



Volume 35 | Issue 1  
Fall 2025

**SCHOOL OF LAW**

**BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY**

Annals  
of  
Health  
Law

**ADVANCE DIRECTIVE**

The Student Health Policy and Law Review of  
Loyola University Chicago School of Law

**ANNALS OF HEALTH LAW**  
*Advance Directive*

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

**BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW**

Beazley Institute for Health Law and Policy

VOLUME 35, STUDENT ISSUE 1

FALL 2025

**CONTENTS**

**Editors' Note**

*Dasha Ignatova and Katelyn Sears*

**ARTICLES**

**HIPAA Compliance and Frontline Privacy Issues**

Kayla Arroyo .....101

**Reforming March-In Rights: The Case for Collaboration Under the Bayh-Dole Act**

Michael Bahu ..... 118

**Overlapping Surgery**

Greta Bosco ..... 136

**Modernizing U.S. Food & Drug Law for Synthetic Biologics**

Briana Crowley ..... 151

**ERISA Preemption and State PBM Reform: Navigating the Balance of Power**

Allison Garcia ..... 168

**Streaming Skepticism: How Live Streaming Has Fueled Vaccine Misinformation  
and What the Law Can Do**

Taran Stahle ..... 186

**Preserving Community Benefits in Hospital Conversions**

Taylor Stamm ..... 205

**Telehealth Providers: Ensuring Data Remains Private for Virtual Mental Health  
Patients**

Noelle Tresser ..... 222

ANNALS OF HEALTH LAW  
Advance Directive

Editors' Note

The Annals of Health Law and Life Sciences is proud to present the first issue of the thirty-fifth volume of our online, student-written publication, *Advance Directive*. This *Fall 2025 Advance Directive* issue focuses on trending topics regarding power and policy in Healthcare.

The *Fall 2025 Advance Directive* issue examines a broad range of topics within the U.S. healthcare framework, including regulation, technology, and innovation. Our student authors also offer thoughtful proposals for refining current implementation practices, legal guidance, and the regulatory landscape governing healthcare innovation.

This issue explores topics spanning overlapping surgeries and biologics in drug manufacturing while addressing persistent challenges in the U.S. healthcare system, including cost, regulation, and access. Articles examine the effects of streaming platforms on health misinformation, privacy in telehealth, for-profit hospital conversion strategies, and rising healthcare costs across various medical specialties. Collectively, these pieces underscore the breadth of legal and systemic challenges facing healthcare in the United States.

The Annals of Health Law members deserve special recognition for their hard work and dedication to the well-thought-out articles included in this issue. We would like to thank Philip Cramer, our *Annals* Editor-in-Chief, for his constant leadership and support. We would also like to thank and acknowledge our *Annals* Executive Board Members, Matt Padilla, Hyunji Haynes, Sara Noronha, Mehak Dureja, Samantha Galinson, and Jack Nelson, for all their hard work. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Charlotte Tschider, and Kristin Finn, for all their guidance.

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

Sincerely,

Dasha Ignatova  
Advance Directive Executive Editor  
*Annals of Health Law*  
Loyola University Chicago School of Law

Katelyn Sears  
Advance Directive Executive Editor  
*Annals of Health Law*  
Loyola University Chicago School of Law

# HIPAA Compliance and Frontline Privacy Issues

*Kayla Arroyo*

## I. HIPAA COMPLEXITIES AND COMPLIANCE

The Health Insurance Portability and Accountability Act (HIPAA), intended as the bedrock of patient privacy, has ironically become a source of inconsistent, high stakes jeopardy for healthcare employees since its enactment in 1996.<sup>1</sup> Hospitals and other health care entities have been tasked with creating training guidelines and sanctions to ensure compliance with the Act.<sup>2</sup> Because each organization has discretion to create their own protocols, there is variance regarding what each organization follows. Ultimately, the employees of these organizations suffer. The employees are left with little clarity on how to handle sensitive patient information, yet their repercussions can be severe for mishandling sensitive information. This article will address the discrepancies among different organizations' interpretations of HIPAA compliance, the various ways each organization chooses to sanction its employees, and the impact this has on certain healthcare employees.

First, this article will explore the legislative reasoning for enacting HIPAA. Then the article will focus on a registered nurse's role in HIPAA compliance, given their frequent handling of sensitive patient information. Next, the article will explore various problems registered nurses encounter regarding HIPAA compliance. Finally, the article will propose solutions for resolving compliance issues with HIPAA training.

---

<sup>1</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No 104-91, 110 Stat. 1936 (Aug. 21, 1996).

<sup>2</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule*, HIPAA for Professionals, Privacy, Laws & Regulations, <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last visited Sept. 23, 2025); See also Steve Adler, *What Happens if a Nurse Violates HIPAA*, HIPAA J. <https://www.hipaajournal.com/what-happens-nurse-violates-hipaa/> (last visited Sept. 23, 2025).

## II. AN INTRODUCTION TO THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

HIPAA was enacted by Congress in 1996 and is considered one of the most important federal healthcare privacy statutes.<sup>3</sup> Overall, HIPAA was intended to simplify and reduce administrative costs in healthcare and provide a measure of insurance coverage portability.<sup>4</sup> Upon its enactment, Congress summed up its purpose by stating:

“An Act to...improve portability and continuity of health insurance coverage in the group and individual markets to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.”<sup>5</sup>

Additionally, standards for electronic transmission of health information were constructed by the Department of Health and Human Services (HHS) to create the HIPAA Privacy Rule.<sup>6</sup> Within the HIPAA Privacy Rule, mandatory standards for covered entities<sup>7</sup> holding Personal Health Information (PHI<sup>8</sup>) are detailed.<sup>9</sup> Further, the HIPAA Security Rule

---

<sup>3</sup> Elizabeth Andreoli et al., *HIPAA for Ostriches or the Otherwise Uninitiated*, 38-FALL ARK. LAW. 14, 14 (2008).

<sup>4</sup> *Id.*

<sup>5</sup> Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

<sup>6</sup> Jack Brill, *Giving HIPAA Enforcement Room to Grow: Why There Should Not (Yet) be a Private Cause of Action*, 83 NOTRE DAME L. REV. 2105, 2108 (2008).

<sup>7</sup> See generally 42 U.S.C.A. § 1320d; Yeager v. Dickerson, 391 S.W.3d 388 (Ky. Ct. App. 2013) (for purposes of HIPAA, Covered Entities usually include “health-care providers, health plans, and health-care clearinghouses and their business associates”).

<sup>8</sup> “Protected Health Information” includes any personally identifiable information in any form that details a patient’s past, present, or future health within a covered entity. See Christopher Burkle & Gregory Casino, *Medicine and the Media: Balancing the Public’s Right to Know With the Privacy of the Patient*, 86 MAYO CLIN. PROC. 1192, 1194 (2011).

<sup>9</sup> Brill, *supra* note 6, at 2108.

was enacted to oversee Electronically Protected Health Information (ePHI).<sup>10</sup>

Given the range of medical professionals, HHS aimed to provide flexibility in its administrative requirements.<sup>11</sup> Per the HIPAA Privacy Rule, covered entities must develop and implement written policies, designate a privacy official to ensure the policies are implemented, train all workforce members on policy, and mitigate violations appropriately.<sup>12</sup> The HIPAA Security Rule requires entities to provide reasonable and appropriate administrative, physical, and technical safeguards to protect ePHI.<sup>13</sup> Covered entities regulated by HIPAA can interpret these requirements broadly to reasonably meet the standards based on their size, technical infrastructure, costs, and internal risks associated with ePHI.<sup>14</sup>

Neither HIPAA's Privacy Rule nor Security Rule outlines how thorough, frequent, or specific training must be for a covered entity's workforce.<sup>15</sup> Rather, an entity is expected to determine how it will prepare its staff to maintain HIPAA compliance.<sup>16</sup> Due to the high volume of staff and lack of enforcement in training procedures, staff are generally not properly trained.<sup>17</sup>

---

<sup>10</sup> *Id.* at 2111-12 (requirements for compliance of this Rule are also vague and grant covered entities the discretion to establish safeguards to reduce potential issues with their EPHI, create physical and technical safeguards to limit access to EPHI).

<sup>11</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 2.

<sup>12</sup> *Id.*

<sup>13</sup> U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Security Rule*, <https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html> (last visited Sept. 23, 2025).

<sup>14</sup> *Id.*

<sup>15</sup> Steve Adler, *HIPAA Training Requirements*, HIPAA J., <https://www.hipaajournal.com/hipaa-training-requirements/> (last visited Dec. 6, 2025).

<sup>16</sup> *Id.*

<sup>17</sup> Steve Adler, *HIPAA Compliance for Nurses*, HIPAA J., <https://www.hipaajournal.com/hipaa-compliance-for-nurses/> (last visited Sept. 23, 2025).

### III. THE ROLE OF NURSES IN HIPAA COMPLIANCE

Since HIPAA's Privacy Rule and Security Rule deal directly with patient confidentiality and properly maintaining those records, it is fitting to address nurses' roles with HIPAA compliance. Registered nurses play several roles beyond serving as a caretaker.<sup>18</sup> Registered nurses make up the nation's largest healthcare profession<sup>19</sup> and are often tasked with the most direct patient care.<sup>20</sup> Thus, while serving on the front lines of patient care, nurses regularly handle sensitive patient information which HIPAA aims to protect.<sup>21</sup>

Although registered nurses making up a large portion of the healthcare workforce,<sup>22</sup> nursing retention rates are troublesome.<sup>23</sup> During the Covid-19 pandemic, nurses were on the front lines and in high in demand.<sup>24</sup> To promote the number of nurses available, several states released executive orders to waive licensure requirements.<sup>25</sup> Additionally, this impacted new graduate nurses since, many states opted to permit recent graduates and

---

<sup>18</sup> According to the American Nurses Association, "nursing integrates the art and science of caring and focuses on the protection, promotion, and optimization of health and human functioning; prevention of illness and injury; facilitation of healing; and alleviation of suffering through compassionate presence. Nursing is the diagnosis and treatment of human responses and advocacy in the care of individual, families, groups, communities, and populations in recognition of the connection of all humanity." Am. Nurses Ass'n, *Nursing: Scope and Standards of Practice*, 1, 4th ed. 2021.

<sup>19</sup> Am. Ass'n of Colls. of Nursing, *Nursing Workforce Fact Sheet*, <https://www.aacnnursing.org/news-data/fact-sheets/nursing-workforce-fact-sheet> (last visited Sept. 23, 2025).

<sup>20</sup> Am. Nurses Ass'n, *supra* note 18.

<sup>21</sup> Adler, *supra* note 17.

<sup>22</sup> Am. Ass'n of Colls. of Nursing, *supra* note 19.

<sup>23</sup> Univ. of St. Augustine for Health Sciences, *Nursing Shortage: A 2024 Data Study Reveals Key Insights*, <https://www.usa.edu/blog/nursing-shortage/> (last visited Sept. 23, 2025).

<sup>24</sup> Brendan Martin et al., *Examining the Impact of the COVID-19 Pandemic on Burnout and Stress Among U.S. Nurses*, 14 J. NURSING REGUL. 4, 4 (2023).

<sup>25</sup> Lori Scheidt, *Challenges to Nursing Regulation During the Pandemic: A Case Study*, 12 J. NURSING REGUL. 47, 47 (2022).

nursing students to begin working under a temporary license.<sup>26</sup> Since the pandemic, nurses have reported an increase in burnout and decreased job satisfaction.<sup>27</sup> This likely resulted from placing too much responsibility on nurses who were not properly trained or prepared for the workload.<sup>28</sup>

With frequently changing inpatient registered nurses, workloads typically increase to accommodate patients. Thus, while their focus is on ensuring quality care, nurses can quickly feel overwhelmed when their patient load increases. This can result in nurses incidentally creating errors, like disclosing more than the “minimum necessary”<sup>29</sup> for PHI, creating HIPAA breaches.

While Covid-19 created significant workload stress among hospital nursing staff, the expectations that nurses learn, retain, and continue educating themselves regarding HIPAA compliance prompts greater hardship. Within a nurse’s role, ethical standards that promote patient confidentiality are highlighted.<sup>30</sup> Ideally, these standards would provide

---

<sup>26</sup> Typically, nurses are required to pass their respective state boards licensing exam. However, during the pandemic, the need for more nurses was so great that many states permitted nurses to begin working upon graduation without this board certification, contingent that it would eventually be taken. Iris Hentze, *Covid-19: Occupational Licensing During Public Emergencies*, NAT’L CONF. STATE LEGISLATURES, <https://www.ncsl.org/labor-and-employment/covid-19-occupational-licensing-during-public-emergencies> (last visited Sept. 23, 2025). Ultimately, this allowed new graduates to begin working and focus on providing care but also created fear among staff who felt they were unable to dedicate appropriate studying time to eventually pass their required licensure exam. *Id.*

<sup>27</sup> HEALTH RES. & SERVS. ADMIN., *2022 National Sample Survey of Registered Nurses Snapshot*, <https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Nurse-Survey-Fact-Sheet-2024.pdf> (last visited Sept. 23, 2025).

<sup>28</sup> *Id.*

<sup>29</sup> The principle of “minimum necessary” is where an entity must make a reasonable effort to disclose the minimum amount of PHI to accomplish an intended purpose. *See* 45 C.F.R. § 164.502.

<sup>30</sup> According to the International Council of Nurses Code of Ethics, “Nurses hold in confidence personal information and respect the privacy, confidentiality, and interest of patients in the lawful collection, use, access, transmission, storage and disclosure of personal

clarity for nursing expectations, yet, due to HIPAA's broad enforcement terms, these expectations are often established by a covered entity, who decide how to mitigate breaches.<sup>31</sup>

When a patient believes their HIPAA rights have been compromised, they can submit a complaint to HHS where the Office for Civil Rights (OCR) will address the claim.<sup>32</sup> If a violation is found, the Secretary of HHS will notify the covered entity accordingly and, if reasonable action is not taken to resolve the issue, a civil fine can be imposed on the covered entity.<sup>33</sup> Typically, a violation will prompt the covered entity to discipline its workforce for the violation.<sup>34</sup> Due to increases in cyberattacks and the vagueness of compliance requirements, data breaches have caused more than 133 million records to be impermissibly accessed.<sup>35</sup> These types of breaches can be extremely costly.<sup>36</sup>

A covered entity's flexibility in structuring HIPAA compliance training likewise extends to its disciplinary actions for workforce violations of HIPAA.<sup>37</sup> Sanctions imposed by a covered entities may vary depending on the severity or intent of the breach but can include providing more

---

information." INT'L COUNCIL NURSES, *The ICN Code of Ethics for Nurses*, 3 INT'L COUNCIL NURSES 1, 7 (2021).

<sup>31</sup> Brill, *supra* note 6, at 2115-16.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 2111.

<sup>35</sup> Steve Adler, *Healthcare Data Breach Statistics*, HIPAA J., <https://www.hipaajournal.com/healthcare-data-breachstatistics>, (last visited Sept. 23, 2025).

<sup>36</sup> Premera Blue Cross paid \$6.85 million to OCR after settling HIPAA Privacy and Security violations. The company also agreed to implement corrective action which will likely cost the company even more to ensure future compliance. U.S. DEPT OF HEALTH & HUMAN SERVS., *Health Insurer Pays \$6.85 Million to Settle Data Breach Affecting Over 10.4 Million People*, Resolution Agreements, <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/premera/index.html> (last visited Sept. 23, 2025).

<sup>37</sup> Adler, *supra* note 17.

training, suspension, or even firing staff.<sup>38</sup> In extreme cases, registered nurses may also have their licenses revoked or face criminal penalties.<sup>39</sup> However, this can be unfair due to the limited education and understanding that healthcare workers are provided with HIPAA training. Although these parameters are implemented to protect PHI, the effect on registered nurses must be taken into account as well.

#### IV. HARDSHIPS FACED BY NURSES DUE TO UNCLEAR HIPAA GUIDELINES

HIPAA violations can result in termination, even if the violation occurred incidentally. For example, a registered nurse in Kentucky was terminated from her position after assisting with a procedure for violating HIPAA by unnecessarily disclosing PHI.<sup>40</sup> During the “time out,”<sup>41</sup> the nurse allegedly called out information linking the patient’s identity to their medical condition, in particular their name and Hepatitis C diagnosis, which qualifies as PHI under HIPAA.<sup>42</sup> The area where the time out occurred was only separated by a curtain.<sup>43</sup> The patient reported this violation since other staff, that were not involved in the procedure, were able to hear sensitive health information, without this patient’s consent.<sup>44</sup> Although the nurse argued this was an incidental mistake, her termination was upheld as a HIPAA breach.<sup>45</sup>

---

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Hereford v. Norton Healthcare, Inc.*, No. 2015-CA-001958-MR (Ky. Ct. App. 2017).

<sup>41</sup> Prior to beginning a procedure, a pause is taken to ensure that the correct procedure is being completed on the correct patient on the correct body part. Marios Papadakis et al., *The WHO Safer Surgery Checklist Time Out Procedure Revisited: Strategies to Optimize Compliance and Safety*, 69 INT’L J. SURGERY 19, 19.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

This is not an isolated incident as other nurses have been suspended or terminated for various HIPAA violations.<sup>46</sup> In 2007, about 40 employees were suspended without pay after being accused of accessing a high-profile client's medical record and giving information to the media.<sup>47</sup> Although a spokesperson for that hospital reported they did not believe any employee leaked the patient's medical information to the media, these files were impermissibly accessed and required discipline.<sup>48</sup>

Ultimately, this demonstrates how lack of specification regarding HIPAA's Privacy and Security Rules does not improve efficiency or effectiveness within the healthcare setting. These types of suspensions are harmful to an already under-supported, high-stress position. Further, these suspensions and terminations perpetuate the nursing shortage within health care settings,<sup>49</sup> since taking away staff for any period of time leaves gaps in scheduling.<sup>50</sup> These scheduling gaps create more strain on nurses' workloads by forcing them to take on more patients or work more hours to ensure proper care is given to patients.<sup>51</sup>

---

<sup>46</sup> Kevin Henry, *Real World Examples of Nurse HIPAA Violations for Healthcare Compliance Teams*, ACCOUNTABLE (Mar. 31, 2024), <https://www.accountablehq.com/post/real-world-examples-of-nurse-hipaa-violations-for-healthcare-compliance-teams>.

<sup>47</sup> In 2007, George Clooney was involved in a motorcycle incident, promoting him to seek medical attention at a New Jersey hospital. According to the Jersey Journal of Jersey City, at least 27 employees had been sanctioned for this violation. *Clooney Comes Out in Support of Suspended Medical Workers*, THE GUARDIAN (Oct. 10, 2007), <https://www.theguardian.com/world/2007/oct/10/usa.film>.

<sup>48</sup> *Id.*

<sup>49</sup> After learning about staffing suspension from accessing his medical information, George Clooney reported that while he respected patient privacy and understood its importance, he did not agree that suspending medical personnel was a proper solution. *Id.*

<sup>50</sup> AM. ASS'N CRITICAL CARE NURSES, *Flexible Staffing Choices* (Oct. 23, 2024), <https://www.aacn.org/nursing-excellence/nurse-stories/flexible-staffing-choices>.

<sup>51</sup> *Id.*

Additionally, law enforcement involvement with patient care can leave nurses more confused than supported, particularly where HIPAA's privacy protection impact patient consent. For example, a nurse was arrested for refusing to provide a blood sample on an unconscious patient.<sup>52</sup> This situation highlighted the conflict with law enforcement and HIPAA compliance.<sup>53</sup> In this case, HIPAA generally prohibits the disclosure of PHI without patient authorization, so the nurse refused to provide a blood sample on the patient's behalf since he was unable to provide consent.<sup>54</sup> When the police officer asked the nurse to provide a blood sample, she provided proof of her hospital's policy, which stated that a blood test could not be provided without an electronic warrant or patient consent unless the patient was under arrest.<sup>55</sup> However, there was no warrant and the patient was not placed under arrest.<sup>56</sup> Once the officer determined he would not receive the blood sample, he forcefully arrested the nurse.<sup>57</sup> Although the nurse received a settlement and the officer was terminated for excessive force, effective guidelines between law enforcement and healthcare workers have not been developed.<sup>58</sup>

This discrepancy causes confusion and fear of impeding litigation for nurses.<sup>59</sup> Because of this fear, nurses could underperform their duties or share beyond what is permitted by HIPAA to avoid sanctions or issues with law enforcement. Nurses have reported feeling pressured to divulge

---

<sup>52</sup> Hollis T. Redden, *My Patient or Law Enforcement, Who Gets First Say?*, 2024 ARK. L NOTES 24, 24.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at 25.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 26.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

medical details of a patient when prompted by law enforcement, even without a warrant.<sup>60</sup> While there have been instances where nurses rightfully withheld information, it is less clear how often information is requested and given to law enforcement.<sup>61</sup> Further, the frequency and accuracy of giving law enforcement medical information are also largely unknown.<sup>62</sup> While it would make sense to turn to the HIPAA Privacy Rule to determine what information is eligible to be shared, the Rule again provides little clarity.<sup>63</sup> Because law enforcement is not considered a covered entity, they are not required to follow HIPAA's Security Rules or Privacy Rules once they acquire certain medical information.<sup>64</sup> So, if a registered nurse incorrectly discloses PHI, HIPAA's aim to promote privacy is further impeded as law enforcement is not required to follow these guidelines.<sup>65</sup>

#### V. DIFFICULTIES NAVIGATING HIPAA COMPLIANCE

There is a lack of clarity when requests by law enforcement conflict with medical standards of practice, like HIPAA compliance.<sup>66</sup> Although certain Acts have tried to clarify these areas, there is no clear answer.<sup>67</sup> By not having a cohesive, concrete answer on how nursing staff should handle patient privacy in certain situations, nurses are likely to continue to

---

<sup>60</sup> Teneille R. Brown, *When Doctors Become Cops*, 97 S. CAL. L. REV. 675, 697 (2024).

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 700-01.

<sup>63</sup> The Privacy Rule permits disclosure to an administrative subpoena or written statement by police that specifies how the request is "relevant and material" to an investigation. *Id.* at 699-700. The only limitation on this is also broad: "to the extent reasonably practicable in light of the purpose for which the information is sought." *Id.* at 700.

<sup>64</sup> *Id.* at 699.

<sup>65</sup> *Id.* at 700.

<sup>66</sup> Redden, *supra* note 52, at 28.

<sup>67</sup> *Id.* at 39.

experiencing uncertainty when delivering patient care. This uncertainty is further exacerbated with increased workloads and less staff available to help complete the necessary work.

Further, due to the flexibility of these training requirements, there are no parameters on how competent staff must be regarding HIPAA. In 2023, a report indicated that more than half of employees within the healthcare field failed their HIPAA assessments.<sup>68</sup> Thus, it is apparent that although employees have completed HIPAA training, they may have failed to understand the material and integrate it into their work habits. Often, what makes HIPAA training compliance so difficult is ensuring that every member is properly versed in HIPAA.<sup>69</sup> The high volume of nurses within a covered entity can make it difficult for the covered entity to ensure their nurses are properly trained on HIPAA compliance.<sup>70</sup>

Although HIPAA training is recommended at least yearly for staff, the training is ineffective.<sup>71</sup> Upon hire, initial HIPAA training is typically provided to employees.<sup>72</sup> Yet, if an employee stays with the organization for years, this is often the only HIPAA training they will receive.<sup>73</sup> Most health care organizations report only providing HIPAA training once a year or less.<sup>74</sup> While it is expected that organizations supply their staff with appropriate training to maintain compliance, employees are encouraged to

---

<sup>68</sup> Todd Shryock, *More Than Half of Employees Don't Understand HIPAA Rules*, MED. ECONS., <https://www.medicaleconomics.com/view/more-than-half-of-employees-don-t-understand-hipaa-rules> (last visited Sept. 23, 2025).

<sup>69</sup> Adler, *supra* note 17.

<sup>70</sup> *Id.*

<sup>71</sup> Shryock, *supra* note 68.

<sup>72</sup> Steve Adler, *How Often is HIPAA Training Required*, HIPAA J. (Oct. 13, 2023), <https://www.hipaajournal.com/how-often-is-hipaa-training-required/>.

<sup>73</sup> *Id.*

<sup>74</sup> Shryock, *supra* note 68.

complete their own refresher courses regarding HIPAA compliance.<sup>75</sup> Without proper training, employees are more susceptible to violating HIPAA. These violations can incur financial penalties, criminal charges, and ongoing compliance issues if they are not appropriately redressed.<sup>76</sup> Covered entities must recognize that their current training methods are insufficient. This is particularly apparent given the influx of HIPAA violations and fines paid each year.<sup>77</sup> In an effort to protect the patient population within a covered entity, and fulfill the obligations of HIPAA, a reduction in monetary penalties for HIPAA violations can incentivize HIPAA compliance.

Further, HIPAA interpretations continue to be difficult for various nursing roles. For example, when nurses are caring for a patient suffering from a mental health crisis, the patient cannot consent or properly speak for themselves, so nurses will likely have to speak as the patient's advocate. Knowing what information can and cannot be shared during this time is difficult to decipher. Per the HIPAA Privacy Rule, the health care provider is given the discretion to make the decision on behalf of the patient's best interest.<sup>78</sup> Without mandating strict requirements on how to navigate these situations, nurses are left making decisions that could go against those patients' "best interests."

