguity, language should affirm that offering medically sound advice or disclosing test results does not constitute "aiding or abetting" an abortion procedure under Section 171.208.[64]

More so, accurate documentation and medical records are imperative to patient care and should be maintained by health care providers without fear of legal repercussions. [65] Documentation of medically necessary abortion care, miscarriage management, or referrals for out-of-state services should not be admissible as evidence of illegal activity.[66] Providers should be protected from lawsuits or criminal charges for accurately recording medical information to ensure patient safety and continuity of care.[67] These

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[63] *See* Susheela Jayaraman, et al., *Prenatal Genetic Counselors' Perceptions of the Impact of Abortion Legislation on Counseling and Access in the United States*, J. GENETIC COUNSELING 1671, 1677, 1678 (Dec. 2021) (reviewing a study indicating that pre-*Dobbs*, counselors in "hostile and middle-ground states" were likely to educate patients on options for traveling out of state to access abortion services. However, the study notes that legislative restrictions will "limit the availability of services by fomenting apprehension and uncertainty among providers.").

[64] Suter & Hercher, *supra* note 39 at 514 (detailing patients' hesitancy to fill out intake forms in Texas and the concerns of genetic counselors over their ability to document abortion procedures and miscarriages).

[65] *Id.*

[66] *See* Ellen Wright Clayton, *Dobbs and the Future of Health Data Privacy for Patients and Healthcare Organizations*, 30 J. OF THE MED. INFORMATICS ASS'N 155, 156 (2023) (proposing a hypothetical situation in which a woman receives an out-of-state abortion and returns to the state she resides—where an elective abortion is forbidden—only to suffer complications from the procedure. In response, her care team in Tennessee must access her electronic health record from the out-of-state location, possibly "by someone with access who may be under the impression that the patient's or clinician's actions are inconsistent with the law." These women also report fearing clinicians of suspecting them of seeking or having attempted abortions that could expose them or their providers to criminal prosecution); *See also* Suter & Hercher, *supra* note 39, at 514 (hypothesizing that state might eventually require "disclosure of information regarding pregnancy losses to help investigators identify medical abortions.").

[67] Clayton, *supra* note 66, at 156.

protections will enable physicians, nurses, and genetic counselors to fulfill their professional obligations without compromising their ethical standards.[68]

B. *Clarifying "Aiding and Abetting" Language*

An amendment to S.B. 8 should include language specifying that a healthcare provider who offers medically accurate information about abortion options will not be considered to have "aided or abetted" an abortion procedure.[69] Such language should define "protected activities" as advising patients on legal abortion services in other states, counseling patients on medically indicated terminations, and providing referrals when deemed necessary for a patient's well-being.[70] The amendment should clarify that healthcare professionals may document patient care, including miscarriage management or out-of-state abortion procedures, without legal risk under Section 171.208.[71] These protections should also apply to pharmacists, nurses, and genetic counselors who are advising patients on available medical care without directly facilitating abortion services.[72]

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[68] *See generally* Suter & Hercher, *supra* note 39.
[69] *See* Sherry L. Pagoto, *The Next Infodemic: Abortion Misinformation*, 25 J. OF MED. INTERNET R'SCH at 3 (2023) (detailing challenges to the abortion infodemic, one of which being physicians fearing professional repercussions for educating patients about the pandemic and becoming targets for harassment. Another unique challenge is how abortion misinformation affects health care professions due to the vagueness of abortion legislation. Texas physicians have reported turning away pregnant patients with complications due to fear of litigation following treatment).
[70] *See generally* Michelle Oberman & Lisa Soleymani Lehmann, *Doctors' Duty to Provide Abortion Information*, J. OF L. AND THE BIOSCIENCES (2023) (addressing the downstream harms caused by lack of access to abortion information and argues that due to these urgent harms, clinicians have a duty to provide patients with abortion information).
[71] *See generally* Clayton, *supra* note 66 (detailing how medical history documentation can find its way into local electronic health record systems and subsequently discovered, "including by someone with access who may be under the impression that the patient's or clinician's actions are inconsistent with the law.").
[72] *See generally* Oberman, *supra* note 70 (discussing the legal and professional risks of providing abortion information for all clinicians who provide medicine and counseling to patients.").