Another gap with HIPAA compliance is the lack of leadership guidance on HIPAA. While HIPAA requires a compliance officer within covered

---

<sup>75</sup> *How Often Do You Need HIPAA Training?*, 360TRAINING (July 10, 2025), <https://www.360training.com/blog/how-often-is-hipaa-training-needed>.

<sup>76</sup> *Id.*

<sup>77</sup> See Adler, *supra* note 35 ("healthcare data breach statistics clearly show there has been an upward trend in data breaches over the past 14 years, with 2021 seeing more data breaches reported than any other year since records first started being published . . .").

<sup>78</sup> 45 CFR § 164.510.

entities, there is no guidance on how available this officer needs to be for registered nurses to answer HIPAA compliance questions.<sup>79</sup> Further, there are no qualifications to serve as a HIPAA compliance officer, and these officers can serve across multiple states.<sup>80</sup> Given the high volume of employees these compliance officers serve, it is unlikely that they can reasonably be relied upon by nurses to provide concrete direction on how to handle specific HIPAA compliance issues.

Nurses are essential to healthcare and with current HIPAA regulations, they must navigate complex ethical and practical challenges.<sup>81</sup> Thus, without entities being required to implement strict measures on HIPAA compliance, nurses are often left wondering whether their present situation is a violation of HIPAA or a required disclosure to provide efficient patient care. Creating an environment that allows for open communication, rewards compliance, and seeks to improve privacy management is imperative to ensuring nurses remain compliant with applicable law and maintain effective patient care.<sup>82</sup> However, this continues to be a challenge for healthcare industries.

#### VI. LEGISLATIVE CHANGES AND CLARIFICATION NEEDED TO OVERCOME HIPAA COMPLIANCE ISSUES

With frequent HIPAA violations, covered entities continue to be fined and HIPAA's implementation purposes not met.<sup>83</sup> To ensure the

---

<sup>79</sup> *What are the Duties of a HIPAA Compliance Officer?*, HIPAA J., <https://www.hipaajournal.com/duties-of-a-hipaa-compliance-officer/> (last visited Oct. 20, 2025).

<sup>80</sup> *Id.*

<sup>81</sup> Ateya Ibrahim et al., *Balancing Confidentiality and Care Coordination: Challenges in Patient Privacy*, 23 BMC NURSING 1, 2 (2024).

<sup>82</sup> *Id.* at 12.

<sup>83</sup> Under HIPAA, individuals were not provided total ownership of their medical records to amend or restrict their release. However, HIPAA was intended to provide other ways to control and access their health information. KARL A. MENNINGER II, AM. JURIS. PROOF FACTS:

protections under HIPAA are followed, stricter regulation regarding competency among nursing staff employed by covered entities must be enforced. Requiring uniformity among these organizations will ensure all nurses are properly versed in HIPAA compliance and allow HIPAA to properly serve its purpose. Because health care facilities have not been thorough or effective in their training, these requirements must be amended at the federal level.

Currently, 45 C.F.R. § 164.530 and 45 C.F.R. § 164.308 are responsible for providing HIPAA training.<sup>84</sup> The primary purpose of 45 C.F.R. § 164.530 is to relay Administrative requirements to protect the privacy of individuals PHI.<sup>85</sup> Meanwhile, 45 C.F.R. § 164.308 is intended to provide Administrative safeguards for ePHI.<sup>86</sup> Because these regulations were created and enforced at the federal level, creating stricter deadlines and supportive measures at the federal level will allow health care entities to understand compliance standards to provide their employees.

Speaking to the standard training implemented by 45 C.F.R. § 164.530, the following changes are proposed to 45 C.F.R. § 164.530(b)(2)(i):

(i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity, unless the employee works directly with PHI, then within 90 days of hire;

---

*CONFIDENTIALITY OF MEDICAL AND OTHER TREATMENT RECORDS*, 259 (3rd ed. 2025). With constant HIPAA violations, individuals' medical records remain violated, something HIPAA intended to avoid. *Id.*

<sup>84</sup> Steve Adler, *HIPAA Training for Healthcare Workers*, HIPAA J. (Nov. 14, 2023), <https://www.hipaajournal.com/hipaa-training-for-healthcare-workers/>.

<sup>85</sup> 45 C.F.R. § 164.530.

<sup>86</sup> 45 C.F.R. § 164.308.

(B) Thereafter, to each new member of the workforce within a 90 day time period after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart or subpart D of this part, within 90 days after the material change becomes effective in accordance with paragraph (i) of this section.

Providing a ninety-day timeframe allows the covered entity to set a realistic and plausible deadline rather than loosely requiring a “reasonable” timeframe.<sup>87</sup> A ninety-day timeframe will allow the registered nurse to become acquainted with the facility and properly integrate HIPAA obligations into their workflow. Additionally, providing support to new staff members and ensuring retained staff members receive competency training can promote employee readiness to handle HIPAA issues. Rather than allow the covered entity to determine how soon a new employee can receive training or determine the frequency of training for current staff, health care organizations are provided with strict parameters to follow and ensure their staff is compliant in training.

As for the Administrative safeguards discussed in 45 C.F.R. § 164.308, the following language is proposed to amend 45 C.F.R. § 164.308 subsections (a)(2) and (3)(ii)(A):

(2) Standard: Assigned security responsibility. Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate. Require the security official mandates competency training session for all employees directly involved with ePHI. Ensure employees have a direct point of contact to address any compliance concerns.

(3)(ii)(A): Authorization and/or supervision (Addressable). Implement procedures for the authorization and/or supervision of workforce members

---

<sup>87</sup> 45 C.F.R. § 164.530.

who work with electronic protected health information or in locations where it might be accessed. Ensure all employees receive competency training within 90 days of hire date and yearly updated training sessions thereafter.

By creating specific requirements for mandating competency training and ensuring employees have a direct point of contact for any concerns, entities can begin implementing safeguard measures to best support their employees. Requiring uniformity among these organizations will ensure all nurses are properly versed in HIPAA compliance and allow HIPAA to properly serve its purpose. Because healthcare facilities have not implemented proper training protocols, to ensure uniform compliance, amended legislation will ensure staff can feel supported and properly understand protocols associated with HIPAA. Additionally, because these regulations require sanctions if not complicit, health care organizations under HIPAA will be incentivized to comply with the proposed regulations.

#### CONCLUSION

While HIPAA incidents range from social media violations to a simple lack of awareness for current law, it is imperative that legislation regarding HIPAA Privacy and Security compliance become more specific to ensure nursing involved with PHI remain aligned with the goals of HIPAA. Ultimately, mandating stricter requirements, like a ninety-day compliance training timeframe, on covered entities that employ registered nurses can reduce costs associated with HIPAA breaches due to improper training or support. Current regulations are not sufficient to support nurses and to reduce burnout, thus facilitating proper guidance and sufficient training for HIPAA compliance is critical. Further, these changes will allow the

covered entity to effectively provide efficient care amongst their patient population and allow nurses to focus on their daily tasks rather than trying to find answers to specific compliance issues.

# Reforming March-In Rights: The Case for Collaboration Under the Bayh-Dole Act

*Michael Bahu*

## I. INTRODUCTION TO THE BAYH-DOLE ACT AND THE TRUMP ADMINISTRATION'S THREAT TO HARVARD

In 2002, the Economist dubbed the Bayh-Dole Act (“Bayh-Dole”) “[p]ossibly the most inspired piece of legislation to be enacted in America over the past half century.”<sup>1</sup> On August 8, 2025, Bayh-Dole made headlines once again after President Donald Trump wrote a letter to Harvard, accusing the University of breaching its contractual and statutory obligations related to its federally funded research programs and patents.<sup>2</sup> Trump threatened to use the government’s “march-in” power, a government statutory authority granted under the Bayh-Dole Act.<sup>3</sup> To date, and throughout Bayh-Dole’s 45-year history, the government has never exercised these rights.<sup>4</sup> Bayh-Dole is an important piece of legislation, and its march-in rights are a significant but underutilized component. Whether the current administration exercises march-in rights against Harvard for the first time in history remains to be seen.

Bayh-Dole was enacted in 1980 and permits federal contractors or grantees to retain patent rights to inventions funded by the federal government.<sup>5</sup> The statute has transformed how federally funded research becomes commercialized.<sup>6</sup> Before Bayh-Dole, inventions arising from

---

<sup>1</sup> Samuel Loewenberg, *The Bayh-Dole Act: A model for Promoting Research Translation?*, 3 MOL. ONCOL. 91 (2009).

<sup>2</sup> THE GUARDIAN, *Trump Administration Threatens to Strip Harvard University of Lucrative Patents*, <https://www.theguardian.com/us-news/2025/aug/09/trump-administration-harvard-patent-review> (last visited Sep. 4, 2025).

<sup>3</sup> *Id.*

<sup>4</sup> Kevin J. Hickey & Emily G. Blevins, PRICING AND MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT (2024).

<sup>5</sup> *Id.*; THE GUARDIAN, *supra* note 2.

<sup>6</sup> THE UNIV. OF UTAH, *Bayh-Dole Act: Turning Research Into Real-World Impact*, <https://technologylicensing.utah.edu/news-events/resources-opportunities/bayh-dole-act-turning-research-into-real-world-impact> (last visited Sep. 25, 2025).

federally funded research were owned by the government, often preventing promising discoveries from ever leaving the laboratory.<sup>7</sup> Bayh-Dole enabled federally funded research to have commercial impact, with the expectation that these inventions would be developed into products and services that benefit the public good.<sup>8</sup>

First, this article examines the Bayh-Dole Act, its march-in rights, and the Trump administration's latest attempt to enforce them against Harvard. It then explores the critical intersection between march-in rights and high drug prices, analyzing the issue through both historical and international perspectives. Further, it compares U.S. and international compulsory licensing laws to march-in rights. Ultimately, this article concludes that Bayh-Dole's march-in rights would be most effective if exercised collaboratively. The government and federally funded institutions should lower drug prices through negotiation, not by force, the threat of force, or the lack thereof, under the guise of march-in authority.

## II. BAYH-DOLE'S ORIGIN, PURPOSE, AND MARCH-IN AUTHORITY

Patent rights grant federal contractors or grantees the exclusive right to use the invention or license it to an industry partner for 20 years.<sup>9</sup> "Federal contractors" or "grantees" include but are not limited to universities, nonprofit research institutions, and small businesses.<sup>10</sup> Under Bayh-Dole, they can retain ownership of their inventions and acquire patent and licensing capabilities and rights.<sup>11</sup> Senators Birch Bayh and Bob Dole

---

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> Hickey, *supra* note 4.

<sup>10</sup> DREXEL UNIV., *Bayh-Dole Act*, <https://drexel.edu/research/innovation/bayh-dole-act> (last visited Sep. 25, 2025).

<sup>11</sup> *Id.*

sponsored the Bayh-Dole Act, which was enacted in part to provide intellectual property incentives for federally funded projects, giving institutions and researchers alike the option to commercialize their research.<sup>12</sup>

Bayh-Dole was enacted to provide incentives to federally funded inventors, but they must attempt to commercialize their discoveries to receive any benefits.<sup>13</sup> However, owning an invention and its intellectual property assets comes with requirements.<sup>14</sup> To retain ownership rights, universities, small businesses, and nonprofit organizations that receive federal funding must seek to protect and commercialize their discoveries.<sup>15</sup> In addition, they must submit progress reports to the funding agency, compensate the inventors with any resulting royalties, and more.<sup>16</sup>

The Trump administration asserted that Harvard was “in breach of the statutory, regulatory, and contractual requirements tied to [its] federally funded research programs.”<sup>17</sup> More specifically, it questioned Harvard’s compliance with the Bayh-Dole requirements and threatened to exercise march-in rights under the Act.<sup>18</sup> Howard Lutnick, the Commerce

---

<sup>12</sup> Nima Zargari et al., *Department of Commerce Initiates Bayh-Dole Compliance Review and Asserts March-In Proceeding Targeting Harvard University Patents*, WILSON SONSINI (Aug. 14, 2025), <https://www.wsgr.com/en/insights/department-of-commerce-initiates-bayh-dole-compliance-review-and-asserts-march-in-proceeding-targeting-harvard-university-patents.html>; THE GUARDIAN, *supra* note 2.

<sup>13</sup> *Id.*

<sup>14</sup> THE UNIV. OF UTAH, *supra* note 6.

<sup>15</sup> THE UNIV. OF MICH., *U.S. Bayh-Dole Act*, <https://innovationpartnerships.umich.edu/resource/u-s-bayh-dole-act/> (last visited Sep. 25, 2025).

<sup>16</sup> *Id.*

<sup>17</sup> Betsy Klein, *Trump Administration Targets Harvard’s Patents*, CNN POLITICS (Aug. 8, 2025), <https://www.cnn.com/2025/08/08/politics/trump-administration-targets-harvards-patents>.

<sup>18</sup> Vicki G. Norton et al., *Commerce Department Singles out Harvard for Bayh-Dole March-In Rights Enforcement*, DUANE MORRIS (Aug. 19, 2025),

Secretary, noted Harvard had not reported its commercialization activities.<sup>19</sup> Lutnick added that Harvard had a “critical responsibility” to ensure that its intellectual property, made possible by federal funding, was used to maximize benefits to the American people.<sup>20</sup> He instructed Harvard to provide a list of its federally funded patents and explain how each was used.<sup>21</sup>

Per Bayh-Dole, the government can march-in if the situation meets any of the following criteria:

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use; (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees; (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.<sup>22</sup>

If the government chose to march in, it could compel universities and other federal contractors with federally funded patents to license inventions to third parties.<sup>23</sup> A march-in would correct and achieve any of the four situational criteria of § 203.<sup>24</sup> The process begins with a written notice to the federally

---

[https://www.duanemorris.com/alerts/commerce\\_department\\_singles\\_out\\_harvard\\_bayh\\_dole\\_march\\_in\\_rights\\_0825.html](https://www.duanemorris.com/alerts/commerce_department_singles_out_harvard_bayh_dole_march_in_rights_0825.html).

<sup>19</sup> *Id.*

<sup>20</sup> THE GUARDIAN, *supra* note 2.

<sup>21</sup> *Id.*

<sup>22</sup> 35 U.S.C. § 203.

<sup>23</sup> Zagari, *supra* note 12.

<sup>24</sup> *Id.*

funded inventor that provides a basis for the march-in.<sup>25</sup> Then, if necessary, the government may conduct discovery.<sup>26</sup> Should it decide to march-in, the contractor can appeal the decision to the U.S. Court of Federal Claims.<sup>27</sup>

Notably, the statute omits the price of the patented product as a basis for a government march-in.<sup>28</sup> Recently, this omission has been the subject of numerous march-in petitions, and the topic remains highly contentious.<sup>29</sup> For instance, in December 2023, under the Biden administration, the National Institute of Standards and Technology (“NIST”) released a proposed framework titled *Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*, which asserted that price should be a factor in determining whether drugs are accessible to the public.<sup>30</sup> Conversely, the administration during Trump’s first term unsuccessfully attempted to amend Bayh-Dole’s march-in provision to prohibit march-in rights based solely on price.<sup>31</sup> Whether the government should have the right to intervene in pricing alone, especially in a patent-related context, is a heavily debated and contentious issue.

---

<sup>25</sup> Hickey, *supra* note 4.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> Stephen D. Sencer et al., *Biden Administration’s Proposal Under Bayh-Dole Act Signals Enhanced Focus on Use of March-In Rights and Lower Drug Pricing*, ROPES & GRAY (Dec. 13, 2025), <https://www.ropesgray.com/en/insights/alerts/2023/12/biden-administrations-proposal-under-bayh-dole-act-signals-enhanced-focus-on-use-of-march-in-rights>.

<sup>31</sup> *Id.*

### III. THE HUMAN COST OF PATENT-DRIVEN DRUG PRICING

Drugs are more expensive in the U.S compared to other industrialized countries.<sup>32</sup> A 2024 report found that U.S. drug prices were, on average, almost three times higher than those in 33 other industrialized countries.<sup>33</sup> In 2021, 79% of Americans considered the price of U.S. prescription drugs to be unreasonable, with almost three in ten reporting that they do not pay for drugs due to the cost.<sup>34</sup> That year, 70% of Americans reported that lowering drug prices was their top healthcare priority.<sup>35</sup>

High drug prices in the U.S. are due to several factors. First, it is primarily attributed to the “highly complex and fragmented reimbursement system and lack of national pricing control.”<sup>36</sup> Compared to European countries, which, on average, have lower drug prices because governments and drug companies work together to set limits to what their state-funded health systems pay, U.S. pharmaceutical companies set prices and negotiate with private insurers.<sup>37</sup> Private insurers are motivated to set high prices to turn a profit, while pharmaceutical companies argue that high costs help fund research and development.<sup>38</sup>

Rewinding to the late 1990s, when the deadly HIV/AIDS epidemic was ravaging developing countries, a revolutionary and breakthrough

---

<sup>32</sup> Karen Gilchrist, *Why Americans Pay so Much More for Prescription Drugs*, CNBC (May 14, 2025), <https://www.cnbc.com/2025/05/14/why-americans-pay-so-much-more-for-prescription-drugs-.html>.

<sup>33</sup> *Id.*

<sup>34</sup> Paul B. Ginsburg & Steven M. Lieberman, *Government Regulated or Negotiated Drug Prices: Key Design Considerations*, USC SCHAEFFER (Aug. 30, 2021), <https://www.brookings.edu/articles/government-regulated-or-negotiated-drug-prices-key-design-considerations/>.

<sup>35</sup> *Id.*

<sup>36</sup> Gilchrist, *supra* note 32.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

antiretroviral combination therapy started being sold at an extremely high price.<sup>39</sup> As a result, many developing countries could not afford the treatment, leading to illness and death that were preventable had prices been reasonable.<sup>40</sup> Production costs were only a fraction of the sales price, and pharmaceutical companies used patent monopolies to bolster their profit margins by setting high prices.<sup>41</sup> In 1995, the 1994 World Trade Organization (“WTO”) within the Trade Related Intellectual Property Agreement (“TRIPS”) set the global patent standard requiring, in part, all countries to award and enforce patents for a minimum of 20 years.<sup>42</sup> This agreement was pushed by pharmaceutical companies in the U.S., who saw an opportunity for commercialization and the advantage that exclusive patent rights would have in privatizing goods.<sup>43</sup> Prioritizing the accessibility and affordability of drugs fell by the wayside in favor of a capitalistic approach.<sup>44</sup> High drug prices due to patent monopolization have led to the inability of developing countries to access affordable HIV/AIDS treatments, resulting in millions of deaths.<sup>45</sup>

The COVID-19 pandemic “provides perhaps the most important test of the concept that profit-making in a crisis should be limited or even eliminated, particularly when . . . based on publicly funded research and incentives.”<sup>46</sup> Pharmaceutical companies in the U.S monopolized the

---

<sup>39</sup> Els Torrelee, *Why are our Medicines so Expensive? Spoiler: Not for the Reasons you are Being Told...*, 30 Eur. J. of Gen. Prac., Jan. 15, 2024, at 2.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> John Aubrey Douglass, *Federally Funded Research, the Bayh-Dole Act, and the COVID Vaccine Race*, U.C. BERKELEY CTR. FOR STUD. IN HIGHER EDUC., Feb. 2021, at 8.

vaccines and drugs they produced during the pandemic.<sup>47</sup> As of February 2024, the U.S. government had spent at least \$31.9 billion on vaccine research and development, yet had not prioritized global access.<sup>48</sup> Other wealthy countries followed suit and led WHO Director-General Tedros Ghebreyesus to dub such vaccine hoarding as the “vaccine apartheid.”<sup>49</sup>

Two major pharmaceutical companies, Pfizer and Moderna, played a significant role during the pandemic.<sup>50</sup> To bring a vaccine to market quickly, the U.S. government initiated “Operation Warp Speed.”<sup>51</sup> This government vaccine program offered \$10 billion to pharma companies to develop vaccines rapidly.<sup>52</sup> In response, Pfizer did not accept any federal funding to avoid the possibility of federal patent control, but Moderna accepted federal funds.<sup>53</sup> The government did not negotiate or contract with pharmaceutical companies that received federal funding, a significant oversight, according to some.<sup>54</sup> Ellen Hoen, director of the research group Medicines Law and Policy, said, “I think it was unwise of our governments to hand over that money without strings attached.”<sup>55</sup> A lawyer stated, “The U.S. government has put up a billion dollars towards [vaccine development] and . . . should have realized that it has significant leverage and [negotiated] contract terms favorable to the American public and worldwide.”<sup>56</sup> Therefore, government implementation of its march-in

---

<sup>47</sup> Torrelee, *supra* note 39.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> Douglass, *supra* note 46.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

rights was the only method to prevent vaccine producers from claiming exclusive rights to profits.<sup>57</sup> For example, in 2020, people questioned whether the U.S. government should exercise its march-in rights when the drug “Remdesivir” was poised to be the FDA-approved COVID-19 treatment in the U.S.<sup>58</sup>

In March 2020, the World Health Organization (“WHO”) declared the COVID-19 pandemic a global health emergency.<sup>59</sup> Just under three years later, in February 2023, the worldwide tally of COVID-19 cases reached 755 million, resulting in 6.8 million deaths.<sup>60</sup> Although the WHO declared an end to the pandemic in May 2023, the lessons learned over the three years continue to shape our world today.<sup>61</sup>

#### IV. MARCH-IN RIGHTS AND THE DEBATE OVER DRUG PRICING

The inclusion of price as a factor warranting march-in rights draws much criticism.<sup>62</sup> The concern is that it counteracts one of the significant purposes of Bayh-Dole—promoting the commercialization of federally funded inventions.<sup>63</sup> Opponents argue that Bayh-Dole was never intended to be a price-control statute, and that the commercialization of a product satisfies the “practical application” requirement regardless of whether the drug is affordable.<sup>64</sup> After the Trump administration attempted to finalize

---

<sup>57</sup> *Id.*

<sup>58</sup> Jordan Paradise, *COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision*, J.L. & BIOSCIENCES, Jan.–June 2020, at 10, 11.

<sup>59</sup> NORTHWESTERN MEDICINE, *When Did the Pandemic Start and End?* (Apr. 2025), <https://www.nm.org/healthbeat/medical-advances/new-therapies-and-drug-trials/covid-19-pandemic-timeline>.

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> Sencer, *supra* note 30.

<sup>63</sup> *Id.*

<sup>64</sup> Hickey, *supra* note 4.

a prohibition on marching-in based on pricing, President Biden issued an executive order in 2023 prohibiting the National Institute of Standards and Technology (“NIST”) from doing so.<sup>65</sup> The NIST did not follow through and prohibited marching-in based on price.<sup>66</sup>

Proponents of government march-in rights based on price alone argue that affordability is directly related to the “practical application” component of Bayh-Dole.<sup>67</sup> They argue, for example, that a drug must be affordable for it to be “available to the public on reasonable terms.”<sup>68</sup> These arguments have been unsuccessful, and the National Institutes of Health (“NIH”) has repeatedly rejected all petitions for “marching-in” based on high price, including petitions for government intervention regarding HIV/AIDS and certain cancer treatments.<sup>69</sup>

#### V. COMPULSORY LICENSING AND BAYH-DOLE ANALOGUES ABROAD

Bayh-Dole transformed how government-funded research is brought to the marketplace.<sup>70</sup> As mentioned at the outset of this article, it is said to be “the most inspired piece of legislation to be enacted in America over the past half-century.”<sup>71</sup> Numerous other countries around the world have enacted legislation similar to and based on Bayh-Dole.<sup>72</sup> By 2007, countries such as Japan, France, the United Kingdom, Germany, Austria,

---

<sup>65</sup> Sencer, *supra* note 30.

<sup>66</sup> *Id.*

<sup>67</sup> Hickey, *supra* note 4.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 MAINE L. REV. 260, (2007).

<sup>71</sup> Wei Yi & Cheryl Xiaoning Long, *Does the Chinese Version of Bayh-Dole Promote University Innovation?*, 1 CHINA ECON. Q. INT’L. 244, (2021).

<sup>72</sup> Mireles, *supra* note 70.

Denmark, Norway, Portugal, Spain, and Finland had either considered or adopted Bayh-Dole-like legislation.<sup>73</sup> To assess the relative success of similar Bayh-Dole legislation in those countries, it is necessary to consider the underlying structural differences in the higher education systems.<sup>74</sup> For instance, “the historical link between universities and industry in Europe has been more attenuated than in the United States.”<sup>75</sup> March-in rights are specific to the U.S. under Bayh-Dole, but other countries use a similar framework called “compulsory licensing.”<sup>76</sup> Similar to march-in rights, compulsory licensing “provides a specific mechanism to bypass a patent owner’s legal monopoly...by which a government licenses companies or individuals other than the patent owner . . . to make, use, sell, or import a product under [the] patent.”<sup>77</sup>

The Trade-Related Aspects of Intellectual Property Rights Agreement (“TRIPS”) permits countries to enact compulsory licensing laws.<sup>78</sup> Compulsory licensing laws are flexible; TRIPS does not limit how or when countries use this power.<sup>79</sup> However, with lower drug prices, there are only a few instances of compulsory laws being granted because the threat

---

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> Paul A. Calvo, *March-In Rights and Compulsory License in the United States*, Sterne, Kessler, Goldstein & Fox (Oct. 16, 2017), <https://www.sternekeessler.com/news-insights/insights/march-rights-and-compulsory-license-united-states/>.

<sup>77</sup> William Alan Reinsch, Sanvid Tuljapurkar & Jack Caporal, *Compulsory Licensing: A Cure for Distributing the Cure?*, CSIS (May 8, 2020), <https://www.csis.org/analysis/compulsory-licensing-cure-distributing-cure>.

<sup>78</sup> WTO, *Compulsory Licensing of Pharmaceuticals and TRIPS*, [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm) (last visited Sep. 25, 2025).

<sup>79</sup> Lauren McGivern, *Trade-Related Aspects of Intellectual Property Rights Flexibilities and Public Health: Implementation of Compulsory Licensing Provisions into National Patent Legislation*, 101 THE MILBANK Q. 1280, 1281 n. 4 (2023).

of using them is usually enough.<sup>80</sup> In 2005, for example, the Chinese government threatened to use a compulsory license to manufacture a generic version of Tamiflu.<sup>81</sup> During the pandemic, Russia issued a compulsory license for Remdesivir.<sup>82</sup> Because the mere threat of a compulsory license is often sufficient to induce drug manufacture by the patent holder, its impact of drug pricing should not be measured solely by the number of compulsory licenses actually issued.<sup>83</sup> Scholars argue that compulsory licensing in other countries has led to the discrepancy between high drug prices in the U.S. and low drug prices elsewhere.<sup>84</sup> However, this claim has not been statistically proven.<sup>85</sup> What we do know, however, is that in other countries, compulsory licensing is rarely imposed or threatened, and in select high-income countries totaled just 21 during 2001-2021.<sup>86</sup>

Compulsory licensing exists in the U.S. as well, but it is similarly rarely invoked.<sup>87</sup> In the U.S., compulsory license episodes totaled 24 during 2001-2021.<sup>88</sup> The government can practice private patents without the patent owner's permission under 28 U.S.C. § 1498—the U.S. compulsory license statute.<sup>89</sup> Under this statute, “the government might authorize a

---

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> Lindor Qunaj, Anna Kaltenboeck & Peter B. Bach, *Compulsory Licensing of Pharmaceuticals in High-Income Countries: A Comparative Analysis*, 100 THE MILBANK Q. 284 n. 1 (2022).

<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> Brian D. Coggio, Cheryl Wang & Sushil Iyer, *Overview of Approaches to Compulsory Licensing*, FISH & RICHARDSON (May 21, 2020), <https://www.fr.com/insights/ip-law-essentials/overview-approaches-compulsory-licensing/>

company to manufacture patented drugs . . . if the government deems the drug prices too high.”<sup>90</sup> However, the government cannot “nullify or forcibly transfer patent title” under § 1498.”<sup>91</sup> In response, patent holders can sue for compensation, while the government continues to practice patented inventions.<sup>92</sup> Bayh-Dole’s march-in rights are a “narrower” set of compulsory licensing power.<sup>93</sup> The federally funded patented invention must be used under certain circumstances (e.g., drug prices not included), and the license must be reasonable.<sup>94</sup> Further, when compulsory licenses are invoked in the pharmaceutical sector, courts typically grant injunctions against the government to incentivize innovation and protect patent rights.<sup>95</sup>

#### VI. CONSEQUENCES OF UNDERUTILIZATION

Bayh-Dole’s march-in provision and compulsory licensing laws, in general, are meant to promote the commercialization of patented inventions.<sup>96</sup> History shows that, legally speaking, if left unchecked, pharmaceutical companies can monopolize patents and set high prices.<sup>97</sup> Bayh-Dole’s march-in rights were enacted to ensure that universities, small businesses, and non-profit organizations protect and commercialize their discoveries.<sup>98</sup> Likewise, U.S. compulsory licensing laws legally permit the government to intervene in non-federally funded patent

---

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> Sencer, *supra* note 30; Reinsch, Tuljapurkar & Caporal, *supra* note 77.

<sup>97</sup> Torreele, *supra* note 39.

<sup>98</sup> UNIV. OF MICH., *supra* note 15.

monopolies.<sup>99</sup> If the government deems the drug's price is too high, it may authorize a company to manufacture patented drugs.<sup>100</sup> Even with all of these regulations and checks on pharmaceutical companies in place, compulsory licensing laws are rarely invoked, and a government march-in under Bayh-Dole has never occurred.<sup>101</sup>

Federally funded drug prices remain high, in part because Bayh-Dole does not permit the government to exercise its march-in rights solely on the basis of excessive pricing.<sup>102</sup> There have been attempts to address this issue, most recently the Biden administration's 2023 framework, which asserted that price should be a factor for march-in rights.<sup>103</sup> However, nothing material has come of this; rather, the Trump administration sought to ban price-based march-ins entirely.<sup>104</sup> The issue remains highly contentious.<sup>105</sup> Whether Bayh-Dole should be treated as a price-control statute is hotly debated, despite never having been enforced.<sup>106</sup> Thus, the public pays twice: once through taxes that fund research, and again for inflated drug prices that the government cannot legally, and has never, controlled.

---

<sup>99</sup> Coggio, Wang & Iyer, *supra* note 89.

<sup>100</sup> *Id.*

<sup>101</sup> Qunaj, *supra* note 84.

<sup>102</sup> Hicky, *supra* note 4.

<sup>103</sup> Sencer et al., *supra* note 30.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

## VII. SOLUTIONS TO FIXING BAYH-DOLE AND COMPULSORY LICENSING UNDERUTILIZATION IN THE U.S.

It is evident that, although a compulsory licensing framework exists in the U.S., it is narrow and underutilized.<sup>107</sup> Courts often enjoin the government's attempts to use compulsory licensing to protect patent rights and innovation incentives, which in turn limits the government's ability to use the tool to counter high drug prices.<sup>108</sup> Therefore, attention should be turned to Bayh-Dole, which provides a more flexible and targeted approach to correcting overpriced federally funded inventions. One solution is to amend Bayh-Dole to include price control as "reasonable terms" to march-in on federally funded patents. However, this has been attempted and proposed before and is impractical.<sup>109</sup> On February 6, 2024, the Federal Trade Commission ("FTC") responded to the NIST's proposal to consider drug pricing as a market criterion.<sup>110</sup> While the FTC agreed with the proposal, implementation challenges remain.<sup>111</sup> First, while march-in rights could in theory be a "valuable tool" to help make drugs more affordable, "patent thickets" make amending Bayh-Dole difficult.<sup>112</sup> Patent thickets are common and arise when pharmaceutical companies use multiple patents to protect a single drug.<sup>113</sup> Often, not all the patents used to develop the drug are federally funded, so the privately funded patents

---

<sup>107</sup> Qunaj, *supra* note 84.

<sup>108</sup> Coggio, Wang & Iyer, *supra* note 89 (finding that from May 2006 to December 2013, courts granted injunctions sought by patent holders against the government 72.5% of the time).

<sup>109</sup> FED. TRADE COMM'N, *FTC Submits Comment on March-In Rights to Promote Efforts to Lower Drug Prices* (Feb. 6, 2024), <https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-submits-comment-march-rights-promote-efforts-lower-drug-prices>.

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

involved in the drug's development end up blocking any government intervention.<sup>114</sup>

The government, instead, should develop a collaborative licensing framework with pharmaceutical companies and universities rather than threatening the use of march-in rights as a punitive measure. For instance, federally funded inventions, regardless of industry sector, should carry an "optional public license" provision that is enacted only if specific qualifications, such as a national emergency or a monetary threshold, are met. This license would be pre-negotiated, emphasizing the collaborative nature of the reformed model. In essence, this would be a contractual agreement between the government and a federally funded party. Patent holders would agree in advance that a license may be invoked under specified conditions. In a contract drafted by the government and proposed to the federally funded entity, an optional public license clause may read as follows:

(1) As a condition of receiving federal funding, the Entity shall agree to grant the United States Government an Optional Public License to the Invention. This license shall be invoked solely upon the occurrence of a declared national public health emergency by the Department of Health and Human Services, or when the Entity's pricing renders the invention unavailable on reasonable terms by exceeding the agreed-upon monetary threshold discussed in this Agreement. The scope, duration, and financial terms of the Optional Public License shall be established in advance and shall govern the parties' rights without the need for additional negotiation or litigation.

(2) If the Entity, its licensee, or assignee fails to comply with the terms and conditions of this Agreement, the funding agency may, after providing written notice, exercise its authority to initiate march-in proceedings pursuant to 35 U.S.C. § 203.

---

<sup>114</sup> *Id.*

This provision sets expectations from the start. It not only provides a federally funded entity with an incentive to keep prices reasonable, but also explicitly gives the government the right to an invention, should any negotiated event in the provision occur. It pre-defines terms and limits any potential litigation. In turn, this promotes public welfare and aligns with international practice, where the threat of government-use licenses encourages fair pricing and access. Because a march-in based on drug pricing is not an available option, the government should instead negotiate terms with patent holders. Bayh Dole states that the “federal agency under whose funding agreement the subject invention was made” has the right to march-in.<sup>115</sup> In accordance with this, the funding agency should negotiate these contractual terms and oversee the entity’s use of the patented invention throughout the commercialization process. During this negotiation period, the government could invite patent holders to voluntarily license their technology on fair pre-negotiated terms. In exchange, the government could offer tax credits or additional research grants.

Next, a monetary threshold provision should be added when march-in rights are being considered. Transparency is paramount in this scenario. Instead of a forceful government march-in, Bayh-Dole could be amended to specify that if the drug price of a federally funded drug exceeds its production cost by a specific value, or if more than a certain percentage of patients report being unable to access the drug due to cost, then the government can begin its review and march-in process. Most importantly, since this solution is meant to be collaborative, the patent holder would not

---

<sup>115</sup> 35 U.S.C. § 203(a).

lose their exclusivity rights. Rather, the government and federally funded institutions would work together and potentially create voluntary licensing agreements, tiered pricing models, or temporary government-use licenses, as authorized by U.S.C. Section 1498.

#### CONCLUSION

Ironically, the government has misused its Bayh-Dole powers for over 40 years without ever enforcing them. Criticism and controversy remain. Proposals to amend Bayh-Dole to allow for march-in rights when drug prices are high have been discussed for 40 years, yet no change has been made. Similarly, in other countries, compulsory licensing laws are rarely threatened or used. Yet, the drug prices in the U.S. remain the highest in the world.

Bayh-Dole has not failed, but reform is necessary for it to work as intended. Amending the Bayh-Dole Act to clarify when march-in rights apply, implementing threshold-based provisions, and, most importantly, fostering collaboration between the government and federally funded institutions, would give it a greater and more effective purpose.

# Overlapping Surgery

Greta Bosco

## I. A CASE STUDY IN OVERLAPPING SURGERY

Imagine that you have consented to surgery with a particular surgeon, and when you wake up, you learn that the surgeon was not present for the entire duration of your procedure. That experience reflects a common knowledge gap between what patients reasonably believe they have authorized during an informed consent process and how overlapping surgery practices function within many hospitals. Overlapping surgery occurs when one attending physician manages two operating rooms while being present for the critical portions of both surgeries.<sup>1</sup> This practice of overlapping surgery is a lawful practice within the medical field.<sup>2</sup> However, the policies for overlapping surgery lack uniform and enforceable requirements that could ensure transparent informed consent and postoperative disclosure of what occurred during surgery. Without both transparent informed consent and postoperative disclosure, patients will lack information they reasonably expect.<sup>3</sup> It is an insufficient solution to prohibit this practice, because when done correctly, it can shorten wait times, maintain operating room efficiency, increase patient access to surgical care, and support resident training under supervision.<sup>4</sup>

---

<sup>1</sup> S. COMM. ON FIN., CONCURRENT AND OVERLAPPING SURGERIES: ADDITIONAL MEASURES WARRANTED 1 (Dec. 6, 2016), <https://www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf> (“the practice involves a surgeon scheduling and conducting operations on two different patients during the same period of time.”).

<sup>2</sup> 42 C.F.R. § 415.172 (2022).

<sup>3</sup> 42 C.F.R. § 415.172 (2022); Daniel R.S. Habib, George Lin & Alexander Langerman, *Gaps in Informed Consent for Intimate Exams Under Anesthesia*, 281 ANNALS SURGERY 723, 723–24 (2025); AM. COLL. SURGEONS, *Statements on Principles*, § II, AM. COLL. SURGEONS (Apr. 12, 2016), <https://www.facs.org/about-ac/s/statements/sto-principles/> [hereinafter ACS].

<sup>4</sup> Daniel Pereira & Donald H. Lee, *What Is the Current Understanding of Overlapping Surgery in Orthopedics, Particularly as it Relates to Patient Outcomes and Perceptions?* 479 CLINICAL ORTHOPEDICS & RELATED RSCH. 1208, 1208 (2020); Erik Zachwieja et al.,

Accordingly, this article aims to advance a policy framework that preserves the clinical and operational benefits of overlapping surgery while imposing clear, enforceable standards for preoperative disclosure and postoperative transparency that align patient expectations with surgical reality. This article proposes continued enforcement of transparent informed consent in addition to a mandatory postoperative debrief after overlapping surgery in Illinois hospitals. An amended policy will align existing law with patient transparency and institutional compliance to support patients' trust in providers and the overall healthcare system. Such policy will require disclosure of the overlapping surgeries, the role and presence of the attending physician with a mandatory debrief identifying participating surgeons in the critical part of the surgery, any deviation from the consented plan, and the duration of such deviation.

## II. CURRENT LANDSCAPE OF HOSPITALS' OVERLAPPING SURGERY PRACTICES

Overlapping surgery is a common practice in many American hospitals today, yet studies show that it remains a source of public concern, particularly when patients feel uncertain about the surgeon's presence or role during their procedure.<sup>5</sup> In this practice, a single attending surgeon manages two operating rooms, remaining physically present for every

---

*Overlapping Surgery Increases Operating Room Efficiency Without Adversely Affecting Outcomes in Total Hip and Knee Arthroplasty*, 35 J. ARTHROPLASTY 1529, 1532 (2020).  
<sup>5</sup> ACS, *supra* note 3, § II; S. COMM. ON FIN., *supra* note 1, at 1–3; Alexandra Arambula et al., *Patient Opinions Regarding Surgeon Presence, Trainee Participation, and Overlapping Surgery*, 129 LARYNGOSCOPE 1337, 1338–39 (2019); BOSTON GLOBE: SPOTLIGHT, *Clash in the Name of Care: Is It Right or Safe for Surgeons to Run Two Operations at Once?* (Dec. 20, 2015), <https://apps.bostonglobe.com/spotlight/clash-in-the-name-of-care/story/> (on file with author).

critical step and immediately available for the rest of the surgery.<sup>6</sup> Work that is not considered critical, such as opening, closing, or routine hemostasis, can be handled by qualified members of the team while the attending steps out briefly to perform a critical portion of a different ongoing surgery in another room.<sup>7</sup>

It is important to distinguish between overlapping and concurrent surgeries because one is professionally accepted within the medical field, while the other is not.<sup>8</sup> In overlapping surgeries, one patient may be in a non-critical phase while the surgeon performs the key step next door, then the surgeon returns.<sup>9</sup> In contrast, concurrent surgery differs because the critical parts of two cases occur simultaneously, and professional guidelines do not permit such an approach.<sup>10</sup> Understanding these differences shows the permissibility of overlapping surgeries and the important role this practice serves medicine, including increasing patients' access to care, increasing efficiency in the operating rooms, and providing valuable training for surgical residents.<sup>11</sup> This article does not aim to prohibit the practice but to ensure its transparency with patients through policy reform.

#### *A. The Disclosure Problem*

A persistent problem in the practice of overlapping surgery is the lack of transparent disclosure: patients are rarely notified that their operation will overlap, and instead receive information in convoluted

---

<sup>6</sup> ACS, *supra* note 3, § II (D).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> Arambula et al., *supra* note 5, at 1337.

language that fails to explain what surgical overlap truly entails.<sup>12</sup> A recent review of U.S. hospital consent forms found that detailed information about overlapping surgery is typically not included.<sup>13</sup> When the topic appears, if at all, consent forms seldom state whether the attending will be physically present or absent; instead, the forms fold the issue into generic language about trainee participation.<sup>14</sup> For example, a University of Illinois Health surgical consent form states:

I am aware that the treatment and care at UI Health may come from people in its training programs. These people may include resident doctors, medical students, and other health students. They might also perform diagnostic tests or healing procedures on me. They will do these things while being supervised by experienced clinicians.<sup>15</sup>

This language addresses trainees but says nothing about the attending's presence during critical steps or whether the case will overlap with another, leaving patients without the information a reasonable person would want before consenting to an invasive surgical procedure.<sup>16</sup>

There are many reasons patients need to be properly informed before consenting to a procedure. One of the most important reasons is that information about an attending's presence and overlapping procedures changes how patients feel about proceeding with the surgery.<sup>17</sup> Qualitative interviews show that patient comfort levels decline as the attending's

---

<sup>12</sup> Michelle M. Mello & Edward H. Livingston, *The Evolving Story of Overlapping Surgery*, 318 JAMA 233, 234 (2017).

<sup>13</sup> *Id.*

<sup>14</sup> Habib et al., *supra* note 3 at 723–24; Mello & Livingston, *supra* note 12 at 233.

<sup>15</sup> UNIV. ILL. HOSP. & HEALTH SCI. SYS., *Consent for Treatment & Authorization (Form UI 3448)* (2020), <https://hospital.uillinois.edu/documents/PatientAndVisitors/UI-3448-Consent-for-Treatment.pdf> [hereinafter UNIV. ILL. HOSP.].

<sup>16</sup> Mello & Livingston, *supra* note 12, at 234.

<sup>17</sup> *Id.*

presence and availability decrease. Patient's experienced 94% comfort when the attending is present; 78% when the attending is absent for closure; 63% when the attending is absent and unavailable.<sup>18</sup> Alternatively, patients' comfort improves when patients can meet the covering attending, understand the clinician's experience and the role that the physician has in their care.<sup>19</sup> This type of clarity and access to digestible information is what patients use to make an informed decision, rather than the vague language typically seen in informed consent documents.<sup>20</sup> These vague consent forms highlight the necessity of a comprehensive consent discussion between the attending physician and the patient to ensure the patient's comprehension of the scope of the procedure and possible risks, benefits, or alternatives that are available to them.<sup>21</sup>

### *B. Lessons from the 2024 Consent Reforms*

The medical profession faced a similar problem regarding informed consent in April of 2024, when the U.S. Department of Health and Human Services (HHS) issued revised national guidance on intimate exams performed while patients are under anesthesia.<sup>22</sup> Historically, it was common for pelvic, breast, or prostate exams to be performed while under anesthesia for an unrelated procedure for teaching purposes without a

---

<sup>18</sup> Arambula et al., *supra* note 5, at 1338–39.

<sup>19</sup> *Id.* at 1340.

<sup>20</sup> UNIV. ILL. HOSP., *supra* note 15.

<sup>21</sup> Margherita Pallocci et al., *Informed Consent: Legal Obligation or Cornerstone of the Care Relationship*, 20 INT'L J. ENV'T RSCH. & PUB. HEALTH 6 (2023), <https://www.mdpi.com/1660-4601/20/3/2118> [<https://doi.org/10.3390/ijerph20032118>].

<sup>22</sup> CTRS. FOR MEDICARE & MEDICAID SERVS., *Revisions and Clarifications to Hospital Interpretive Guidelines for Informed Consent* 5, 1 (Apr. 1, 2024), <https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos-states-and-cms-locations/revisions-and-clarifications-hospital-interpretive-guidelines-informed-consent> [hereinafter CMS MEMORANDUM].

patient's knowledge or explicit permission.<sup>23</sup> This practice was lawful but widely criticized for compromising bodily autonomy and undermining trust in the medical system.<sup>24</sup> In response to public pressure, media investigations, and advocacy from students and physicians, HHS clarified that this longstanding practice was unacceptable.<sup>25</sup>

The 2024 reforms required hospitals to change both their forms and their workflows.<sup>26</sup> Since the 2024 reforms, consent for intimate exams has to be explicit, written, and procedure-specific.<sup>27</sup> Additionally, patients are given the explicit right to refuse such exams, and documentation requirements have been tightened to ensure that the record demonstrates that consent for these exams was obtained.<sup>28</sup> Together, these changes shifted the medical profession from a practice of implied consent toward affirmative, explicit authorization from patients.<sup>29</sup> The result is a new national standard that reflects the principle of bodily autonomy.<sup>30</sup> Even though intimate exams under anesthesia remain lawful when performed with patient permission, the critical change from this new standard is the

---

<sup>23</sup> Emma Goldberg, *She Didn't Want a Pelvic Exam. She Received One Anyway.*, N.Y. TIMES (Feb. 17, 2020), <https://www.nytimes.com/2020/02/17/health/pelvic-medical-exam-unconscious.html> (on file with author).

<sup>24</sup> *Id.*

<sup>25</sup> CMS MEMORANDUM, *supra* note 22, at 3.

<sup>26</sup> CMS MEMORANDUM, *supra* note 22, at 4.

<sup>27</sup> Meghan Rosen, *Pelvic Exams at Hospitals Require Written Consent, New U.S. Guidelines Say*, SCI. NEWS (Apr. 24, 2024), <https://www.sciencenews.org/article/pelvic-exam-informed-consent-guidelines> (on file with author); Hannah Thompson, *Hospitals Must Now Obtain Written Consent for Certain Medical Exams, New Federal Guidance Says*, PBS NEWSHOUR (Apr. 23, 2024), <https://www.pbs.org/newshour/health/hospitals-must-now-obtain-written-consent-for-certain-medical-exams-new-federal-guidance-says>; Pallocci, *supra* note 21, at 6.

<sup>28</sup> Rosen, *supra* note 27; Pallocci, *supra* note 21, at 6.

<sup>29</sup> Rosen, *supra* note 27; Pallocci, *supra* note 21, at 6.

<sup>30</sup> Rosen, *supra* note 27.

revised policy closed the consent gap and established transparency for patients regarding the practice of intimate exams under anesthesia.<sup>31</sup>

The lesson that can be taken from the 2024 reforms is that lawfulness alone does not cure a consent gap.<sup>32</sup> Intimate exams under anesthesia were lawful, but failing to disclose and document them violated patient expectations and bodily autonomy, which are both protected by the informed consent requirement.<sup>33</sup> Similarly, overlapping surgery is also lawful under Medicare rules and professional guidance, but the consent process for overlapping surgery is either vague or missing completely.<sup>34</sup> Just as HHS required explicit disclosure, written authorization, and documentation for intimate exams, overlapping surgery should require a similar consent process to ensure patients are reasonably informed about the details of their surgery.<sup>35</sup> This would also ensure the record proves that disclosure was made, and the documentation reflects that what actually happened during the procedure is consistent with the given consent.<sup>36</sup>

### *C. The Missing Postoperative Debrief*

While informed consent establishes a patient's expectations before surgery, a postoperative debrief verifies for the patient whether those expectations were met and whether the consented plan was actually followed.<sup>37</sup> Even when overlapping surgery is disclosed preoperatively,

---

<sup>31</sup> Rosen, *supra* note 27; Habib et al., *supra* note 3 at 723; 20 ILL. COMP. STAT. 301/30-5 (2025).

<sup>32</sup> Habib et al., *supra* note 3 at 723; 20 ILL. COMP. STAT. 301/30-5 (2025).

<sup>33</sup> Habib et al., *supra* note 3 at 723; 20 ILL. COMP. STAT. 301/30-5 (2025).

<sup>34</sup> CMS MEMORANDUM, *supra* note 22, at 4.

<sup>35</sup> CMS MEMORANDUM, *supra* note 22, at 2–3.

<sup>36</sup> CMS MEMORANDUM, *supra* note 22, at 2–3.

<sup>37</sup> Jennifer Moore, Marie Bismark & Michelle M. Mello, *Patients' Experiences with Communication-and-Resolution Programs After Medical Injury* 177 JAMA INTERNAL MED. 1595, 1596 (2017) [doi: 10.1001/jamainternmed.2017.4002] (explaining that patients reported the disclosure meeting was central to feeling heard and to rebuilding trust).

patients are rarely informed afterward about who was present, which surgeon performed each critical step, or whether coverage changed during the case.<sup>38</sup>

Illinois hospitals currently have no statutory duty to provide postoperative debriefs beyond operative notes and adverse events, which are not designed to communicate the operative process in a manner understandable to patients.<sup>39</sup> As such, postoperative communication through a structured debrief would fill a transparency gap by conveying to the patient who performed each critical portion of the procedure, and whether the attending's presence or coverage varied from the consented plan. Illinois' existing legal framework already recognizes a duty of disclosure after adverse events. The Medical Patient Rights Act guarantees patients "the right to receive information concerning [their] care" and "to be informed of [their] condition and proposed treatment," establishing an expectation that patients will be kept meaningfully informed throughout the course of medical decision-making.<sup>40</sup> That commitment is reinforced at the institutional level by the Hospital Licensing Act, which authorizes the state to regulate hospital practices and enforce compliance with standards designed to protect patient welfare, and by the Adverse Health Care Events Reporting Law of 2005, which requires hospitals to report serious, preventable events to the Department of Public Health.<sup>41</sup> A postoperative debrief would operationalize these transparency principles

---

<sup>38</sup> Mello & Livingston, *supra* note 12, at 234.