C. *Emergency Medical Conditions Clarification*

Section 170A.002 should be revised to clarify the definition of "serious risk of substantial and irreversible impairment of a major bodily function."[73] The amendment should specify that physicians may act in accordance with their "good faith medical judgement" when determining that a patient's conditions meet this threshold.[74] The language should emphasize that physicians will not be held criminally or civilly liable for acting promptly in medical emergencies, such as cases of ectopic pregnancies, sepsis, or other conditions requiring immediate intervention.[75] This clarity would reduce hesitation among healthcare providers when deciding whether to provide life-saving medical care.

VI. CONCLUSION

The implementation and codification of S.B. 8 and H.B.1280 have created an environment of uncertainty and fear for healthcare providers in Texas,

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[73] *See* Bridget Balch, *What Doctors Should Know About Emergency Abortions in States with Bans*, ASS'N OF AM. MED. COLL. (Sep. 26, 2023), https://www.aamc.org/news/what-doctors-should-know-about-emergency-abortions-states-bans ("[Y]es, we're trying to operate withing the bounds of these laws, but the laws don't tell us what counts as necessary to save the life of the mother, so we get to set those standards until it gets taken away from us."); *See also* Brittni Frederiksen, et al., *A National Survey of OBGYNs' Experiences After Dobbs*, KFF (June 21, 2023), https://www.kff.org/womens-health-policy/report/a-national-survey-of-obgyns-experiences-after-dobbs) ("Most OBGYNs (68%) say the ruling [*Dobbs*] has worsened their ability to manage pregnancy-related emergencies. Large shares also believe that the *Dobbs* decision has worsened pregnancy-related mortality (64%) . . .").

[74] *See* Laurie Sobel, et al., *Who Decides When a Patient Qualifies for an Abortion Ban Exception? Doctors vs. the Courts*, KFF (Dec. 14, 2023), https://www.kff.org/policy-watch/who-decides-when-patient-qualifies-for-abortion-ban-exception/ (The Texas abortion ban specifies that the physician must determine that the abortion is based on their "reasonable medical judgement." This standard leaves physicians in a legally vulnerable situation and understandably reluctant to certify a pregnancy as qualifying for a life or health exception.").

[75] Amanda Seitz, *Dozens of Pregnancy Women, Some Bleeding or in Labor, are Turned Away From ERs Despite Federal Law*, AP NEWS (Aug. 14, 2024), https://apnews.com/article/pregnant-women-emergency-room-ectopic-er-edd66276d2f6c412c988051b618fb8f9 (demonstrating Texas state laws' chilling effects on physicians in the face of severe punishment for performing an illegal abortion).

particularly those tasked with counseling pregnant patients on their medical options. These laws, while intended to restrict abortion access, inadvertently restrict healthcare providers from acting in accordance with medical ethics and best practices.[76] By introducing amendments that clearly define what constitutes "aiding and abetting," protecting genetic counselors and physicians who provide medically accurate information, and ensuring emergency medical care can proceed without legal risk, Texas can strike a balance between enforcing its restrictive abortion policies and safeguarding healthcare providers.[77] These changes will not expand abortion access in Texas but will instead provide clarity for providers who are striving to fulfill their professional and ethical obligations.

Ensuring that medical professionals can deliver accurate information and timely medical care without fear of legal retaliation is essential to maintaining the quality and integrity of healthcare in Texas. Without such amendments, healthcare providers will continue to face legal ambiguity that hinders their ability to provide appropriate care, ultimately placing patients at greater risk. By protecting medical professionals, Texas can better uphold its commitment to life and health while ensuring the safety and well-being of its residents.

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[76] *Id.*

[77] *See id.* ("[The Texas Supreme Court] did not rule specifically on the medical situation facing the patient. Instead, they found that the physician's "good faith belief" was insufficient to qualify for the exception, and only abortions that are certified to be necessary under the "reasonable medical judgement" standard are allowable under Texas law. A similar situation could arise in the other states that have narrow life or health exceptions and don't grant deference to the physician's judgment.").