<sup>39</sup> 410 ILL. COMP. STAT. 522/10 (2025); Yan Wang et al., *A Study of Actions in Operative Notes*, 21 J. SURG. RES. 420, 421–22 (2013) (stating that "operative reports are created after every surgical procedure for the purposes of documentation and billing").

<sup>40</sup> 410 ILL. COMP. STAT. 50/3 (2025).

<sup>41</sup> 210 ILL. COMP. STAT. 85/1 (2025); 410 ILL. COMP. STAT. 522/1 (2025).

by ensuring that patients are informed not only before surgery, but also after the fact, about what occurred to their bodies during the procedure.<sup>42</sup>

### III. APPLYING THESE LESSONS TO OVERLAPPING SURGERY

Informed consent for overlapping surgery must contain two non-negotiable components to close the current transparency gap: (1) an explicit statement disclosing whether the procedure will overlap with another operation, and (2) a clear acknowledgment that the primary attending surgeon will not be present for the entire case.<sup>43</sup> Building on those basics, a straightforward upgrade must be implemented to existing forms and workflows through a consent process that clearly delineates the role and presence of the surgeon “performing” the surgery, or rather, the critical parts of the surgery.<sup>44</sup> This consent should specify whether overlap is planned, identify the operation’s critical steps which requires the attending to be physically present, and name the covering attending during any absence.<sup>45</sup> To ensure accountability, this consent will be paired with time-stamped intraoperative documentation that verifies who operated at each stage of the surgery and where the attending physician was at those times.<sup>46</sup> Following the surgery, there will be a physician-to-patient debrief on this information and any additional information that was not disclosed in the informed consent process.<sup>47</sup> The result is a solution that adapts the 2024 consent guidelines for intimate exams to the timing and staffing

---

<sup>42</sup> Wendy Levinson & Thomas H. Gallagher, *Disclosing Medical Errors to Patients: A Status Report in 2007*, 177 CANADIAN MED. ASS’N J. 265, 265 (2007); Habib et al., *supra* note 3 at 724; 20 ILL. COMP. STAT. 301/30-5 (2025).

<sup>43</sup> Mello & Livingston, *supra* note 12 at 234.

<sup>44</sup> CMS MEMORANDUM, *supra* note 22, at 4.

<sup>45</sup> Jean-Nicolas Gallant & Alexander Langerman, *How Should Trainee Autonomy and Oversight Be Managed in the Setting of Overlapping Surgery?* 20 AMA J. ETHICS, 342, 346 (2018).

<sup>46</sup> Mello & Livingston, *supra* note 12 at 233.

<sup>47</sup> Mello & Livingston, *supra* note 12 at 233.

consent requirements of overlapping operations. This ensures consent is verifiable with the patient on the event of the surgery.<sup>48</sup>

#### IV. THE SOLUTION

The solution is not to outlaw lawful overlapping surgery, but to align Illinois hospital policy with the existing legal and ethical foundations of informed consent and patient disclosure.<sup>49</sup> State law already recognizes a patient’s right to receive information about their care, but existing statutory protections are largely confined to the preoperative informed-consent process and do not impose clear obligations for postoperative disclosure.<sup>50</sup> Illinois law, including the Hospital Licensing Act and the Medical Patient Rights Act, require hospitals and physicians to safeguard patient rights and ensure that individuals are “informed of their condition and proposed treatment.”<sup>51</sup> Yet, these legal protections are largely confined to the preoperative informed-consent process and do not impose clear requirements for postoperative discussions verifying whether the consented plan was actually followed.<sup>52</sup>

Illinois should amend section 6.17 of the Hospital Licensing Act (210 ILCS 85/6.17) to include a new subsection mandating a postoperative debrief after every surgical procedure, including those performed under an overlapping-surgery model.<sup>53</sup> This amendment would establish a

---

<sup>48</sup> CMS MEMORANDUM, *supra* note 22, at 2–3.

<sup>49</sup> 42 C.F.R. § 482.13(b)(2) (2025) (requiring hospitals to ensure that patients “are informed of their health status” and can participate in their care).

<sup>50</sup> 410 ILL. COMP. STAT. 50/3(a) (2025); 735 ILL. COMP. STAT. 5/2-622 (2025); 410 ILL. COMP. STAT. 522/1 (2025).

<sup>51</sup> 410 ILL. COMP. STAT. 50/3(a) (2025); 210 ILL. COMP. STAT. 85/1 (2025).

<sup>52</sup> 410 ILL. COMP. STAT. 50/3(a) (2025); 210 ILL. COMP. STAT. 85/1 (2025).

<sup>53</sup> 210 ILL. COMP. STAT. 85/6.17 (2025) (authorizing the Department of Public Health to regulate surgical services and establish standards for safe hospital practice).

structured, surgeon-led conversation with the patient to confirm what occurred during the operation and whether the attending's role and presence conformed to the plan described during consent. The following is the proposed amendment to Illinois Statute 210 ILCS 85/2.17(f):

For any surgical procedure conducted in a hospital licensed under this Act, the attending surgeon or designee shall provide a postoperative disclosure ('debrief') to the patient or, when appropriate, the patient's authorized representative. The debrief shall include:

- (1) the identity of all attending physicians present for each critical portion of the operation;
- (2) any participation by other attendings or covering surgeons during those portions;
- (3) any participation by trainees or students in the procedure and the supervision provided for that participation.
- (4) a summary of the intraoperative course, including any unanticipated deviation from the consented plan; and
- (5) an explanation of the patient's immediate postoperative outcome and next steps in care.

When any portion of the operation was performed as part of an overlapping or teaching surgery, the disclosure shall specify the timing and duration of any overlap, the attending's availability, and the covering physician's identity. Documentation of the debrief shall be included in the patient's medical record in accordance with 42 C.F.R. § 482.24 and applicable CMS Conditions of Participation.

This statutory addition would convert postoperative debriefing from a voluntary ethical practice into a licensure-based requirement enforceable by the Illinois Department of Public Health (IDPH).<sup>54</sup> Such an approach parallels the transparency obligations already imposed under the Adverse

---

<sup>54</sup> 210 ILL. COMP. STAT. 85/6.17 (2025); ILL. DEP'T PUB. HEALTH, *Hospital Licensing*, <https://dph.illinois.gov/topics-services/health-care-regulation/hospitals.html> (last visited Sept. 25, 2025).

Health Care Events Reporting Law of 2005, but extends those obligations proactively to all surgical cases rather than waiting until harm occurs.<sup>55</sup> Implementing this reform would integrate patient transparency for overlapping surgeries into the same statutory structure that already governs informed consent, documentation, and patient rights in Illinois hospitals.

#### V. CONCERNS WITH MANDATING POSTOPERATIVE DEBRIEF

Critics may argue that requiring a statutory postoperative debrief adds unnecessary bureaucracy to an already heavily regulated health care system. However, Illinois hospitals already operate under a licensure framework that conditions operations on compliance with the Hospital Licensing Act and regulations promulgated by the Illinois Department of Public Health (IDPH).<sup>56</sup> This proposal would not create a new layer of oversight, but would instead extend the existing patient-communication standards to the postoperative period of care to ensure transparency under the same statutory authority that already governs informed consent and hospital reporting.<sup>57</sup>

Another foreseeable concern might relate to the time or efficiency of mandating an informative debrief with the patient. However, structured debrief programs have been successfully implemented in high-volume surgical centers without significant workflow disruption and have been shown to improve team communication, capture intraoperative deviations, and enhance safety culture.<sup>58</sup> Since hospitals already conduct structured

---

<sup>55</sup> 410 ILL. COMP. STAT. 522/10 (2025).

<sup>56</sup> 210 ILL. COMP. STAT. 85/3(a) (2025); ILL. DEP'T PUB. HEALTH, *supra* note 54.

<sup>57</sup> 410 ILL. COMP. STAT. 50/3(a) (2025).

<sup>58</sup> Katharina Brigitte Margarethe Siew Lan Leong et al., *Effects of Perioperative Briefing and Debriefing on Patient Safety: A Prospective Intervention Study*, *BMJ OPEN*, Oct. 2017 at

postoperative debriefings internally to assess performance and patient safety, Illinois can reasonably require that comparable transparency be extended to patients.<sup>59</sup>

Others worry that disclosing attending coverage or deviations from the consented plan may provoke anxiety or litigation.<sup>60</sup> Yet empirical studies show that patients respond more positively to honest communication than to silence.<sup>61</sup> Research on communication-and-resolution programs (CRPs) demonstrates that when hospitals proactively explain what occurred, patients report higher satisfaction and a stronger sense of trust in their physicians.<sup>62</sup> Ethical standards mirror these findings as the AMA Code of Medical Ethics recognizes that postoperative disclosure demonstrates respect for patient autonomy and fosters trust.<sup>63</sup> Similarly, open-disclosure research confirms that debriefing enables patients to “reclaim agency and understanding” after surgery, transforming a potentially adversarial encounter into one rooted in transparency and respect.<sup>64</sup>

Finally, critics may contend that operative notes already fulfill this purpose. However, operative reports serve regulatory, billing, and

---

2; Mary E. Brindle et al., *Implementation of Surgical Debriefing Programs in Large Health Systems: An Exploratory Qualitative Analysis*, BMC HEALTH SERV. RSCH., 2018, at 5, 7.

<sup>59</sup> Leong et al., *supra* note 58, at 2; Brindle et al., *supra* note 58, at 5, 7.

<sup>60</sup> Rick Iedema et al., *Patients' and Family Members' Views on How Clinicians Enact and How They Should Enact Incident Disclosure: The "100 Patient Stories" Qualitative Study*, 20 INT'L J. FOR QUALITY IN HEALTH CARE, 2011, at 1–2.

<sup>61</sup> Levinson, *supra*, note 42, at 265; Iedema et al., *supra* note 60, at 2.

<sup>62</sup> Moore, *supra* note 37, at 3.

<sup>63</sup> AM. MED. ASS'N, *Code of Medical Ethics Op. 8.6, Promoting Patient Safety*, <https://code-medical-ethics.ama-assn.org/ethics-opinions/promoting-patient-safety> (last visited Feb. 12, 2026) (stating that disclosure of adverse events “is fundamental to the trust in the patient-physician relationship”); AM. MED. ASS'N, *Code of Medical Ethics Op. 2.1.3, Withholding Information from Patients*, <https://code-medical-ethics.ama-assn.org/ethics-opinions/withholding-information-patients> (last visited Feb. 12, 2026) (explaining that “respect for patient autonomy” requires providing patients with the information necessary for informed decision-making).

<sup>64</sup> Iedema et al., *supra* note 60, at 423–24.

continuity-of-care functions, not patient comprehension.<sup>65</sup> Federal law (42 C.F.R. § 482.24) and CMS guidelines define these documents as proof of compliance and medical necessity for payment.<sup>66</sup> A patient-centered postoperative debrief, therefore, fills the communication gap left by administrative documentation, bridging what the law requires hospitals to record with what patients deserve to know.

#### CONCLUSION

Overlapping surgery is not inherently improper medical practice because, when properly supervised, it promotes efficiency, resident education, and timely patient access to care.<sup>67</sup> The real issue lies in ensuring its transparency. While Illinois law guarantees that patients are informed before surgery, there is no statutory mandate ensuring patients are told afterward who performed the critical portions of the operation or whether the attending's role deviated from the consented plan.<sup>68</sup> The absence of such communication creates a knowledge gap between what is promised during informed consent and what actually occurs in the operating room.

An amendment to the Hospital Licensing Act to require a postoperative debrief would close this knowledge gap by transforming an ethical ideal of transparency into a licensure-based obligation enforceable by IDPH.<sup>69</sup>

---

<sup>65</sup> 42 C.F.R. § 482.24(c)(1)(v) (2025); CTRS. FOR MEDICARE & MEDICAID SERVS., MLN006347, GUIDELINES FOR TEACHING PHYSICIANS, INTERNS, & RESIDENTS 10–11 (2024) [hereinafter CMS GUIDELINES].; M.B. Flynn et al., *The Operative Note as Billing Documentation*, 170 AM. J. SURG. 507 (1995).

<sup>66</sup> CMS GUIDELINES, *supra* note 65, at 10–11.

<sup>67</sup> See ACS, *supra* note 3, at § II(D).

<sup>68</sup> 410 ILL. COMP. STAT. 50/3(a) (2025).

<sup>69</sup> 210 ILL. COMP. STAT. 85/3(a) (2025).; 210 ILL. COMP. STAT. 85/6.17 (2025); ILL. DEP'T PUB. HEALTH, *supra* note 54.

This reform would align Illinois’s regulatory framework with federal patient-rights standards, which guarantee that patients “receive information concerning [their] care.”<sup>70</sup> It would also complement the Adverse Health Care Events Reporting Law of 2005, which requires disclosure after unanticipated outcomes by ensuring that patients are informed even when no harm occurs.<sup>71</sup> The mandated debriefing would integrate seamlessly with Illinois’s existing statutory structure. Since hospitals document operative details for compliance and quality assurance, adding a short postoperative, surgeon-led explanation for the patient makes those disclosures meaningful outside of the patient’s chart. By codifying this duty, Illinois would create a continuous model of transparency where informed consent and postoperative disclosure operate as a single continuum of respect for patient autonomy.<sup>72</sup> This reform would not disrupt surgical workflow or restrict clinical judgment, but it would ensure that patient trust in medicine is preserved through honest and complete transparency.

---

<sup>70</sup> 42 C.F.R. § 482.13(b)(2) (2025).

<sup>71</sup> 410 ILL. COMP. STAT. 522/10 (2025).

<sup>72</sup> Levinson & Gallagher, *supra*, note 42, at 266.

# Modernizing U.S. Food & Drug Law for Synthetic Biologics

*Briana Crowley*

## I. SYNTHETIC BIOLOGY BACKGROUND

Synthetic biology involves designing and engineering new biological components—like enzymes, genetic circuits, and cells—or modifying existing biological systems to perform new functions.<sup>1</sup> In simpler terms, scientists use synthetic biology to “build” biology: they can reprogram how living systems behave in order to produce medicines, vaccines, or other useful materials.<sup>2</sup> This rapidly evolving, interdisciplinary field has already begun to reshape how modern drugs and vaccines are made, enabling researchers to design biologic products through modular manufacturing techniques.<sup>3</sup> Messenger-RNA vaccines and viral-vector therapies, for example, use a reusable manufacturing framework that can be adapted for new diseases simply by changing the genetic instructions inserted into it.<sup>4</sup> This flexibility allowed researchers to produce COVID-19 vaccines in record time, drawing on years of federally funded work on lipid nanoparticles and mRNA chemistry.<sup>5</sup>

Despite these advances, U.S. laws regulating medical products were written for an earlier era. The Federal Food, Drug, and Cosmetic Act (FDCA) regulates both drugs and biologics, requiring that manufacturers obtain a biologics license application for the latter.<sup>6</sup> The Public Health

---

<sup>1</sup> ENG’G BIOL. RSCH. CONSORTIUM (EBRC), *What is Synthetic/Engineering Biology?*, <https://ebrc.org/what-is-synbio/> (last visited Nov. 16, 2025).

<sup>2</sup> *Id.*

<sup>3</sup> Sagardip Majumder & Allen P. Liu, *Bottom-Up Synthetic Biology: Modular Design for Making Artificial Platelets*, 15 *PHYS. BIOL.* 013001 (2018), <https://doi.org/10.1088/1478-3975/aa9768>.

<sup>4</sup> Sara Sousa Rosa et al., *mRNA Vaccines Manufacturing: Challenges and Bottlenecks*, 39 *VACCINE* 2190, 2191 (2021), <https://doi.org/10.1016/j.vaccine.2021.03.038>.

<sup>5</sup> *Id.*

<sup>6</sup> FDA, *Frequently Asked Questions About Therapeutic Biological Products* (May 16, 2024), <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products>.

Service Act (PHSA) separately requires biologics licenses under Section 351.<sup>7</sup> Neither statute explicitly anticipates biologics that share an identical framework or production method across multiple products. As a result, developers often submit complete Investigational New Drug (IND) applications for each new antigen or therapeutic target regardless of the manufacturing data similarities.<sup>8</sup>

The absence of a statutory pathway for what this Article calls “synthetic biologics” has practical and normative consequences. It can slow regulatory response during public health emergencies, obscure the scale of federal investment in underlying platforms, and leave no mechanism for ensuring that publicly funded science yields public benefit. This Article argues that Congress should amend PHSA § 351 to recognize synthetic biologics, abbreviate reviews of products, require disclosure of federal research support in approval submissions, and mandate consideration of dual-use concerns.

## II. STATUTORY AND REGULATORY BACKGROUND

The FDCA, first enacted in 1938 and repeatedly amended, provides the central framework for FDA oversight of drugs and certain biologics.<sup>9</sup> Section 505 requires sponsors of “new drugs” to demonstrate safety and effectiveness before marketing.<sup>10</sup> Although the statute has been updated

---

<sup>7</sup> *Id.*

<sup>8</sup> Glenn Petrie, *Antibody Drug Conjugate Development: Keys to Rapid IND Submission and Approval*, EAG LABS, (rev. Jan. 5, 2018), <https://www.eag.com/wp-content/uploads/2018/01/M-028517-Keys-to-Rapid-IND-Submission.pdf>.

<sup>9</sup> CLINTON LAM & PREETI PATEL, *Food, Drug, and Cosmetic Act*, in STATPEARLS. (July 31, 2023), <https://www.ncbi.nlm.nih.gov/books/NBK585046/>.

<sup>10</sup> FDA GRP, *FDA’s 505(b)(2) Explained: A Guide to New Drug Applications* (July 17, 2024), <https://www.thefdagroup.com/blog/505b2>.

to allow accelerated approval and other flexible mechanisms, it continues to assume that each application concerns a distinct, self-contained product.<sup>11</sup> FDA guidance on emergency use authorizations (EUAs) offers expedited review in crises but does not alter the baseline requirement that every formulation be evaluated individually.<sup>12</sup>

Licensure of most biologics occurs under § 351 of the PHSA, a provision dating back to the Act's original enactment in 1944.<sup>13</sup> Section 351 focuses on the safety, purity, and potency of biological products.<sup>14</sup> In practical terms, this means that before a biologic can be marketed, a sponsor must obtain a Biologics Application (BLA) demonstrating that both the product and the manufacturing process meet rigorous standards.<sup>15</sup> Unlike a New Drug Application (NDA) under the FDCA, which emphasizes clinical safety and efficacy, the BLA process places heavier weight on the control of production and facilities because biologics are derived from living systems and therefore inherently variable.<sup>16</sup> To receive licensure, manufacturers must also permit FDA inspection of facilities and provide detailed chemistry, manufacturing, and control (CMC) data demonstrating that each batch of product conforms to the licensed

---

<sup>11</sup> FDA, *Accelerated Approval Program* (Dec. 24, 2024), <https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approval-program>.

<sup>12</sup> FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.

<sup>13</sup> Public Health Service Act of 1944, Pub. L. No. 78-410, § 351, 58 Stat. 682, 702 (1944), <https://govtrackus.s3.amazonaws.com/legislink/pdf/stat/58/STATUTE-58-Pg682a.pdf>.

<sup>14</sup> DDREG PHARMA, *What Are 351a 351k In Biologics*, <https://www.ddregpharma.com/what-are-351a-351k-in-biologics>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

specifications.<sup>17</sup> Section 351 lacks any mechanism for licensing a manufacturing process or molecular scaffold that could support multiple derivatives.<sup>18</sup> Consequently, even if a company uses an identical platform or delivery system, each new product must independently demonstrate compliance with the safe, pure, and potent standard.<sup>19</sup>

The FDA has adapted within existing statutory boundaries. During the COVID-19 pandemic, the agency issued EUAs for mRNA vaccines after reviewing extensive chemistry, manufacturing, and control data on the underlying production process.<sup>20</sup> Yet the EUAs were product-specific; later vaccines using similar lipid nanoparticles and mRNA synthesis would need to present a full evidentiary package, although there is some reliance on prior data. Scholars have noted that this case-by-case approach may slow down the release timeline when only a genetic insert changes while the manufacturing platform remains stable.<sup>21</sup>

### III. CHALLENGES POSED BY SYNTHETIC BIOLOGICS

Synthetic biologics often rely on a modular, platform-based approach that uses the same core technologies or molecular frameworks. For instance, mRNA vaccines may differ only in the nucleotide sequence coding for an antigen, while the lipid nanoparticle formulation and

---

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> FDA *supra* note 12.

<sup>21</sup> Mehrshid Alai-Safar et al., *Regulatory and Manufacturing Pathways to Expand Access to Genetically Modified Cell-Based Therapies*, FRIENDS OF CANCER RESEARCH & PARKER INST. FOR CANCER IMMUNOTHERAPY, at 8 (rev. Jan. 5, 2025), <https://friendsofcancerresearch.org/wp-content/uploads/Regulatory-and-Manufacturing-Pathways-to-Expand-Access-to-Genetically-Modified-Cell-Based-Therapies.pdf>.

production methods remain constant.<sup>22</sup> Regardless, the FDCA and PHSA necessitate that each formulation undertake an evidentiary review. This repetition consumes agency resources and delays access to urgently needed products, particularly in outbreak settings.<sup>23</sup>

A second difficulty concerns the disclosure of government contributions to the science underlying synthetic biologics. Federal funding has supported many of the basic technologies that enabled recent vaccines, including mRNA chemistry, lipid carriers, and large-scale manufacturing equipment.<sup>24</sup> Yet the FDCA does not explicitly require sponsors to disclose direct federal grants in approval applications.<sup>25</sup> For this reason, regulators and the public cannot accurately assess the magnitude to which taxpayer dollars de-risked product development or whether public-interest licensing obligations attach to the underlying inventions.<sup>26</sup>

The absence of statutory tools to integrate public-return conditions has downstream effects on affordability and availability. Products that have been developed with the aid of public research may result in monopoly prices even amid emergencies. Scholars have debated over whether this

---

<sup>22</sup> Linde Schoenmaker et al., *mRNA-lipid Nanoparticle COVID-19 Vaccines: Structure and Stability*, 601 INT'L J. PHARMACEUTICS 120586 (2021), <https://pubmed.ncbi.nlm.nih.gov/33839230/>.

<sup>23</sup> SUSANNE HEMPEL ET AL., *Resource Allocation and Pandemic Response: An Evidence Synthesis To Inform Decision Making*, (AGENCY FOR HEALTHCARE RSCH. & QUALITY, Oct. 5, 2020), <https://www.ncbi.nlm.nih.gov/books/NBK562921/>.

<sup>24</sup> Hussain S Lalani et al., *US Public Investment in Development of mRNA Covid-19 Vaccines: Retrospective Cohort Study*, 380 BMJ E587 (2023), <https://www.bmj.com/content/380/bmj.p587>.

<sup>25</sup> Katherine R. Leibowitz, *FDA Issues Draft Guidance on Financial Disclosure by Clinical Investigators*, REGUL. AFFS. PROS. SOC'Y (RAPS) (2011), [https://www.hoganlovells.com/-/media/hogan-lovells/pdf/publication/raps-financial-disclosure-article--july-2011\\_pdf.pdf](https://www.hoganlovells.com/-/media/hogan-lovells/pdf/publication/raps-financial-disclosure-article--july-2011_pdf.pdf).

<sup>26</sup> Ian Ayres & Lisa Larrimore Ouellette, *A Market Test for Bayh-Dole Patents*, 102 CORNELL L. REV. 271, 273-74 (2017).

could cause a strain on public budgets and limit widespread distribution.<sup>27</sup> The Bayh-Dole Act imparts on federal agencies the authority to proceed over the original patent created with federal support. However, this is seldom used and does not pertain to all intellectual property relevant to biologics.<sup>28</sup> Incorporating cost-effective solutions or open-licensing conditions into product certification—specifically for items substantially financed by federal spending—would potentially help to secure public shares in the benefits of its investment.

In the end, synthetic biologics can raise dual concerns because the same methods used to create beneficial vaccines or therapies could also be used to make harmful agents.<sup>29</sup> The FDA's framework for approving biologics is based on a comprehensive benefit-risk assessment.<sup>30</sup> However, this framework does not explicitly account for dual-use risks inherent in synthetic biology, where the same manufacturing tools could be misapplied to create harmful agents. Addressing such risks within product review would ensure that innovation in biologics proceeds with appropriate safeguards.

---

<sup>27</sup> Helen Yu, *Return of Benefit to Society of Publicly Funded Innovations to Combat COVID-19*, J. HEALTH CARE ORG., PROVISION, & FIN., Jan.-Dec. 2021., <https://pmc.ncbi.nlm.nih.gov/articles/PMC8649745/>.

<sup>28</sup> Emily G. Blevins & Kevin J. Hickey, *Pricing and March-In Rights Under the Bayh-Dole Act*, CONGRESS.GOV (Dec. 3, 2024), <https://www.congress.gov/crs-product/IF12582>.

<sup>29</sup> Yakun Ou & Shengjia Guo, *Safety Risks and Ethical Governance of Biomedical Applications of Synthetic Biology*, 11 FRONTIERS BIOENG'G & BIOTECH. 1292029 (2023), <https://doi.org/10.3389/fbioe.2023.1292029>.

<sup>30</sup> Leila Lackey, Graham Thompson, & Sara Eggers, *FDA's Benefit-Risk Framework for Human Drugs and Biologics: Role in Benefit-Risk Assessment and Analysis of Use for Drug Approvals*, 55 THERAP. INNOVATION & REGUL. SCI. 170 (2020), <https://link.springer.com/article/10.1007/s43441-020-00203-6>.

#### IV. PROPOSED REFORMS

Three reforms would modernize the regulation of synthetic biologics under the Public Health Service Act. First, Congress should define and recognize “synthetic biologics” as a distinct statutory category to reflect the platform-based nature of contemporary biologic development. Second, the FDA should be authorized to abbreviate review for products derived from an already licensed manufacturing platform or molecular scaffold, allowing regulatory scrutiny to focus on genuinely novel risks rather than duplicative data. Third, biologics licensure should expressly incorporate consideration of dual use risks inherent in synthetic biology. These reforms are not alternatives but complements: each addresses a distinct regulatory gap, and together they promote efficiency, transparency, and security while preserving rigorous oversight.

##### *A. Define “Synthetic Biologic” in the Statute*

Congress should amend § 351 of the Public Health Service Act (PHSA) to define and recognize a new category of “synthetic biologics.” A statutory definition could describe a synthetic biologic as a “biological product manufactured using an adaptable platform, scaffold, or process that can be reused to create different products.” Adding this language directly to §351 would enable the FDA to distinguish between traditional biologics and products built from shared manufacturing backbones, ensuring that regulatory expectations match technological reality.<sup>31</sup>

---

<sup>31</sup> *Emergency Technology Program (ETP)*, FDA (Feb. 2, 2025), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program-ctp>. (suggesting that definitional clarity is crucial for the FDA to exercise consistent authority over emerging biomedical technologies).

Adding this language directly to §351 would enable the FDA to distinguish between traditional biologics and products built from shared manufacturing backbones, ensuring that regulatory expectations match technological reality.<sup>32</sup>

Section 351 of the PHSA currently requires that biologic products be “safe, pure, and potent” and authorizes the Secretary of Health and Human Services to issue licenses for their manufacture.<sup>33</sup> The statute incorporates many FDCA enforcement provisions but does not specify how its requirements should interact with any future FDCA amendments addressing synthetic biologics.<sup>34</sup> To avoid overlap or regulatory gaps, Congress should insert language clarifying that § 351 licensure may rely on a platform approval issued under the FDCA, provided the product-specific data support safety and potency for the intended indication. This coordination would permit the FDA’s biologics center to leverage platform evaluations conducted under the FDCA while preserving the independent licensing function required by § 351.

*B. Abbreviate Reviews of Products with the Same Manufacturing Process or Molecular Scaffold*

Congress should authorize the FDA to license not only finished biologic products but also the manufacturing process or molecular scaffold that supports them. Sponsors could seek the initial “Platform Biologics

---

<sup>32</sup> *Artificial Intelligence in Software as a Medical Device*, FDA (Mar. 25, 2025), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device>. (noting that without definitional clarity, the FDA must rely on guidance documents or ad hoc interpretations, which can create uncertainty for sponsors and investors).

<sup>33</sup> 42 U.S.C. § 262 (2022).

<sup>34</sup> *Id.*

License” demonstrating safety, purity, and potency of the process, as is tested in the BLA Process.<sup>35</sup> Once the FDA approves the platform, subsequent products that merely swap a genetic insert or antigen could undergo an abbreviated review, akin to the way the agency reviews seasonal influenza vaccines.<sup>36</sup>

A platform-licensing model would align statutory authority with current regulatory practice, where FDA informally evaluates shared data across related mRNA vaccines but lacks an explicit mechanism to recognize the platform itself.<sup>37</sup> Such a pathway could shorten approval timelines in emergencies without sacrificing evidentiary standards, provided the FDA retains discretion to require full submissions if manufacturing changes pose new risks.

Platform Supplement for biologics, whose safety and manufacturing characteristics has been reviewed through platforms license, could be accepted by the FDA should congress authorize it. Similar to the supplemental biologics license process for seasonal influenza vaccines, the Platform Supplement would permit expedited evaluation when the only change is the genetic or antigenic component inserted into a previously licensed chassis.<sup>38</sup> Such a procedure would codify existing regulatory

---

<sup>35</sup> *The Biologics License Application (BLA) Process Explained*, FDA GRP. (Sep. 10, 2024), <https://www.thefdagroup.com/blog/2014/07/test-the-biologics-license-application-bla-process/>.

<sup>36</sup> Annalee Armstrong, *FDA Rolls Out Platform Technology Guidance to Smooth Future Regulatory Encounters*, FIERCE BIOTECH (May 30, 2024), <https://www.fiercebiotech.com/biotech/fda-rolls-out-platform-technology-guidance-smooth-future-regulatory-encounters>.

<sup>37</sup> John H Skerritt et al., *The Platform Technology Approach to mRNA Product Development and Regulation*, PUBMED CENT. (May 11, 2024), <https://pmc.ncbi.nlm.nih.gov/articles/PMC11126020/>.

<sup>38</sup> *Id.*

practices—where the agency informally relies on prior data for similar mRNA vaccines—but would anchor it in statutory text. By reducing unnecessary duplication, the approach would conserve agency resources and accelerate public access to countermeasures in emergencies.

*C. Require FDA to Consider Dual-Use Concerns During Review*

A third reform would require the FDA to consider potential dual-use concerns when reviewing synthetic biologics under § 351. The statute could direct the Secretary of Health and Human Services to request a Dual-Use Risk Assessment from applicants whose products involve genome editing, viral vectors, or other techniques with plausible misuse potential. While the FDA currently considers biosafety and manufacturing integrity through its inspection and quality-control programs, there is no formalized or standardized mechanism for evaluating how a biologic platform might be repurposed for harmful applications.<sup>39</sup> The proposed assessment would fill that gap by requiring sponsors to identify foreseeable misuse scenarios and describe the safeguards in place—such as personnel vetting, biosecurity training, controlled-material inventories, and physical or cyber protections of production data. This approach would parallel existing guidance developed by the National Science Advisory Board for Biosecurity (NSABB) and the Department of Health and Human Services’ framework for dual-use research of concern (DURC) but would extend those principles into the product-licensing context, where they currently

---

<sup>39</sup> *Developing and Manufacturing Drugs Including Biologics*, FDA (Dec. 30, 2020), <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/developing-and-manufacturing-drugs-including-biologics>.

do not apply.<sup>40</sup> This assessment would summarize safeguards in manufacturing and distribution, such as biosecurity training or inventory controls. International guidance from the World Health Organization emphasized embedding risk-management principles into oversight of the life sciences; incorporating similar language into § 351 would harmonize U.S. law with these recommendations while ensuring that biosecurity considerations are integrated into regulatory decision-making rather than addressed only after approval.<sup>41</sup>

#### V. IMPLEMENTATION AND ADMINISTRATIVE CONSIDERATIONS

Even after Congress enacts statutory amendments, the FDA will need to translate new provisions into workable procedures. The agency has long relied on notice-and-comment rulemaking and interpretive guidance to operationalize changes in food and drug law.<sup>42</sup> Congress could instruct the FDA to issue regulations within a fixed period—such as eighteen months after enactment—establishing criteria for synthetic biologic designations, platform licenses, and platform supplements. Similar implementation timelines have accompanied prior congressional reforms to FDA regulatory authority, reflecting a balance between urgency and

---

<sup>40</sup> See generally NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* (2011); See generally ADM. FOR STRATEGIC PREPAREDNESS & RESPONSE, *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern* (Sep. 24, 2015), <https://aspr.hhs.gov/S3/Documents/durc-policy.pdf>.

<sup>41</sup> WORLD HEALTH ORG., *Global Guidance Framework for the Responsible Use of the Life Sciences* (2022), at xxvi.

<sup>42</sup> *Informal Rulemaking*, LEGAL INFO. INST., [https://www.law.cornell.edu/wex/informal\\_rulemaking](https://www.law.cornell.edu/wex/informal_rulemaking).

administrative feasibility.<sup>43</sup> Clear timelines can help prevent regulatory drift and give industry confidence that investments in modular technologies will not be stranded by uncertainty. When the agency provides notice in advance how and when it will implement new statutory provisions, sponsors can plan development strategies with predictable expectations, rather than delaying projects until the rules are finalized. This kind of procedural clarity encourages early engagement with regulators and sustains momentum for innovation even as the agency adapts to new legislative mandates.

Guidance documents could elaborate on evidentiary expectations, manufacturing standards, and post-market obligations for synthetic biologics. The FDA has used a similar approach to implement the Prescription Drugs User Fee Act (PDUFA) and other major reforms.<sup>44</sup> Draft guidance could be released for public comment, allowing patient groups, academic scientists, and manufacturers to suggest refinements before policies become final.

The statutory proposals outlined implicate both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). Congress might direct the Secretary of Health and Human Services to designate a lead office—likely CBER—for platform biologic review, while ensuring that CDER remains involved when

---

<sup>43</sup> See, e.g., Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011), (requiring the FDA to issue various foundational food safety regulations within fixed periods, including proposed or final rules within one to two years, and selected rules within 18 months, of enactment).

<sup>44</sup> *Guidance Documents and MaPPs (PDUFA)*, FDA (Oct. 8, 2024), <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/guidance-documents-and-mapps-pdufa>.

synthetic components resemble small-molecule drugs.<sup>45</sup> Establishing an inter-center working group could reduce duplicative reviews and foster consistent interpretation of synthetic-biologic standards.

Outside the FDA, other HHS components could provide expertise. The Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health (NIH) possess technical knowledge about vaccine manufacturing and could advise on the scientific merits of platform applications.<sup>46</sup> Their experience with Operation Warp Speed illustrated the value of early collaboration between regulators and research funders.<sup>47</sup>

Implementing a new approval pathway may require additional resources. Congress could authorize the FDA to collect user fees for platform licenses and supplements. Fees should be calibrated to avoid deterring small innovators, perhaps through a tiered structure that discounts submissions from academic spin-offs or nonprofit developers. Revenue could support specialized review teams and enhanced biosecurity training for staff evaluating dual-use risks.

A platform-based system does not eliminate the need for robust surveillance after licensure. The FDA should retain authority to require post-market studies or revoke a platform license if safety or manufacturing

---

<sup>45</sup> *Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research*, FDA (Mar. 7, 2022), <https://www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research>.

<sup>46</sup> Institute of Medicine (US) Committee, *Priorities for the National Vaccine Plan*, NAT'L LIBR. MEDICINE (2010), <https://www.ncbi.nlm.nih.gov/books/NBK220052/>.

<sup>47</sup> Rosaly Correa-de Araujo et al., *Synergistic Strategies to Accelerate the Development of Function-Promoting Therapies: Lessons From Operation Warp Speed and Oncology Drug Development*, PUBMED CENT. (Jun. 16, 2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC10272982/>.

concerns arise. For products licensed under § 351 of the PHSA, the FDA might condition approval on submission of periodic safety updates addressing both product-specific and platform-wide experience.

Finally, successful implementation will depend on coordination with foreign regulators. The European Medicines Agency (EMA) and the World Health Organization have issued guidance on advanced therapies and life-sciences risk management.<sup>48</sup> Aligning U.S. rules with these frameworks could facilitate reciprocal recognition of platform data, reduce redundant trials and accelerate access in global emergencies. An express congressional directive encouraging the FDA to consult international standards would signal U.S. commitment to harmonization while preserving domestic safety requirements.

#### VI. ADDRESSING OBJECTIONS AND COUNTERARGUMENTS

A frequent critique of expanded disclosure or access conditions is that they may discourage private firms from investing in high-risk research. Some industry representatives have expressed concern that requiring applicants to report federal funding or to accept reasonable-pricing terms could undermine the return on capital necessary to finance late-stage development.<sup>49</sup> However, empirical work on Bayh-Dole march-in rights and other public-interest licensing tools suggests that carefully tailored

---

<sup>48</sup> WORLD HEALTH ORG., *supra* note 41, at 6; *Guideline on Safety and Efficacy Follow-Up and Risk Management of Advanced Therapy Medicinal Products – Scientific Guideline*, EUR. MEDS. AGENCY (Nov. 21, 2008), <https://www.ema.europa.eu/en/guideline-safety-efficacy-follow-risk-management-advanced-therapy-medicinal-products-scientific-guideline>.

<sup>49</sup> Bailey Crane, *The Effect of Reference Pricing on Pharmaceutical Innovation*, CTR. FOR STRATEGIC & INT’L STUD. (July 12, 2023), <https://www.csis.org/blogs/perspectives-innovation/effect-reference-pricing-pharmaceutical-innovation>.

obligations rarely deter commercial participation.<sup>50</sup> Federal agencies have granted thousands of licenses under Bayh-Dole while rarely exercising march-in authority.<sup>51</sup> By limiting access conditions to cases where federal support represents a substantial share of total research and where public-health stakes are acute, Congress could minimize any “chilling effect” while ensuring public value from taxpayer-funded science.

Another argument is that granting the FDA power to impose access or security conditions risks impermissible delegation of legislative authority. Courts, however, have consistently upheld broad delegations so long as Congress provides an “intelligible principle” to guide agency discretion.<sup>52</sup> Reforms proposed here could include explicit statutory standards—for example, triggering access conditions only where federal funding exceeds a specified percentage or where a declared emergency exists—thus satisfying constitutional limits on delegation.

Stakeholders may also argue that imposing new requirements on synthetic biologics would place U.S. manufacturers at a disadvantage relative to foreign competitors. Yet comparable jurisdictions are moving toward similar oversight of platform technologies.<sup>53</sup> The European Medicines Agency has issued guidance on advanced therapy medicinal products, encouraging adaptive regulatory models for gene and cell

---

<sup>50</sup> *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, EVERY CRS REP. (Dec. 3, 2012), <https://www.everycrsreport.com/reports/RL32076.html>.

<sup>51</sup> Blevins and Hickey, *supra* note 28.

<sup>52</sup> *Artl.S1.5.3 Origin of Intelligible Principle Standard*, CONGRESS.GOV, [https://constitution.congress.gov/browse/essay/artI-S1-5-3/ALDE\\_00001317/](https://constitution.congress.gov/browse/essay/artI-S1-5-3/ALDE_00001317/) (last visited Sept. 25, 2025).

<sup>53</sup> *Advanced Therapy Medicinal Products: Overview*, EUR. MEDS. AGENCY (Apr. 28, 2020), <https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview>.

therapies.<sup>54</sup> The World Health Organization's guidance on responsible use of life sciences likewise emphasizes transparency and biosecurity in emerging-technology approvals.<sup>55</sup> Aligning U.S. law with these standards could foster regulatory convergence and market acceptance rather than hindering competitiveness.

#### CONCLUSION

Synthetic biology has transformed the way vaccines and other biologics are conceived, manufactured, and deployed. Messenger-RNA vaccines, viral-vector therapies, and other modular biologic platforms demonstrate the potential of reusable manufacturing scaffolds to respond rapidly to emerging health threats. Yet, the principal federal statutes governing drug and biologic approvals—including the Public Health Service Act—remain oriented toward discrete, stand-alone products rather than flexible manufacturing systems.<sup>56</sup> This structural mismatch can delay access to life-saving interventions, obscure the role of public funding in technological breakthroughs, and leave biosecurity concerns insufficiently addressed.<sup>57</sup>

Amending PHSA § 351 to define synthetic biologics, abbreviate reviews of products, and require consideration of dual-use concerns could align the statute with modern science. Clarifying its relationship with the FDCA by codifying platform supplements, integrating dual-use

---

<sup>54</sup> *Id.*

<sup>55</sup> WORLD HEALTH ORG., *supra* note 41, at xix, xxi.

<sup>56</sup> FDA, *supra* note 6.

<sup>57</sup> Donald Berwick et al., *Aligning Investments in Therapeutic Development with Therapeutic Need: Closing the Gap* 43 (Committee on Strategies to Better Align Investments in Innovations for Therapeutic Development with Disease Burden and Unmet Needs, 2025).

assessments, and ensuring transparency would create a coherent framework for biologics regulation. Implementation can proceed through notice-and-comment rulemaking, inter-center collaboration, and user-fee mechanisms that provide stable resources while protecting small innovators.

By modernizing statutory tools, Congress can foster both innovation and equitable access, ensuring that publicly funded scientific advances translate swiftly and safely into public benefit. These reforms would not eliminate the need for rigorous safety and effectiveness review. Rather, they would channel regulatory effort to the aspects of synthetic biologics that present novel risks or ethical stakes, while avoiding needless duplication when only a genetic insert or antigen changes.

# ERISA Preemption and State PBM Reform: Navigating the Balance of Power

*Allison Garcia*

## I. INTRODUCTION

Prescription drug pricing remains one of the most contentious and politically salient issues in American health law and policy.<sup>1</sup> In the middle of this crisis stand pharmacy benefit managers (PBMs), entities that negotiate rebates, control formularies, and determine reimbursement rates for pharmacies.<sup>2</sup> PBMs were once obscure administrative intermediaries, but they have evolved into powerful market actors capable of shaping access and costs across the U.S. drug supply chain.<sup>3</sup> The rise of PBMs has provoked growing scrutiny from patients, pharmacies, state legislatures, and federal regulators.<sup>4</sup>

The conflict at the core of PBM regulation lies in the tension between state policy innovation and the structural power PBMs wield under the Employee Retirement Income Security Act of 1974 (ERISA) preemption framework.<sup>5</sup> PBMs hold substantial economic and informational power

---

<sup>1</sup> Kavita Patel, MD, MS and Kevin A. Schulman MD, MBA, *Policy Options to Reduce Prescription Drug Costs Across Medicare, Medicaid, and Commercial Insurance*, STANFORD MED. DEP'T. MED. NEWS, <https://med.stanford.edu/medicine/news/current-news/standard-news/policy-options-white-paper> (last visited Dec. 12, 2025); *Prescription Drug Costs Should the U.S. Government Regulate Prescription Drug Prices?*, ENCYC. BRITANNICA (Nov. 17, 2025) <https://www.britannica.com/procon/prescription-drug-costs-debate>.

<sup>2</sup> *What Are Pharmacy Benefit Managers (PBMs) and Why We Need Reform?*, AMA (Aug. 7, 2025), <https://www.ama-assn.org/health-care-advocacy/access-care/what-are-pharmacy-benefit-managers-pbms-and-why-we-need-reform>.

<sup>3</sup> PSSNY, *PBM Basics*, <https://www.pssny.org/page/PBMBasics> (last visited Sept. 25, 2025). (“PBMs are third-party administrators contracted by health plans, large employers, unions and government entities to manage prescription drug benefits programs. They were created in the 1960s to process claims for insurance companies. By the 1970s, PBMs were serving as fiscal intermediaries adjudicating prescription drug claims.”).

<sup>4</sup> Matthew Fiedler et al., *A Brief Look at Current Debates About Pharmacy Benefit Managers*, BROOKINGS (Sept. 7, 2023), <https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/>.

<sup>5</sup> See *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 86–87 (2020) (explaining state attempts at PBM regulation and ERISA preemption tension).

within the drug distribution system.<sup>6</sup> Policymakers at state and federal levels have attempted to constrain that power through transparency mandates, reimbursement floors, and ownership restrictions.<sup>7</sup> But these efforts collide with the broad preemptive scope of ERISA.<sup>8</sup> Originally designed to provide uniformity for multistate employers administering benefit plans, ERISA's preemption clause, in practice, has become a litigation weapon for PBMs and their industry groups to block state reforms.<sup>9</sup>

This article will discuss that while *Rutledge v. PCMA* cracked open the door for state regulation of PBMs, doctrinal uncertainty surrounding ERISA preemption continues to chill meaningful reform.<sup>10</sup> To restore balance, states should design PBM laws as cost regulation governing PBM market conduct, rather than as mandates that dictate ERISA plan structure or administration, and Congress should adopt a federal baseline statute that affirms states' authority to supplement protections. Without such recalibration, large PBMs will continue to exploit the regulatory vacuum, perpetuating opaque pricing practices that inflate drug costs.

---

<sup>6</sup> FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES 5–7 (2024), [https://www.ftc.gov/system/files/ftc\\_gov/pdf/pharmacy-benefit-managers-staff-report.pdf](https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf).

<sup>7</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-498, *Medicaid Managed Care: Improvements Needed to Better Oversee Payment Arrangements* 15–19 (2019).

<sup>8</sup> See *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 319–21 (2016) (describing breadth of ERISA preemption); see also AMA, *Issue Brief: ERISA Preemption and Challenges to Health Care Plans* (2025), <https://www.ama-assn.org/system/files/issue-brief-erisa.pdf> (stating that a state law may aim to regulate how a pharmacy benefit manager operates, but if that law governs a central matter of plan administration or interferes with national uniform administration, it risks being preempted).

<sup>9</sup> SEGAL, *ERISA Preempts State PBM Law* (July 9, 2025), <https://www.segalco.com/consulting-insights/erisa-preempts-state-pbm-law>.

<sup>10</sup> See *Rutledge*, 592 U.S. at 83–84 (upholding an Arkansas law regulating PBM reimbursement rates against an ERISA preemption challenge but leaving open the scope of ERISA's application to other state PBM reforms).

The analysis proceeds in five parts. First, I will outline PBMs' market dominance and its consequences. Second, I examine the ERISA preemption doctrine and its tension with state PBM regulation. Next, I will provide an analysis of the Supreme Court's decision in *Rutledge*, followed by a discussion of the subsequent circuit splits. Lastly, I propose targeted solutions to restore regulatory balance.

## II. PBMS AND MARKET POWER IN THE DRUG SUPPLY CHAIN

PBMs originated in the 1960s as claims processors for prescription benefits.<sup>11</sup> Their role expanded dramatically, and today, they negotiate rebates with drug manufacturers, determine which drugs are placed on insurance formularies, and set reimbursement rates for retail and specialty pharmacies.<sup>12</sup> In doing so, they serve as fiscal intermediaries between manufacturers, pharmacies, insurers, and patients.<sup>13</sup>

The "Big Three" PBMs—CVS Caremark, Express Scripts (owned by Cigna), and OptumRx (owned by UnitedHealth Group)—now control roughly 80% of the market.<sup>14</sup> Each is vertically integrated with insurers and, in some cases, large retail or mail-order pharmacies.<sup>15</sup> This integration allows PBMs to leverage their position in multiple parts of the distribution chain, raising concerns about conflicts of interest.<sup>16</sup> For example, a PBM that owns a mail-order pharmacy has a financial incentive to steer patients away from independent community pharmacies.<sup>17</sup>

---

<sup>11</sup> PSSNY, *supra* note 3.

<sup>12</sup> AMA, *supra* note 2.

<sup>13</sup> PSSNY, *supra* note 3.

<sup>14</sup> FED. TRADE COMM'N, *supra* note 6, at 5.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 53.

<sup>17</sup> *Id.* at 54.

Independent pharmacies, particularly in rural and underserved areas, report being reimbursed below acquisition cost by PBMs, a practice that erodes local access and consolidates PBM power.<sup>18</sup> For example, in 2018, the Ohio Auditor General found that CVS Caremark overcharged the state Medicaid program by more than \$200 million through spread pricing,<sup>19</sup> thus prompting contract terminations.<sup>20</sup> Patients, meanwhile, often face formulary exclusions or higher copayments based on concealed rebate arrangements between PBMs and manufacturers.<sup>21</sup> Employers and plan sponsors cannot tell whether rebates lower costs or just boost PBM profits through spread pricing.<sup>22</sup>

Empirical studies reinforce these concerns. A 2024 report from the Department of Health and Human Services Office of Inspector General (OIG) found issues with inconsistent data on pharmacy reimbursement, thus hindering states' ability to monitor drug spending and oversight of potential PBM inflation of Medicaid costs through practices like spread

---

<sup>18</sup> BloomingWell, *Pharmacy Deserts: How PBMs Are Creating a Healthcare Crisis*, MEDIUM (May 2, 2025), <https://bloomingwell.medium.com/pharmacy-deserts-how-pbms-are-creating-a-healthcare-crisis-3d87d45c8a6f>.

<sup>19</sup> See NAT'L. CMTY. PHARMACISTS ASS'N, *Spread Pricing Explained for Pharmacists*, <https://ncpa.org/spread-pricing-101> (last visited Oct. 21, 2025) (stating "spread pricing is the PBM practice of charging payers like Medicaid more than they pay the pharmacy for a medication and then the PBM keeps the 'spread' or difference as profit"). This is an issue because Medicaid drug spending keeps climbing even as pharmacy reimbursements keep shrinking, leaving providers under and hurting both pharmacies and the Medicaid patients who rely on them. *Id.* [hereafter Nat'l. Cmty.]

<sup>20</sup> Allison Inzerro, *Ohio Tells Medicaid PBMs That 2019 Will Be a Time for Transparent Contracts*, AM. J. MANAGED CARE (Aug. 16, 2018), <https://www.ajmc.com/view/ohio-tells-medicaid-pbms-that-2019-will-be-a-time-for-transparent-contracts>.

<sup>21</sup> Kristi Martin, *What Are Pharmacy Benefit Managers and Why Are They Under Scrutiny?*, COMMONWEALTH FUND (Mar. 17, 2025), <https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending>.

<sup>22</sup> *Id.*

pricing.<sup>23</sup> Specifically, the OIG found that PBMs often failed to report the difference between what they reimbursed pharmacies and what they billed state Medicaid programs, sometimes exceeding several dollars per prescription.<sup>24</sup> The Federal Trade Commission's (FTC) 2024 report similarly concluded that PBMs exploit their market position to extract rebates while maintaining nontransparent pricing structures that obscure the flow of funds.<sup>25</sup> RAND Corporation studies show that drug prices in the United States remain several times higher than in peer nations,<sup>26</sup> and corporate PBM practices are a significant contributor.

In short, PBMs occupy a structural chokepoint in the drug supply chain. Their market dominance, vertical integration, and shielded contracting practices create incentives that often conflict with patient and payer interests.<sup>27</sup> These dynamics have pushed states to intervene, but ERISA preemption could be imminent as the key obstacle.<sup>28</sup>

---

<sup>23</sup> Ann Maxwell, *Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN. (May 2024).

<sup>24</sup> *Id.* at 11.

<sup>25</sup> FED. TRADE COMM'N, *supra* note 6, at 59–61, 66.

<sup>26</sup> Andrew Mulcahy et al., *Prescription Drug Prices in the U.S. Are 2.78 Times Those in Other Countries*, RAND PRESS RELEASE (Feb. 1, 2024), <https://www.rand.org/news/press/2024/02/01.html>.

<sup>27</sup> See David Wainer, *What Happens When Your Insurer Is Also Your Doctor and Your Pharmacist: Health Insurers Like UnitedHealth Group Are Seeking to Control Many Parts of Our Healthcare System, Creating Potential Conflicts of Interest*, WALL ST. J. (June 13, 2024), <https://www.wsj.com/health/healthcare/what-happens-when-your-insurer-is-also-your-doctor-and-your-pharmacist-8df727af> (noting UnitedHealth's monopoly, a call to break it up, and the balance of getting good care when health insurers are both your doctor and pharmacist).

<sup>28</sup> Susie Bilbro et al., *Stuck in the Middle: Self-Funded Health Plans and Recent Challenges to State PBM Laws*, BASS BERRY & SIMS: HR LAW TALK (May 2, 2025), <https://www.bassberryhrlawtalk.com/self-funded-health-plans-challenge-state-pbm-laws/>.

### III. ERISA PREEMPTION DOCTRINE

The Employee Retirement Income Security Act (ERISA) was enacted in 1974 to protect employee benefit plan participants and ensure uniform national standards for plan administration.<sup>29</sup> ERISA’s preemption statute, Section 514, provides that ERISA “shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.”<sup>30</sup> The breadth of this preemption clause has generated decades of litigation and judicial refinement.<sup>31</sup>

The Supreme Court has generally applied two broad tests to assess preemption. First, a state law is preempted if it has a “reference to” ERISA plans, meaning it explicitly mentions or relies on such plans.<sup>32</sup> Second, a state law may be preempted if it has an impermissible “connection with” ERISA plans, typically when it interferes with plan administration or imposes burdens inconsistent with ERISA’s goal of uniformity.<sup>33</sup> Over time, the Court has narrowed its interpretation of preemption, which has helped to avoid creating a regulatory vacuum. In *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, the Court upheld New York’s hospital surcharge, emphasizing that the state’s surcharge statutes are not preempted by ERISA because they do not relate to employee benefit plans.<sup>34</sup> The Court distinguished between laws that

---

<sup>29</sup> Wendy K. Mariner, *Liability for Managed Care Decisions: The Employee Retirement Income Security Act (ERISA) and the Uneven Playing Field*, 86 AM. J. PUB. HEALTH 863, 864 (June 1996).

<sup>30</sup> Employee Retirement Income Security Act, 29 U.S.C.S. §1144(a) (2025).

<sup>31</sup> Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. 389, 392–93 (2020).

<sup>32</sup> *Id.* at 419.

<sup>33</sup> *Id.*

<sup>34</sup> *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 659, 664 (1995).

regulate plan administration, which are preempted, and laws that impose generally applicable economic or market rules, which states may enforce.<sup>35</sup> Thus, laws with merely indirect economic effects on ERISA plans do not trigger preemption under ERISA's preemption clause, §514(a).<sup>36</sup>

Yet, other cases have cut in the opposite direction. In *Gobeille v. Liberty Mutual Insurance Co.*, the Court invalidated Vermont's all-payer claims database, holding that state reporting requirements intruded on ERISA's domain of plan administration.<sup>37</sup> The Court emphasized that ERISA's preemption clause invalidates state laws imposing inconsistent reporting duties on ERISA plans,<sup>38</sup> thereby creating the kind of conflict ERISA preemption is meant to prevent.

The result is a doctrinal tension where PBM reforms sit directly at this fault line. ERISA protects employers from a patchwork of state laws but simultaneously blocks states from regulating significant cost drivers in their health systems.<sup>39</sup> ERISA effectively shields PBMs from state-level regulation by preempting state laws that "relate to" employee benefit plans. This broad preemption clause has been interpreted to block state laws that directly or indirectly affect plan administration, even if the law is aimed at regulating PBMs as third-party administrators. Are reimbursement floors and transparency mandates mere cost regulations, or do they impermissibly interfere with plan design and administration? The answer matters enormously for state power.

---

<sup>35</sup> *Id.* at 665.

<sup>36</sup> *Id.* at 664–65.

<sup>37</sup> *Gobeille v. Liberty Mutual Ins. Co.*, 55 U.S. 312, 326 (2016).

<sup>38</sup> *Id.* at 324.

<sup>39</sup> *Fuse Brown*, *supra* note 31 at 393–94.

#### IV. *RUTLEDGE V. PCMA* (2020): THE DOCTRINAL SHIFT

In 2015, Arkansas enacted Act 900, which required PBMs to reimburse pharmacies no less than the pharmacies' acquisition cost for generic drugs and permitted pharmacies to decline to dispense drugs reimbursed below cost.<sup>40</sup> The Pharmaceutical Care Management Association (PCMA), the association representing PBMs in the United States, challenged the law as preempted by ERISA.<sup>41</sup> The Supreme Court unanimously upheld the statute.<sup>42</sup> Justice Sotomayor, writing for the Court, reasoned that Act 900 regulated the rates at which PBMs reimburse pharmacies, not the design of ERISA plans or their core administrative functions.<sup>43</sup> Because the Arkansas law neither referenced ERISA plans nor directly governed central matters of plan administration, it was not preempted.<sup>44</sup> Therefore, "Act 900 applies to PBMs whether or not the plans they service fall within ERISA's coverage."<sup>45</sup> The Court concluded that ERISA does not insulate plans from all state cost regulation but only from laws that dictate plan design or create inconsistent administrative burdens.<sup>46</sup>

*Rutledge* was seen as a victory for state authority and as a blow to PBMs' reliance on ERISA preemption to evade oversight.<sup>47</sup> By classifying

---

<sup>40</sup> Ark. Code Ann. § 17-92-507.

<sup>41</sup> Sarah Lanford & Jennifer Reck, *Supreme Court Hears Arkansas Pharmacy Benefit Manager Challenge Today*, NAT'L ACAD. FOR STATE HEALTH POL'Y, <https://nashp.org/supreme-court-hears-arkansas-pharmacy-benefit-manager-challenge-today/> (last visited Sept. 23, 2025).

<sup>42</sup> *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 83 (2020).

<sup>43</sup> *Id.* at 84.

<sup>44</sup> *Id.* at 87–88.

<sup>45</sup> *Id.* at 89.

<sup>46</sup> *Id.* at 90.

<sup>47</sup> Thomas N. Bulleit et al., *Rutledge vs. PCMA: SCOTUS Greenlights State Regulation of Pharmacy Benefit Manager Drug Reimbursement*, ROPES & GRAY, (Jan. 13, 2021), <https://www.ropesgray.com/en/insights/alerts/2021/01/rutledge-vs-pcma-scotus-greenlights-state-regulation-of-pharmacy-benefit-manager-drug-reimbursement>.

reimbursement rate rules as permissible cost regulation, the Court gave states a green light to experiment with the regulation of PBMs' economic practices.<sup>48</sup> Yet, *Rutledge* left critical questions unanswered. The Court did not address whether state laws regulating PBM ownership structures, pharmacy networks, or formulary design would survive.<sup>49</sup> The Court also did not provide a clear framework for distinguishing permissible cost regulation from impermissible plan design interference.<sup>50</sup> This doctrinal ambiguity fueled subsequent litigation and conflicting circuit court rulings.<sup>51</sup>

#### V. POST-*RUTLEDGE* LITIGATION AND EMERGING CIRCUIT SPLIT

In the wake of *Rutledge*, states accelerated their legislative efforts to regulate PBMs, and unsurprisingly, PCMA responded with new lawsuits.<sup>52</sup> The most prominent post-*Rutledge* case is *Pharm. Care Mgmt. Ass'n v. Mulready*, where the Court struck down significant portions of Oklahoma's PBM Access Act.<sup>53</sup>

---

<sup>48</sup> Keenan Briefings, *ERISA Preemption: Supreme Court's Decision on PCMA v. Mulready and Its Impact on PBMs*, KEENAN (July 15, 2025), <https://www.keenan.com/knowledge-center/news-and-insights/briefings/erisa-preemption-supreme-courts-decision-on-pcma-v-mulready-and-its-impact-on-pbms/>.

<sup>49</sup> Troy Filipek et al., *Implications of Rutledge v. PCMA for Pharmacy Benefit Managers and Employers*, MILLIMAN WHITE PAPER (Mar. 3, 2021), [https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2021-Articles/3-8-21-Rutledge\\_vs\\_PCMA.pdf](https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2021-Articles/3-8-21-Rutledge_vs_PCMA.pdf).

<sup>50</sup> *Id.*

<sup>51</sup> Keenan Briefings, *supra* note 48.

<sup>52</sup> See generally Leah Nguyen, *ERISA Preemption: Impact on State PBM Laws*, SEQUOIA (Apr. 16, 2025), <https://www.sequoia.com/2025/04/erisa-preemption-impact-on-state-pbm-laws/> (discussing recent state legislative initiatives).

<sup>53</sup> Madison Connor, *US Supreme Court ERISA Preemption Update*, EMPLOYERS HEALTH (July 2, 2025), <https://www.employershealthco.com/resource-center/articles/us-supreme-court-erisa-preemption-update>; *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183 (10th Cir. 2023).

Oklahoma's law sought to protect independent pharmacies and patient access by requiring PBMs to admit all willing pharmacies into their networks, prohibiting mandatory mail-order provisions, and regulating pharmacy steering.<sup>54</sup> The Tenth Circuit distinguished *Rutledge*, holding that, unlike Arkansas's rate regulation, Oklahoma's rules went to the heart of plan design and administration.<sup>55</sup> By forcing network composition and limiting benefit structures, the law impermissibly interfered with ERISA plans and was therefore preempted.<sup>56</sup>

This ruling has produced a circuit split with the Eighth Circuit, which has interpreted *Rutledge* more broadly to permit state PBM regulation so long as it merely limits the accreditation requirements that PBM may impose on pharmacies and does not explicitly mandate plan design.<sup>57</sup> The Supreme Court denied certiorari in *Mulready*, leaving the split unresolved and creating profound uncertainty for states contemplating PBM reforms.<sup>58</sup> As a result, states now operate in a precarious environment. Some reforms, like reimbursement floors, appear safe post-*Rutledge*, while others, like pharmacy access, risk being struck down under *Mulready*.<sup>59</sup> The boundaries of permissible state regulation remain contested and unsettled.

---

<sup>54</sup> Patient's Right to Pharmacy Choice Act, 36, §§ 6958-6969 (effective May 14, 2024).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> Joanne Roskey & Anthony F. Shelley, *The ERISA Edit: Supreme Court Asked to Address Circuit Split on Preemption of State PBM Laws*, MILLER & CHEVALIER EMP. BENEFITS ALERT (May 16, 2024), <https://www.millerchevalier.com/publication/erisa-edit-supreme-court-asked-address-circuit-split-preemption-state-pbm-laws>.

<sup>58</sup> SEGAL, *supra* note 9.

<sup>59</sup> Alan J. Arville et al., *State Regulation of Pharmacy Benefit Managers: Tenth Circuit Holds That ERISA and Medicare Part D Preempt Key Parts of Oklahoma PBM Law*, EPSTEIN BECKER & GREEN, P.C. (Aug. 31, 2023), <https://www.ebglaw.com/insights/publications/state-regulation-of-pharmacy-benefit->

Despite litigation risks, states continue to legislate aggressively. Earlier in 2025, Illinois enacted House Bill 1697, requiring PBMs to pass rebates directly to insurers and mandating greater transparency in pricing practices.<sup>60</sup> Arkansas doubled down in 2025 by banning PBMs from owning or operating pharmacies in the state, a bold attempt to dismantle vertical integration.<sup>61</sup> Ohio pursued administrative enforcement, with the state auditor exposing spread pricing abuses in Medicaid managed care contracts.<sup>62</sup> These efforts reflect bipartisan frustration. Legislators argue that PBMs have exploited their market dominance to inflate costs and reduce pharmacy access, and that states cannot afford to wait for federal action.<sup>63</sup> Yet, the patchwork of state laws creates compliance complexity for PBMs and uncertainty for employers operating across state lines.<sup>64</sup> Without clearer guidance from Congress or the Supreme Court, PBM regulation will remain inconsistent and contested.

---

managers-tenth-circuit-holds-that-erisa-and-medicare-part-d-preempt-key-parts-of-oklahoma-pbm-law.

<sup>60</sup> *HB 1697: Prescription Drug Affordability Act*, ILL. PHARMACISTS ASS'N, <https://www.ipha.org/assets/pdf/HB1697+-+Prescription+Drug+Affordability+Act/> (last visited Sept. 29, 2025).

<sup>61</sup> H.B. 1150, 95th Gen. Assemb., Reg. Sess. (Ark. 2025), codified at Ark. Code Ann. § 17–92–416(f).

<sup>62</sup> Keith Faber, *Auditor's Report: Pharmacy Benefit Managers Take Fees of 31% on Generic Drugs Worth \$208M in One-Year Period*, OHIO AUDITOR STATE (Aug. 16, 2018), <https://ohioauditor.gov/news/pressreleases/details/5042>.

<sup>63</sup> AMA, *supra* note 2.

<sup>64</sup> Alex Maged & Percy Lee, *Drug Benefit Compliance is a State-by-State Test for Sponsors*, BLOOMBERG L. (Sept. 19, 2025), <https://news.bloomberglaw.com/legal-exchange-insights-and-commentary/drug-benefit-compliance-is-a-state-by-state-test-for-sponsors>.

## VI. THE POLICY PROBLEM: A REGULATORY VACUUM

The overarching problem is that ERISA preemption has created a regulatory vacuum.<sup>65</sup> States, motivated by rising drug costs and pharmacy closures, want to regulate PBMs.<sup>66</sup> But ERISA's preemptive reach prevents them from fully addressing the problem, particularly for self-funded employer plans that cover the majority of Americans with private insurance.<sup>67</sup> Meanwhile, the federal government has yet to act.<sup>68</sup> For example, the Centers for Medicare & Medicaid Services (CMS) exercise oversight on Medicare Part D, but there is no comprehensive federal framework governing PBMs.<sup>69</sup>

This vacuum leaves PBMs, mainly the “Big Three,” largely free to operate without effective oversight. They exploit information asymmetries, impose contract terms that disadvantage pharmacies, and extract rebates without accountability to patients or plan sponsors.<sup>70</sup> Consider a self-funded employer that operates across multiple states. Because its plan is governed by ERISA, state laws requiring transparency or rebate pass-through do not apply, leaving the employer dependent on whatever limited data the PBM chooses to disclose. The same lack of oversight has produced tangible harm in public programs. In Ohio, a 2018 audit revealed that CVS Caremark and OptumRx had billed the state Medicaid program \$224 million more than they paid pharmacies in a single

---

<sup>65</sup> Lily Moran, *Pretextual Preemption: The Modern Weaponization of Preemption in the Regulation of Concentrated Animal Farming Operations*, 170 U. PA. L. REV. 1589, 1614–15 (2022).

<sup>66</sup> Fiedler et al., *supra* note 4.

<sup>67</sup> Nguyen, *supra* note 52.

<sup>68</sup> Fuse Brown, *supra* note 31, at 415.

<sup>69</sup> FED. TRADE COMM'N, *supra* note 6, at 24.

<sup>70</sup> *Id.* at 17–23.

year through spread pricing.<sup>71</sup> Pharmacies were reimbursed below cost while PBMs pocketed the difference, underscoring how the absence of meaningful federal or state oversight can cause exploitation of pharmacies and payers.<sup>72</sup> In effect, ERISA's broad preemption clause has become a shield for these large PBMs, entrenching their power by disabling state innovation in cost regulation.<sup>73</sup>

This dynamic of federal inaction, coupled with judicially expansive preemption, shifts regulatory power away from states and patients into the hands of nontransparent PBMs. Unless recalibrated, the system will continue to privilege administrative uniformity over cost control and patient access.

## VII. RECALIBRATING ERISA

States must continue designing PBM regulations that focus on cost and market conduct rather than plan-design to avoid ERISA preemption. Measures such as reimbursement floors, spread-pricing bans, and rebate pass-through requirements fall within *Rutledge's* approval of state rate regulation, so long as they apply uniformly to PBMs regardless of the plan type they service.<sup>74</sup> For instance, requiring PBMs to submit quarterly reports showing acquisition-cost benchmarks and pharmacy reimbursement rates would allow state regulators to detect below-cost

---

<sup>71</sup> Faber, *supra* note 62; *Ohio Seeks to Recover Overcharges from OptumRx*, CONSTANTINE CANNON (Feb. 21, 2019), <https://constantinecannon.com/whistleblower/ohio-seeks-to-recover-overcharges-from-optumrx>.

<sup>72</sup> Faber, *supra* note 62; *Ohio Seeks to Recover Overcharges from OptumRx*, CONSTANTINE CANNON (Feb. 21, 2019), <https://constantinecannon.com/whistleblower/ohio-seeks-to-recover-overcharges-from-optumrx>.

<sup>73</sup> Fuse Brown, *supra* note 31, at 448.

<sup>74</sup> *Rutledge*, 592 U.S. at 80.

reimbursement or inflated spreads.<sup>75</sup> Such reporting would strengthen pharmacy access and help plan sponsors evaluate whether PBM-negotiated savings are real and not absorbed by obscured intermediary pricing.<sup>76</sup> Likewise, states can demand disclosure of aggregate rebate and fee data if framed as general market oversight. Ohio’s administrative model in Medicaid, in which PBMs may charge no more than the exact reimbursement paid to pharmacies plus a dispensing and administrative fee, demonstrates how targeted oversight can expose spread-pricing abuses without dictating benefit design.<sup>77</sup> These state-level strategies, however, remain precarious because ERISA preemption continues to shield PBMs’ pricing practices whenever a court interprets a cost-regulation measure as altering plan design.<sup>78</sup> Without clearer federal guidance, states will continue legislating in uncertainty.

To stabilize the regulatory environment and restore state authority, Congress should adopt a narrow amendment to ERISA that clarifies the distinction between PBM market conduct and plan administration. ERISA’s preemption clause was drafted decades before PBMs evolved into vertically integrated pricing entities, leaving courts to guess whether reimbursement rules fall on the permissible “cost-regulation” side of *Rutledge* or the impermissible “plan-design” side of *Mulready*. A concise statutory clarification could resolve this ambiguity. Congress should add a new subsection to ERISA’s preemption clause, § 514:

---

<sup>75</sup> Faber, *supra* note 62.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Keenan, *supra* note 51 (noting preemption of plan-related rules).

For purposes of this section, state laws that regulate the pricing, reimbursement, rebate retention, spread-pricing practices, audit rights, pharmacy network adequacy, or other market conduct of a Pharmacy Benefit Manager shall not be deemed to “relate to” an employee benefit plan. Regulation of PBM market conduct does not constitute regulation of plan design, benefit structure, eligibility criteria, coverage terms, or claims administration. Nothing in this Act shall preempt state authority to establish minimum reimbursement rates, spread-pricing bans, rebate pass-through requirements, audit obligations, or pharmacy-access protections.

This language preserves ERISA’s core purpose, uniformity for employers, while confirming that PBMs, as outside vendors whose economic practices distort the drug market, may be regulated by states in the interest of cost control and consumer protection.

A complementary federal transparency floor is also necessary to ensure enforceability. Congress can address this by establishing standardized reporting obligations applicable to all PBMs. A federal transparency provision could state:

Pharmacy Benefit Managers shall submit quarterly reports to the Federal Trade Commission containing (1) aggregate pharmacy reimbursement amounts compared to nationally recognized acquisition-cost benchmarks; (2) aggregate rebates, fees, and price concessions received from drug manufacturers; (3) the percentage and dollar amount of rebates and fees passed through to plan sponsors; and (4) all spread amounts retained on pharmacy claims. The FTC and CMS shall jointly issue guidance defining key reporting terms, establishing uniform reporting formats, and specifying audit procedures. Aggregated, de-identified reports shall be made publicly available to assist states, employers, and plan sponsors in evaluating PBM market conduct.

This federal reporting floor maintains ERISA’s protection of plan-specific information while supplying the market-level transparency needed for oversight.

With ERISA clarified and transparency standardized, states would finally be empowered to enforce meaningful oversight. State Departments of Insurance could examine PBM contracts, conduct spread-pricing audits, verify rebate pass-through rates, and impose penalties, including restitution, fines, or license suspension, when violations occur. Ohio’s model demonstrates the feasibility of this enforcement structure.<sup>79</sup> Independent audits exposed more than \$200 million in spread-pricing losses in a single year, prompting contract termination and reform.<sup>80</sup> Under a clarified § 514, similar audits could extend to commercial markets without triggering preemption challenges.

Finally, Congress should establish a federal–state PBM data partnership modeled on Medicaid’s cooperative structure.<sup>81</sup> While the federal government establishes minimum standards for eligibility and benefits, states retain broad discretion to expand coverage, set provider reimbursement, and implement supplemental cost-control measures.<sup>82</sup> Under this system, the FTC and CMS would maintain a shared national PBM data repository, and states would access aggregated pricing and

---

<sup>79</sup> Faber, *supra* note 62; Trevor Royce, Sheetal Kircher & Rena Conti, *Pharmacy Benefit Manager Reform: Lessons from Ohio*, JAMA 1, 2 (2019).

<sup>80</sup> NAT’L. CMTY., *supra* note 19.

<sup>81</sup> See *Medicaid State Plan Amendments*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/medicaid-state-plan-amendments> (last visited Sept. 29, 2025) (stating “the state plan sets out groups of individuals to be covered, services to be provided, methodologies for providers to be reimbursed and the administrative activities that are underway in the state”).

<sup>82</sup> *Id.*

rebate information through secure data-use agreements. Employers and ERISA plans could access de-identified market-level data to evaluate PBM performance. This structure preserves federal oversight of minimum reporting standards while allowing states to innovate with additional cost-control measures. Together, a narrow amendment to ERISA § 514, a federal transparency floor, and coordinated enforcement mechanisms would restore regulatory balance, curb PBM market abuses, and ensure that drug-pricing policy prioritizes patients, pharmacies, and plan sponsors rather than opaque intermediary profit models.

#### CONCLUSION

PBMs have evolved from administrative intermediaries into powerful market actors that shape drug costs, pharmacy access, and patient outcomes. Their economic dominance and vertical integration pose structural challenges for healthcare affordability. Yet, state efforts to regulate PBMs are consistently chilled by ERISA preemption, producing a policy vacuum that PBMs exploit. The Supreme Court's decision in *Rutledge* opened the door for states to regulate reimbursement and pricing practices, but subsequent cases like *Mulready* have narrowed the scope of permissible state reforms. This unresolved tension undermines regulatory clarity and perpetuates high drug costs. To address this, states should continue experimenting with carefully designed cost regulation, while Congress should establish a federal baseline statute affirming state authority. Federal agencies should likewise expand oversight to promote transparency and competition. Realigning power through a recalibrated federal-state framework is essential to restore accountability and ensure

that prescription drug policies serve public interest rather than private intermediaries.

# Streaming Skepticism: How Live Streaming Has Fueled Vaccine Misinformation and What the Law Can Do

*Taran Stahle*

## I. INTRODUCTION

Livestreaming platforms are growing significantly and are expected to find even more success in the next five years.<sup>1</sup> This growth raises concerns regarding power and responsibility, as platforms host streamers capable of spreading health misinformation to millions of viewers, potentially contributing to vaccine hesitancy and declining rates of vaccine uptake. Under the current legal framework, internet services cannot be held liable for the content their users publish. This results in the question of whether a platform moves beyond a content-housing service when its algorithm actively promotes certain users.

This article will detail how anti-vaccine rhetoric can grow on a livestreaming platform and why that puts Americans in a dangerous position. Next, this article will review the current legal framework that insulates interactive computer services from liability and demonstrate how this antiquated statute fails to account for modern technology. Finally, this article will propose new legislation that prevents health misinformation from substantially growing.

---

<sup>1</sup> *Live Streaming Market to Grow by USD 20.64 Billion (2025-2029), Driven by Smartphone Penetration & Internet Access, with AI Redefining Landscape – Technavio*, YAHOO FIN. (Feb. 12, 2024), <https://finance.yahoo.com/news/live-streaming-market-grow-usd-113000946.html>.

## II. THE RISE OF LIVESTREAMING MEDIA

For the first time in history, more Americans get their news from social media than from traditional outlets.<sup>2</sup> A new form of social media, livestreaming, has gained immense popularity over the last decade.<sup>3</sup>

Twitch is the largest livestreaming platform in the world and has an average of 31 million visitors each day.<sup>4</sup> In August 2025 alone, there were 1.5 billion hours watched.<sup>5</sup> For comparison, Fox News, the highest-rated television network in August 2025, averaged roughly 1 billion total hours watched.<sup>6</sup> Streamer engagement with their community “fosters a sense of closeness” serving as “an effective tool for cultivating a following.”<sup>7</sup> Streamers may feel driven to create close communities, which often means higher revenue through subscriptions<sup>8</sup> and donations.<sup>9</sup>

---

<sup>2</sup> NIC NEWMAN ET AL., DIGITAL NEWS REPORT 2025 11 (Reuters Institute, 14th ed. 2025). (noting a stark difference between generations, where over half of those under 35 years old say that social media is their main source of news).

<sup>3</sup> JOHANNA BREWER ET AL., REAL LIFE IN REAL TIME: LIVE STREAMING CULTURE 9 (Bo Ruberg et al. eds., 2023).

<sup>4</sup> Roland Martin, *Twitch*, BRITANNICA (Sept. 22, 2025), <https://www.britannica.com/topic/Twitch-service>.

<sup>5</sup> STREAM CHARTS, <https://streamscharts.com/overview> (last visited Sept. 6, 2025).

<sup>6</sup> Mark Mwachiro, *Here Are the Cable News Ratings for August 2025*, ADWEEK (Sept. 4, 2025), <https://www.adweek.com/tvnewser/here-are-the-cable-news-ratings-for-august-2025/>.

<sup>7</sup> Rachel Kowert & Emory Daniel Jr., *The One-and-a-Half Sided Parasocial Relationship: The Curious Case of Live Streaming*, 4 COMPUT. HUM. BEHAV. REP. Aug.–Dec. 2021, at 1, 2.

<sup>8</sup> A Twitch tier 1 subscription is \$4.99 per month, Tier 2 is \$9.99 per month, and Tier 3 is \$24.99 per month. TWITCH, *How to Subscribe*, <https://help.twitch.tv/s/article/how-to-subscribe> (last visited Sept. 7, 2025).

<sup>9</sup> Zorah Hilvert-Bruce et al., *Social Motivations of Live Streaming Viewer Engagement on Twitch* 84 COMPUT. HUM. BEHAV. 58, 64 (2018) (discussing how each subscription tier grants community-specific perks, like emoticons and badges and that donations are often acknowledged live and highlighted in chat, sometimes appearing as “Recent Donator”).

Twitch's algorithm uses real-time data, including watch time, engagement, and stream type, to promote creators.<sup>10</sup> Creators with large communities generate high activity and retention rates, keeping those streams promoted across the platform.<sup>11</sup> Twitch's profitability is driven primarily by creators who attract and retain the largest number of subscribers at the most expensive subscription tiers.<sup>12</sup>

Researchers find that viewers are most motivated by the sense of community and social interactions with streamers and their chat.<sup>13</sup> Community-specific perks, like special emoticons and badges can elicit public thanks from streamers, deepening viewer attachment.<sup>14</sup> Additionally, financial contributions foster community interaction as subscribers bond with others who support the streamer.<sup>15</sup> Livestreaming platforms have found a niche within the internet sphere, where viewers can have real-time, personal conversations with streamers who wield immense amounts of social power.<sup>16</sup> This parasocial relationship can lead to intense

---

<sup>10</sup> Christine Weber, *Twitch State of Engineering 2023*, TWITCH (Sept. 28, 2023), <https://blog.twitch.tv/en/2023/09/28/twitch-state-of-engineering-2023/>; *Recommendations on Twitch*, TWITCH LEGAL (Sept. 22, 2025), <https://legal.twitch.com/legal/recommendations-on-twitch/>.

<sup>11</sup> Dewan Ysul Zulkarnain, *Twitch Algorithm: How Twitch's Algorithm Actually Works in 2025*, AWISEE (July 8, 2025), <https://awisee.com/twitch-algorithm/>.

<sup>12</sup> CES, *The Power of Community in a Connected World*, (Jan. 9, 2025), <https://www.ces.tech/videos/the-power-of-community-in-a-connected-world/> (mentioning that Twitch CEO Dan Clancy's comments at the 2025 Consumer Electronics Show that 66% percent of Twitch's revenue comes from subscriptions alone).

<sup>13</sup> Hilvert-Bruce et al., *supra* note 9, at 58 (discussing a study that looked at elements of entertainment, information seeking, meeting new people, social interactions, social support, sense of community, social anxiety, and external support, and observed how those related to four factors of engagement: emotional connectedness, time spent, time subscribed, and donations).

<sup>14</sup> *Id.* at 64.

<sup>15</sup> *Id.*

<sup>16</sup> Andres Navarro & Francisco J. Tapiador, *Twitch as a Privileged Locus to Analyze Young People's Attitudes in the Climate Change Debate: A Quantitative Analysis* 10 HUMAN. & SOC. SCI. COMM'N., Nov. 2023, at 1, 2.

trust between the viewer, the chat community, and the streamer.<sup>17</sup> As livestreaming becomes a dominant source of news, its intersection with public health poses unique challenges.

### III. SCIENCE POPULISM AND HEALTH MISINFORMATION PROMOTION

Though not indicative of causation, there is a positive correlation between controversial opinions and increased viewership on livestreams.<sup>18</sup> Research shows that “viewers find more successful, edgier content entertaining, which may serve to normalize subjects or ideas that would not have been normalized without their being featured in these streams.”<sup>19</sup>

#### A. *The Role of Science Populism in Health Misinformation*

The rise in provocative content is neither inherently beneficial nor detrimental; it is the rise in science populism<sup>20</sup> that should concern Americans. The COVID-19 pandemic served as a catalyst for science populism, as people were exposed to mass amounts of health misinformation, particularly through social media.<sup>21</sup> Researchers found that “Alt-Right supporters hold significantly stronger science populist

---

<sup>17</sup> Kowert & Daniel Jr., *supra* note 7, at 2.

<sup>18</sup> Griffin O’Grady, *From Tainted Memes To Trending Streams: How Live Streaming Serves As A Vector In Far-Right Meme Normalization*, at 19 (June 2024) (B.A. thesis, Clark Honors College at University of Oregon) (on file with the Clark Honors College Library, University of Oregon).

<sup>19</sup> *Id.* at 17-18.

<sup>20</sup> Blue Lerner, Austin Y. Hubner & Hillary C. Shulman, *Science Populism Impacts Perceptions of Credibility Across Scientific Professions*, 15 SCI. REP., Aug. 2025, at 1 (explaining that science populists believe the “scientific elite,” including academics, scientists, government agencies, and other experts, are taking advantage of ordinary people by pushing their own agenda for a variety of reasons).

<sup>21</sup> Ian Hawkins & Sedona Chinn, *Populist Views of Science: How Social Media, Political Affiliation, and Alt-Right Support Affect Scientific Attitudes in the United States*, 27 INFO., COMM’N. & SOC’Y. 520, 520-521 (2024).

attitudes than Republicans, who hold stronger science populist beliefs than Democrats.”<sup>22</sup> However, research has also found that “Democrats who consume a great deal of social media hold similar populist views as Alt-right supporters and Republicans.”<sup>23</sup> Data collected during the pandemic showed “apolitical and liberal-leaning social media creators,” expressed skepticism for expert opinions.<sup>24</sup> This suggests that social media plays an incredibly powerful role in the development and progression of science populism.<sup>25</sup>

Science populists have had significant effects on healthcare, most notably vaccinations.<sup>26</sup> “Anti-vaccination movements similarly reject the consensus within the scientific community regarding the safety and importance of vaccines, relying on anecdotal evidence, misinformation, and conspiracy theories instead.”<sup>27</sup> This movement often times reframes vaccine decisions as a matter of personal freedom and individual choice, rather than a collective responsibility rooted in public health and community protection.<sup>28</sup>

Because livestreaming platforms tend to reward edgier content with higher viewership, mainstream trust in science can lack the novelty that attracts attention.<sup>29</sup> This dynamic may create a particularly fertile environment for science populist perspectives to emerge and gain traction. Importantly, streamers may not intentionally promote or spread science

---

<sup>22</sup> *Id.* at 530.

<sup>23</sup> *Id.* at 531.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> Gustavo Ortiz-Millan, *How Populism Affects Bioethics*, CAMBRIDGE Q. HEALTHCARE ETHICS 84, 92 (2024).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> O’Grady, *supra* note 18, at 17-18.

populist views. Rather the platform's culture, which rewards attention-grabbing or controversial opinions can foster science-populist perspectives and create a breeding ground for anti-vaccine rhetoric.

*B. The Amplification of Health Misinformation on Livestreaming Platforms*

Researchers define health misinformation as “a health-related claim of fact that is currently false due to its contradiction to expert consensus and/or best available evidence at the time, inaccurate due to its use of incomplete evidence, or unsubstantiated due to a lack of evidence.”<sup>30</sup> “Studies find that exposure to misinformation can undermine vaccination uptake and compliance with public-health guidelines.”<sup>31</sup>

The informal nature of livestreaming amplifies the possibility of spreading health misinformation.<sup>32</sup> Streamers are not required to fact check statements made, nor are there systematic repercussions for sharing false information, unless the streamer knowingly or intentionally shares misinformation repeatedly.<sup>33</sup> “There is also a notable positive correlation [of increasing viewership by] streamers who speak more during their streams, leaving less time to consider possible implications of what the streamer is saying.”<sup>34</sup> Yet influence can extend beyond their words; streamers may choose to play a video and not speak, leaving viewers to

---

<sup>30</sup> YUAN WANG, KATHRYN THEIR & XIAOLI NAN, *DEFINING HEALTH MISINFORMATION* 11 (2022).

<sup>31</sup> Sander van der Linden, *Misinformation: Susceptibility, Spread, and Interventions to Immunize the Public*, 28 *NATURE MED.* 460, 460 (2022).

<sup>32</sup> MARÍA JOSE ALDAVE-CARRANZA & PAOLA PALOMINO-FLORES, *STREAMERS AS EMERGING JOURNALISTIC FIGURES: A STUDY ON THEIR INFLUENCE AND INFORMATIVE QUALITY* 580 (Paulo Carlos Lopez-Lopez et al. eds., 2024).

<sup>33</sup> *Id.* at 578.

<sup>34</sup> O'Grady, *supra* note 18, at 16.

assume an endorsement of the ideas in it.<sup>35</sup> This demonstrates that the impact of a streamer's misinformation is not dependent on their actual voices but arises from the influence of their platform. Moreover, the close bond between the streamer, the chat community, and the viewer can reduce the viewer's inclination to verify information through other sources.<sup>36</sup>

Streamers may offer conflicting vaccine views, posing risks when viewers treat them as health advice rather than consulting professionals. For example, Nick Kolcheff, a Twitch streamer with 6.7 million followers<sup>37</sup> posted to his 2 million followers on X, “[m]y son has 0 vaccinations. We trust the advice of our doctors . . . .”<sup>38</sup> On the contrary, xQc, one of the most popular streamers online, with 12.2 million Twitch followers seemingly holds the opposite viewpoint as he livestreamed his reaction to Kolcheff's post saying, “you want to know why he's lucky . . . because everybody else isn't stupid . . . they get herd immunity.”<sup>39</sup>

Anti-vaccine rhetoric can also spread through support of certain political leaders.<sup>40</sup> Streamer Adin Ross<sup>41</sup> hosted Donald Trump during the 2024 presidential race, gaining 580,000 live viewers and 2.9 million

---

<sup>35</sup> *Id.*

<sup>36</sup> ALDAVE-CARRANZA & PALOMINO-FLORES, *supra* note 32, at 580.

<sup>37</sup> NICKMERCES, <https://www.twitch.tv/nickmercs/videos> (last visited Sept. 19, 2025) (identifying a streamer who streams for four to eight hours at a time playing video games and interacting with his chat community).

<sup>38</sup> Nick Kolcheff (@NICKMERCES), X, <https://x.com/NICKMERCES/status/1857230119653318760> (last visited Sept. 19, 2025).

<sup>39</sup> xQc, Twitch, [https://www.twitch.tv/xqc/clip/DeafSmallBadgerBCouch-gUU3xzVcdP6v2\\_IV](https://www.twitch.tv/xqc/clip/DeafSmallBadgerBCouch-gUU3xzVcdP6v2_IV) (last visited Sept. 19, 2025).

<sup>40</sup> Grayson Jackon, *The American Anti-Vaccine Movement: An Investigation of Populism, Polarization, and Public Policy* (May 2020) (B.A. Honors College thesis, Baylor University).

<sup>41</sup> Adin Ross has 7 million followers on Twitch and 2 million followers on Kick. Adin Ross, TWITCH.TV, <https://www.twitch.tv/adinross>; Adin Ross, KICK, <https://kick.com/adinross>.

YouTube views.<sup>42</sup> While hosting does not necessarily signal agreement with all of an individual's opinions, viewers may perceive it as implicit support and extend their trust to figures the streamer appears to endorse. For example, Trump's election and subsequent appointment of adamant vaccine skeptic, Robert F. Kennedy Jr.,<sup>43</sup> as the Secretary of Health and Human Services ("HHS") may have signaled to Ross's viewers and other Trump supporters that Kennedy deserved their support.<sup>44</sup> Although many streamers do not overtly reject vaccines or deliberately promote science populism, expressions of support for Trump may amount to tacit endorsement of Kennedy's anti-vaccine stance.

Streaming platforms benefit financially from subscriptions, regardless of whether that engagement arises from factual content or misinformation. Anti-vaccine rhetoric and health misinformation can subsequently become a profitable byproduct of the algorithms employed.

#### IV. THE CURRENT FEDERAL LEGAL FRAMEWORK FOR ONLINE PLATFORMS

Section 230 of the Communications Decency Act of 1996 broadly protects online platforms from being held legally responsible for the content their users' posts.<sup>45</sup> 47 U.S.C. § 230(c)(1) states that "[n]o provider or user of an interactive computer service shall be treated as the

---

<sup>42</sup> Kat Tenbarge, *Trump Interviewed by Controversial Livestreamer Adin Ross, Who Gave Him a Cybertruck and a Rolex*, NBC NEWS (Aug. 5, 2024, 3:49 PM), <https://www.nbcnews.com/tech/internet/adin-ross-interviews-trump-gifts-cybertruck-rolex-rcna165225>.

<sup>43</sup> CHILDREN'S HEALTH DEFENSE, *Robert F. Kennedy Jr.*, <https://childrenshealthdefense.org/authors/robert-f-kennedy-jr/>.

<sup>44</sup> Donald Trump (@realDonaldTrump), X, <https://x.com/realDonaldTrump/status/1857170020427595797> (last visited Sept. 22, 2025).

<sup>45</sup> 47 U.S.C. § 230 (1996).

publisher or speaker of any information provided by another information content provider.”<sup>46</sup>

In *Zeran v. Am. Online, Inc.*, the Fourth Circuit interpreted Section 230 in a defamation suit arising from AOL’s failure to promptly remove or retract defamatory posts.<sup>47</sup> The court held “lawsuits seeking to hold a service provider liable for its exercise of a publisher’s traditional editorial functions—such as deciding whether to publish, withdraw, postpone or alter content—are barred.”<sup>48</sup> A Third Circuit decision later clarified that “[i]nteractive computer services (ICSs) are immunized only if they are sued for someone else’s expressive activity or content . . . but they are not immunized if they are sued for their own expressive activity or content . . . .”<sup>49</sup> Thus, courts have continuously found that platforms are merely neutral conduits of information, rather than creators.<sup>50</sup> Since the companies act as impartial hosts, they are provided Section 230 immunity.<sup>51</sup>

The Health Misinformation Act of 2021, a proposed amendment to Section 230, would make ICSs liable for algorithmically promoting “health misinformation that is created or developed” on their platform during a public health emergency unless the “promotion occurs through a neutral mechanism” like “chronological functionality.”<sup>52</sup>

---

<sup>46</sup> *Id.*

<sup>47</sup> *Zeran v. Am. Online, Inc.*, 129 F.3d 327, 328-329. (4th Cir. 1997).

<sup>48</sup> *Id.* at 330.

<sup>49</sup> *Anderson v. TikTok, Inc.*, 116 F.4th 180, 183 (3rd Cir. 2024).

<sup>50</sup> *Zeran*, 129 F.3d at 335.

<sup>51</sup> *Id.*

<sup>52</sup> Health Misinformation Act of 2021, S. 2448, 117th Cong. (2021). The Health Misinformation Act of 2021 was not passed and did not become law.

In 2023 an amendment to Section 230 titled, Safeguarding Against Fraud, Exploitation, Threats, Extremism, and Consumer Harms Act (“SAFE TECH Act”) suggested immunity protection should only extend to third party speech, not shared information.<sup>53</sup> If enacted, the ICS would not receive protection if they received payment to publish user speech or distributed payment to the creators for such speech.<sup>54</sup> Accordingly, the ICS could be held accountable for paid content and advertisements.<sup>55</sup>

Twenty-seven years after *Zeran*, a Third Circuit ruling found that a platform’s algorithmic recommendations may amount to liability.<sup>56</sup> Months before the Third Circuit decision, the Supreme Court considered if state laws that “restrict the ability of social-media platforms to control whether and how third-party posts are presented to other users” violate the First Amendment.<sup>57</sup> The Supreme Court found that “a platform’s algorithm that reflects ‘editorial judgments’ about ‘compiling the third-party speech it wants in the way it wants’ is the platform’s own ‘expressive product’ and is therefore protected by the First Amendment.”<sup>58</sup> The Third Circuit in *Anderson v. TikTok, Inc.* opined that “[g]iven the Supreme Court’s observations that platforms engage in protected first-party speech under the First Amendment when they curate compilations of others’ content via their expressive algorithms, it follows that doing so amounts to first-party

---

<sup>53</sup> SAFE TECH Act, S. 560, 118th Cong. (2023). The SAFE TECH Act was not passed and remains stalled in Congress.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Anderson*, 116 F.4th at 184.

<sup>57</sup> *Moody v. NetChoice, LLC.*, 603 U.S. 707, 717 (2024).

<sup>58</sup> *Anderson*, 116 F.4th at 184. (citing *Moody v. NetChoice, LLC.*, 603 U.S. 707, 717 (2024)).

speech under § 230, too.”<sup>59</sup> The Court reasoned that TikTok, by actively recommending and promoting videos posted by third parties, went beyond the scope of a neutral host and became an active participant.<sup>60</sup> The *Anderson* court is the first to break the Section 230 mold of unquestionable immunity.

#### V. VACCINE HESITANCY AND THE EROSION OF HERD IMMUNITY

In 2019, the World Health Organization labeled vaccine hesitancy as one of the top ten threats to global health.<sup>61</sup> Studies have collectively conveyed that health misinformation “can shape trust and belief about vaccines, leading to increased hesitancy, especially when it originates from popular social media platforms.”<sup>62</sup> Moreover, vaccine hesitancy can be exacerbated from “personal beliefs, reliance on social media for information, and misconceptions about vaccine safety and efficacy.”<sup>63</sup>

Vaccine hesitancy affects not only the unsure patient, but their community members as well.<sup>64</sup> “Besides individual protection, vaccination programs also rely on population or ‘herd’ immunity: the immunization of large portions of the population to protect the unvaccinated, immunocompromised, and immunologically naïve by reducing the number of susceptible hosts to a level below the threshold

---

<sup>59</sup> *Anderson*, 116 F.4th at 184.

<sup>60</sup> *Id.*

<sup>61</sup> WORLD HEALTH ORG., *Ten Threats to Global Health in 2019*, <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>.

<sup>62</sup> TONG LIN ET AL., *COMMUNICATION AND MISINFORMATION: CRISIS EVENTS IN THE AGE OF SOCIAL MEDIA* 96 (Kevin B. Wright eds., 2025).

<sup>63</sup> *Id.*

<sup>64</sup> Michael L. Mallory, Lisa C. Lindesmith & Ralph S. Baric, *Vaccination-Induced Herd Immunity: Successes and Challenges*, 142 *J. ALLERGY & CLINICAL IMMUNOLOGY* 64, 64 (2018).

needed for transmission.”<sup>65</sup> Infants younger than six months old and the immunocompromised are not eligible to receive the measles vaccine due to their immune systems’ inability to process the vaccine properly.<sup>66</sup> So, while some people may argue that the decision to be vaccinated is personal, one’s personal decision could have a life-or-death impact on children and disabled persons who do not have the privilege of choice.<sup>67</sup> Those without the opportunity to choose rely on herd immunity.<sup>68</sup>

In 2018, Italy had the second largest measles outbreak in Europe, resulting in more than 4,000 cases.<sup>69</sup> This occurred following two consecutive years when vaccine rates fell below 90%, after the escalation of science populist viewpoints.<sup>70</sup> During this time, the populist Five Star Movement and the far-right League actively supported anti-vaccine theories and even proposed legislation against vaccines, claiming that they caused disease rather than prevented it.<sup>71</sup> The Five Star Movement formed a coalition with the League and took office in 2018.<sup>72</sup> This is an example of when strong anti-vaccine rhetoric is present, vaccine hesitancy can follow, and subsequently produce lower vaccine rates.

---

<sup>65</sup> *Id.*

<sup>66</sup> E. Ben-Chetrit et al., *Measles-related Hospitalizations and Associated Complications in Jerusalem, 2018- 2019*, 26 *CLINICAL MICROBIOLOGY & INFECTION* 637, 640-42 (2019).

<sup>67</sup> Barbara Pfeffer Billauer, *Anti-Vax FEAR\* Speech: A Public-Health-Driven Policy Initiative When Counter-Speech Won't Work (\*Fake, Flawed, Fraudulent, False, Endangering, and Reckless)*, 32 *HEALTH MATRIX: J. OF L.-MED.*, 2022, at 215, 228-229.

<sup>68</sup> *Id.*

<sup>69</sup> Ortiz-Millan, *supra* note 26, at 92.

<sup>70</sup> *Id.*

<sup>71</sup> Sarah Boseley et al., *Rightwing Populists Ride Wave of Mistrust of Vaccine Science*, *GUARDIAN* (Dec. 21, 2018, at 09:01 ET), <https://www.theguardian.com/world/2018/dec/21/rightwing-populists-ride-wave-of-mistrust-of-vaccine-science>.

<sup>72</sup> Stefano Fella, *The New Italian Government*, *HOUSE COMMONS LIBR.* (June 29, 2018), <https://commonslibrary.parliament.uk/research-briefings/cbp-8357/>.

In 2024, the Centers for Disease Control and Prevention (“CDC”) reported 285 measles cases in the United States.<sup>73</sup> As of December 2025, there are 1,912 cases.<sup>74</sup> 67% of Americans infected with measles are 19 years old or younger.<sup>75</sup> Research shows that hesitancy towards vaccinations is most common in 25- to 49-year-olds, the most likely ages of parents with young children.<sup>76</sup> The United States is experiencing the highest number of measles cases since 1992, which was two years after the second dose was publicly recommended and eight years before the country declared the disease eliminated.<sup>77</sup>

This development mirrors broader political dynamics in which right-leaning figures in the United States have increasingly questioned public-health recommendations, strengthening science-populist sentiments that contribute to declining vaccination rates.<sup>78</sup> A Gallup poll reported that the “declining belief in the importance of vaccines is essentially confined to Republicans and Republican-leaning independents, as the views of Democrats and Democratic-leaning independents have changed little over the past 24 years.”<sup>79</sup>

Even with advances in vaccine technology that address weak immune responses, “public policy plays a critical role in achieving the high

---

<sup>73</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, *Measles Cases and Outbreaks*, <https://www.cdc.gov/measles/data-research/index.html> (last visited Dec. 12, 2025).

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> Timothy B. Gravelle et al., *Estimating the Size of “Anti-Vax” and Vaccine Hesitant Populations in the US, UK, and Canada: Comparative Latent Class Modeling of Vaccine Attitudes* 18 HUM. VACCINES & IMMUNOTHERAPIES 2021, at 1, 3.

<sup>77</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 73.

<sup>78</sup> Gravelle et al., *supra* note 76, at 3-5.

<sup>79</sup> Jeffrey M. Jones *Far Fewer in U.S. Regard Childhood Vaccinations as Important*, Gallup (Aug. 7, 2024), <https://news.gallup.com/poll/648308/far-fewer-regard-childhood-vaccinations-important.aspx>.

population vaccination rate needed to achieve herd immunity and freedom from disease.”<sup>80</sup> When political leaders appoint individuals and promote rhetoric that undermines trust in the scientific institutions responsible for researching and producing vaccines, it is not unreasonable to expect a decline in herd immunity.<sup>81</sup> In August 2025, Kennedy, as Secretary of HHS, withdrew \$500 million worth of funding across 22 projects focused on mRNA vaccine development.<sup>82</sup> The following month, the CDC and its Advisory Committee on Immunization Practices recommended eliminating routine COVID-19 vaccine suggestions, instead requiring those who wish to receive the vaccine to first consult with a health care provider.<sup>83</sup> The current administrative developments illustrate how political interference in public health policy can directly undermine well-established scientific understandings.<sup>84</sup>

## VI. EXPANDING INTERACTIVE COMPUTER SERVICE LIABILITY

In addressing these problems, an appropriate solution to prevent the spread of health misinformation is to amend Section 230 by combining the

---

<sup>80</sup> Mallory et al., *supra* note 64, at 65-66.

<sup>81</sup> Billauer, *supra* note 67, at 228-29.

<sup>82</sup> See Press Release, Health and Human Services, HHS Winds Down mRNA Vaccine Development Under BARDA, (Aug. 5, 2025), <https://www.hhs.gov/press-room/hhs-winds-down-mrna-development-under-barda.html>.

<sup>83</sup> See Press Release, Health and Human Services, ACIP Recommends COVID-19 Immunization Based on Individual Decision-making (Sept. 19, 2025), <https://www.hhs.gov/press-room/acip-recommends-covid19-vaccination-individual-decision-making.html>. Grace Halsey, *ACIP Agenda for First Meeting Since Committee Was Replaced by RFJ Jr Raises Questions for What's On It and What's Not*, PATIENT CARE (June 25, 2025), <https://www.patientcareonline.com/view/acip-agenda-for-first-meeting-since-committee-was-replaced-by-rkf-jr-raises-questions-for-what-s-on-it-and-what-s-not>. (This recommendation was published from the new committee members, as the previous advisors were fired upon RFK Jr.'s appointment as Secretary of HHS).

<sup>84</sup> Gravelle et al., *supra* note 76, at 3-5.

Health Misinformation Act and the SAFE TECH Act. Integrating these bills would expand liability for platforms that algorithmically promote or profit from health misinformation. This proposed Health Misinformation Accountability Act (“HMAA”) could incorporate language from both the Health Misinformation and SAFE TECH Acts to read as follows:

(1) TREATMENT OF PUBLISHER - A provider of an interactive computer service shall be treated as the publisher or speaker of health misinformation that is created or developed through the interactive computer service if the provider promotes that health misinformation through an algorithm used by the provider (or similar software functionality), except that this subparagraph shall not apply if that promotion occurs through a neutral mechanism, such as through the use of chronological functionality.<sup>85</sup>

(2) COMPENSATION EXCEPTION – Section 230 immunity shall not be granted under this section if –

(A) The interactive computer service provides payment in exchange for the creation or distribution of such content; or

(B) The provider receives payment related to such content, including revenue from advertisements displayed in connection with that content.

*A. Scope of Liability and Enforcement*

By enacting this legislation, Congress would expand liability to interactive computer service providers under existing laws. Livestreaming services like Twitch could be treated as publishers if their algorithms amplify health misinformation or if they profit from third-party users, like streamers, who share false health claims either through ad revenue or subscriptions. Thus, plaintiffs may bring civil claims against a platform under laws such as negligence, public nuisance, consumer protection laws, or personal injury claims.

---

<sup>85</sup> Health Misinformation Act of 2021, S. 2448, 117th Cong. (2021).

However, if enacted, private litigators may have difficulties formulating concrete claims. The most challenging step would be proving a direct causal link between the livestreaming service allowing health misinformation to be broadcasted on its platform and an individual suffering actual harm as a result of that livestream.<sup>86</sup> For example, it would be difficult for an individual to demonstrate that a streamer's claim of vaccines' harms directly caused them to forgo vaccination and subsequently become ill as a result. Because numerous intervening factors contribute to health outcomes, proving the platform's algorithmic amplification of that content was a substantial factor would pose a significant evidentiary challenge.

Ultimately, it may be easier for a state actor to file suit, as the state could demonstrate broad, systematic injury to their citizens. A state might argue that a platform's algorithm multiplied the number of views for a stream sharing health misinformation, thereby increasing the rates of vaccine hesitancy and ultimately contributing to a public health crisis. While this Act may present additional challenges in litigation, it remains a far greater opportunity to hold companies liable than the current immunity block under Section 230.

Redefining the boundaries of Section 230, this proposal acknowledges that streaming platforms are not passive conduits but active participants in shaping online discourse, specifically content distributing health misinformation. Although litigation may be complex, the reform ultimately provides a necessary and workable mechanism to hold

---

<sup>86</sup> The foundation of a successful negligence lawsuit is grounded in proving a causal link between an alleged breach and the resulting injury.

companies accountable for amplifying potentially harmful health misinformation.

### *B. Nonlegislative Solutions*

While proposed legislation combining aspects of the Health Misinformation Act and the SAFE TECH Act would be a significant step toward platform accountability, there remain viable, nonlegislative options to address the overarching issue of health misinformation distribution.

Livestreaming services would likely follow the HMAA's lead and enforce their own internal policies to prevent the spread of health misinformation and consequently liability. Given that the Act strips immunity when a platform profits from shared health misinformation, livestreaming companies may choose to withhold ad revenue or subscriptions tied to streams flagged as problematic. Platforms could allow viewers to report streams, triggering an independent review and require the stream remain live with a public flag indicating potential health misinformation. Additionally, moderators could work with the company's software engineers to turn off the promotional algorithm for streamers who repeatedly share health misinformation after being warned. Platforms may update their terms of service stating users may not share health misinformation and require acknowledgement prior to streaming.<sup>87</sup> Although these would not categorically protect the platform from liability, it would show a good faith attempt at prevention and may mitigate potential damages.

---

<sup>87</sup> Twitch currently changes their terms of service every 6-8 months. See TWITCH LEGAL, *Changes to Terms of Service*, <https://legal.twitch.com/en/legal/terms-of-service/archive> (last visited Dec. 12, 2025).

Internal and Federal Trade Commission (“FTC”) compliance mandates may require yearly transparency reports detailing the amount of health misinformation shared on their services and the proportion they remove. The FTC would then investigate the platform’s identification and removal process, their moderation and policy enforcement efforts, and overall reporting practices.<sup>88</sup> Where a streaming service publicizes their policies against health misinformation, but the FTC finds internal data suggesting otherwise, they may impose fines or mandate an independent third-party monitoring system for a fixed period. Moreover, the FTC could issue summaries of their findings allowing the public and other companies to review the evidence. The compliance regulations would incentivize companies to continuously monitor for health misinformation not only to avoid potential penalties, but also to uphold their reputational standing.

#### CONCLUSION

The rise of livestreaming has transformed how millions of Americans consume information, creating intimate and engaged communities around individual content creators.<sup>89</sup> The online environment, engineering, and culture contribute to the promotion of health misinformation, which can directly affect vaccine hesitancy and vaccine uptake.<sup>90</sup> The current legal framework does not adequately regulate the online material that is increasingly seen with the aid of generous algorithms. The HMAA offers

---

<sup>88</sup> FTC Act Section 5 prohibits “unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45.

<sup>89</sup> Navarro & Tapiador, *supra* note 16, at 2.

<sup>90</sup> ALVADE-CARRANZA & PALOMINO-FLORES, *supra* note 32, at 582.; Van der Linden, *supra* note 31, at 460.

a targeted statutory response, treating platforms as publishers when they algorithmically support health misinformation or profit from its dissemination. Congress must modernize its regulations to evolve with public health concerns in a digital age.

# Preserving Community Benefits in Hospital Conversions

*Taylor Stamm*

## I. INTRODUCTION

Nonprofit hospitals are required by law to prioritize public service over profit-making, deeming them more likely than for-profit hospitals to provide public and private goods to the community.<sup>1</sup> However, with rising healthcare costs, many nonprofit hospitals are choosing to convert to for-profit hospitals.<sup>2</sup> When a for-profit entity purchases a nonprofit hospital, a conversion foundation is formed.<sup>3</sup> The assets from the sale of a nonprofit are used to form the conversion foundation, which is a separate entity intended to charitably serve the community that the nonprofit hospital had served.<sup>4</sup> When a conversion occurs, access to these communal health services is in jeopardy, as for-profit hospitals are no longer required to provide services that meet the specific needs of the specific community.<sup>5</sup> Healthcare professionals have expressed concern that the essence and goal of healthcare will be lost if a service ethos is replaced by an economic motive, which may occur when profits become the priority in a hospital.<sup>6</sup>

Despite this concern, for-profit hospitals continue to grow in number and the effects on the community are material.<sup>7</sup> As of 2021, a total of 303

---

<sup>1</sup> Jill R. Horwitz, *Why We Need The Independent Sector: The Behavior, Law, And Ethics of Not-For-Profit Hospitals*, 50 UCLA L. REV. 1345, 1347-48 (2003).

<sup>2</sup> Karen Joynt et al., *Association Between Hospital Conversions to For-Profit Status and Clinical and Economic Outcomes*, 312 JAMA 1644, 1644-52 (2014) (explaining the results of a study showing that the conversion of non-profit hospitals to for-profit status is connected to gains in financial margins of the hospital).

<sup>3</sup> CASEY P. BAILO ET AL., *THE ROLE OF HEALTHCARE CONVERSION FOUNDATIONS IN INVESTING IN POPULATION HEALTH* 2 (2023).

<sup>4</sup> *Id.* at 2; *see also id.* at 13 (discussing how state-level policies affect the formation and operation of CF's leaving their respective communities to feel the effects).

<sup>5</sup> CONSUMER REPORTS, *Conversions 101* (Jan. 1, 2007), <https://advocacy.consumerreports.org/research/conversions-101/>.

<sup>6</sup> INST. OF MED., *FOR-PROFIT ENTERPRISE IN HEALTH CARE* 182 (Braford H. Gray ed., 1986).

<sup>7</sup> Cronin, *infra* note 27 (discussing a correlation between the presence of for-profit hospitals and higher unemployment, higher uninsured rates, and higher levels of residents reporting poor health).

conversion foundations existed, indicating the increase in for-profit conversion in the United States.<sup>8</sup> Nonprofit hospitals have a direct interest in the needs of the communities they serve.<sup>9</sup> Post-conversion, to further community interests and satisfy economic pressures, a universal framework would ensure that nonprofit to for-profit conversion not only promotes growth within the healthcare system but also advances the overall community health, balancing the interests of both power and policy.

This article introduces a federal conversion procedure to ensure that communities do not lose access to communal benefits after a for-profit conversion. It discusses the criteria distinguishing a nonprofit entity from a for-profit entity, specifically focusing on the differences in tax status. An understanding of this status is crucial for analyzing the communal benefits provided by nonprofit entities. Next, the article examines the positive impact nonprofit entities have on the communities they serve, followed by a discussion on the increase in for-profit conversions driven by their appeal to investors. Subsequently, it will discuss the issue arising from this increase. Lastly, the article presents a proposed solution to maintain benefits for communities affected by a nonprofit to for-profit hospital conversion.

## II. CRITERIA TO ESTABLISH A NONPROFIT ENTITY

Several key distinctions separate for-profit and nonprofit hospitals; however, this section focuses solely on their contrasting tax status.<sup>10</sup> It is

---

<sup>8</sup> BAILO, *supra* note 3 (surpassing 155 conversions in 1994 and 1995).

<sup>9</sup> Beth A. Tapper, *Nonprofit to For-Profit Hospital Conversions: Policy Implications and Alternatives*, ADVOCATES' FORUM 17, 19 (2004).

<sup>10</sup> Ethan Popowitz, *What is the Difference Between Non-Profit and For-Profit Hospitals?*, DEFINITIVE HEALTHCARE (Nov. 9, 2023), <https://www.definitivehc.com/blog/the-difference->

important to understand the mechanics of a nonprofit's tax exempt status to fully comprehend the effect the loss of this status has on a community. "Under federal and almost all state laws, the assets of a nonprofit organization must be permanently dedicated to a charitable purpose."<sup>11</sup> The Internal Revenue Code ("IRC"), a comprehensive body of tax laws created by Congress, lists certain organizations that may qualify for tax exempt status.<sup>12</sup> A hospital must demonstrate that it "operates to promote the health of a class of persons that is broad enough to benefit the community," also known as the community benefit standard.<sup>13</sup> In addition, the entity must meet an operational requirement outlined in IRC § 501(c)(3).<sup>14</sup> Finally, Revenue Ruling 69-545, an interpretation by the Internal Revenue Service of the IRC, designates factors that indicate the communal benefit standard is met, with no single factor being determinative.<sup>15</sup> Adherence to these requirements ensures a hospital receives tax-exempt status.

---

between-non-profit-and-for-profit-hospitals (describing that differences between for-profit and not-for-profit entities include ownership, financial objectives, and access to funding).

<sup>11</sup> See CONSUMER REPORTS, *supra* note 5 (discussing when a conversion occurs the charitable purpose is replaced by a dedication to maximizing profits).

<sup>12</sup> 26 U.S.C. §501(c)(3) (1995) ("[c]orporations, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes . . .").

<sup>13</sup> *Charitable Hospitals - General Requirements for Tax-Exemption Under Section 501(c)(3)*, IRS (July 1, 2025), <https://www.irs.gov/charities-non-profits/charitable-hospitals-general-requirements-for-tax-exemption-under-section-501c3> (noting that one of these demonstrations is that none of the net earnings are given to shareholders).

<sup>14</sup> *Id.* (outlining that a § 501(c)(3) entity is: (1) required to operate exclusively for tax exempt purposes, (2) prohibited against inurement, (3) barred from becoming an action organization, and (4) not allowed to receive a significant private benefit).

<sup>15</sup> *Id.* (mentioning factors, which include (1) operating an equitable emergency room, (2) forming a board of directors from the community, (3) developing an open medical staff policy, (4) accepting public payment programs such as Medicaid and Medicare, and (5) using surplus funds to improve hospital facilities, patient care, and advancement of hospital training and research).

### III. THE IMPACT OF TAX-EXEMPT STATUS ON THE COMMUNITY

The benefits provided by tax-exempt hospitals to communities are profound.<sup>16</sup> In 2020, an estimated \$129 billion in benefits were provided to communities throughout the United States solely by nonprofit hospitals.<sup>17</sup> A study conducted by Ernst & Young (2020 EY Study) reviewed the Form 990 Schedule H's of general hospitals, which delineates specific categories of benefits nonprofit hospitals provide to their communities.<sup>18</sup> This study was conducted on approximately 2,500 general hospitals, meaning this estimate likely underrepresents the total value of benefits provided to communities nationwide.<sup>19</sup>

Policies imposed on nonprofits are effective tools to promote the subjective well-being of the community.<sup>20</sup> Communities with greater access to public-serving entities experience a greater subjective well-being.<sup>21</sup> Positive feelings and experiences related to one's life serve as an evaluation of subjective well-being, which is a direct indicator of overall community well-being.<sup>22</sup> Subjective well-being is a direct indicator of

---

<sup>16</sup> AM. HOSP. ASS'N., *Estimates of the Value of Federal Tax Exemptions and Community Benefits Provided by U.S. Nonprofit Hospitals, 2022* (Nov. 2025), <https://www.aha.org/guidesreports/estimates-value-federal-tax-exemptions-and-community-benefits-provided-us-nonprofit-hospitals-2022>.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*; see AM. HOSP. ASS'N., *Tax-Exempt Hospitals Provided \$149 Billion in Total Benefits to Their Communities* (Sep. 10, 2025), <https://www.aha.org/guidesreports/2025-09-10-tax-exempt-hospitals-provided-149-billion-total-benefits-their-communities> (providing that categories include: (1) financial assistance such as subsidizing health services, and funding health professionals' education and medical research, (2) bad debt expenses, (3) Medicare shortfall, and (4) community building activities).

<sup>19</sup> See AM. HOSP. ASS'N., *supra* note 16 (describing that “[t]he analysis does not account for other nonprofit specialty hospitals, such as psychiatric or long-term acute care”).

<sup>20</sup> Robert W. Ressler et al., *Nonprofits: A Public Policy Tool for the Promotion of Community Subjective Well-Being*, 31 J. PUB. ADMIN. RSCH. THEORY 822, 823 (2021).

<sup>21</sup> *Id.* at 823-24.

<sup>22</sup> *Id.* at 823.; Sarah Atkinson et al., *Being Well Together: Individual Subjective and Community Wellbeing*, 21 J. HAPPINESS STUD. 1903 (2019).

overall community well-being.<sup>23</sup> Societies with a higher subjective well-being are better at meeting citizens' basic needs—most of which can be provided through healthcare systems.<sup>24</sup> “Nonprofits represent a critical component of service provision in the United States both currently and historically.”<sup>25</sup> Thus, tax status is granted to nonprofit entities because they are expected to benefit the public, and evidence suggests that their efforts are successful.<sup>26</sup>

#### IV. UNDERSTANDING THE INCREASE IN FOR-PROFIT CONVERSIONS

For-profit conversions are on the rise, largely due to the economic benefits derived from hospital systems.<sup>27</sup> The economy is stimulated because for-profit entities have a business-oriented model focused on generating profits for owners.<sup>28</sup> Generally, the for-profit, business-oriented model is favored by investors for financial purposes.<sup>29</sup> One concern for any entity is the profitability of services and a for-profit system yields greater financial security, making it more intriguing to investors.<sup>30</sup>

---

<sup>23</sup> Ressler, *supra* note 20, at 823.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 832.

<sup>26</sup> Nicole Rapfogel & Emily Gee, *How Nonprofit Hospitals Can Support Communities and Advance Public Health*, CTR. FOR AM. PROGRESS (Aug. 19, 2021), <https://www.americanprogress.org/article/nonprofit-hospitals-can-support-communities-advance-public-health/>.

<sup>27</sup> Cory E. Cronin et al., *For-Profit Hospitals Have a Unique Opportunity to Serve as Anchor Institutions in the U.S.*, 22 PREVENTATIVE MED. REPS. (2021).

<sup>28</sup> Popowitz, *supra* note 10.

<sup>29</sup> DAVID M. CUTLER & JILL R. HORWITZ, CONVERTING HOSPITALS FROM NOT-FOR-PROFIT TO FOR-PROFIT STATUS WHY AND WHAT EFFECTS? 45, 46-47, 57-58, 77, 86 (2000) (noting the considerations, which include the ability of for-profit entities to cut costs such as shortening the length of hospital stays, for-profit's increased access to capital which allows for purchasing of new equipment, and for-profit's favorability to investors because of their equitable stake).

<sup>30</sup> *Id.*

For-profit conversions also allow entities to remain competitive in the market.<sup>31</sup> As conversions become more common, competitive pressures grow, prompting additional nonprofit hospitals to pursue conversion.<sup>32</sup> When a nonprofit hospital's owner is faced with significant debt obligations incurred from its community benefit requirements, "selling to a cash-rich, for-profit buyer provides one way of meeting" these oftentimes immense obligations.<sup>33</sup> For-profit conversions also tend to increase efficiency through enhanced managerial skill and market responsiveness.<sup>34</sup> Furthermore, for-profit entities face reduced regulatory constraints compared to nonprofit entities.<sup>35</sup>

A case study of Wesley Medical Center illustrates the application of conversion principals and the reasoning behind why a nonprofit hospital may pursue a conversion. Interviewees in the case study indicated three primary reasons for the for-profit conversion.<sup>36</sup> In this case, the reasoning behind the conversion was not purely economic, rather financial issues took precedent in the directors' decision-making to pursue a conversion.<sup>37</sup>

---

<sup>31</sup> *Id.* at 46 (discussing how "having a large debt load and gaining access to cheaper sources of capital are also important in the conversion decision" because it may allow for greater competitiveness).

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> Gary Claxton et al., *Public Policy Issues In Nonprofit Conversions: An Overview*, 16 HEALTH AFFS., 9, 13 (1997).

<sup>35</sup> *Id.* at 14-15.

<sup>36</sup> CUTLER, *supra* note 29, at 61 (indicating the three primary reasons as: (1) belief that the non-profit mission had been met, (2) excitement around making a deal with a powerful corporation, and (3) concerns surrounding future viability by transferring financial difficulties to an affluent managerial team).

<sup>37</sup> *Id.* (outlining directors' financial motivations underlying the decision to pursue conversion).

## V. THE PROCESS OF FOR-PROFIT CONVERSION AND SUBSEQUENT ISSUES

A for-profit conversion occurs when all assets of a nonprofit entity are shifted to for-profit use.<sup>38</sup> There are a range of conversion transactions including, “sales or leases of assets, joint ventures, mergers, affiliations, acquisitions, mutualizations, the formation of for-profit subsidiaries and holding companies, or other deals that effectively transform the nonprofit into a for-profit corporation.”<sup>39</sup> The most common conversion transaction in the healthcare industry involves a for-profit entity purchasing a nonprofit hospital’s assets, with the nonprofit settling outstanding debts and allocating excess funds to a charitable purpose.<sup>40</sup> At this stage, communal benefits often cease, creating significant issue.

State law dictates for-profit conversion.<sup>41</sup> Additionally, a state’s attorney general interprets and applies their state’s statutes to the conversion procedure.<sup>42</sup> Therefore, the process of conversion varies greatly among states based on the attorney general’s discretion on how the process will occur, leading to varying effects on the communities.<sup>43</sup> While the attorney general holds the power, the public has an interest in ensuring that nonprofit communal benefits are not appropriated by a for-profit buyer.<sup>44</sup> This interest leads to inconsistent regulations for conversion

---

<sup>38</sup> Claxton, *supra* note 34, at 10-11.

<sup>39</sup> CONSUMER REPORTS, *supra* note 5.

<sup>40</sup> CUTLER, *supra* note 29, at 47.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.* at 49.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

transactions among states and generally a public that suffers losses from a lack of benefits.<sup>45</sup>

## VI. THE SOLUTION: A MODEL FOR-PROFIT CONVERSION

This proposal suggests a federal conversion procedure that would ensure the newly formed for-profit hospital continues to provide benefits to the community. The goal of the proposed federal conversion procedure is to maintain community benefits so vulnerable populations do not suffer from the consequences of conversion. For-profit entities have a unique opportunity to serve as an “economic anchor” within the community just as nonprofit entities do.<sup>46</sup> Thus, this proposal’s framework incorporates the economic capacity of a for-profit entity with the community benefit capacity of a nonprofit entity, for comprehensive success.

### A. *Independent Appraisal Prior to Conversion*

The first step in the proposed federal conversion procedure is an independent appraisal of the nonprofit hospital’s assets and community benefit contributions.<sup>47</sup> This would involve a review of the hospital’s Form 990 Schedule H, as done in the 2020 EY Study.<sup>48</sup> Reviewing the number of community benefits reported will provide an accurate representation of the portion of the hospital’s expenses spent on the community.<sup>49</sup> If

---

<sup>45</sup> Hossein Zare et al., *When States Mandate Hospital Community Benefit Reports, Provision Increases*, 68(2) J. HEALTHCARE MGMT. 83, 103 (2023) (indicating there is wide variety in the data hospitals are required to report).

<sup>46</sup> Cronin, *supra* note 27 (explaining that for-profit entities are “providing jobs to local residents, incentivizing their employees to live nearby and support the local economy, and through the acquisition of hospital supplies from local businesses”).

<sup>47</sup> *A Model Nonprofit Conversion Act*, CONSUMERS UNION U.S., INC. (2003),

<https://advocacy.consumerreports.org/wp-content/uploads/2020/12/ModelAct03.pdf>.

<sup>48</sup> *See, e.g.*, AM. HOSP. ASS’N., *supra* note 16 (explaining the process of reviewing Schedule H forms to assess community benefit contributions).

<sup>49</sup> *Id.*

implemented, the Schedule H community benefit contributions would be evaluated over a period of the ten previous years by a neutral third party with no stake in the conversion.<sup>50</sup> A longer review period, rather than an evaluation of only the previous year, would allow for a well-rounded understanding of the type of community benefits being allocated, and the extent to which the community was receiving those. A neutral third party ensures an unbiased evaluation and accurate reporting of the nonprofit's community benefit contribution.

Next, this proposed conversion procedure would require that the conversion entity defines their charitable contributions, meaning for each community benefit contribution identified in the audit, the entity must demonstrate the impact it has on the community.<sup>51</sup> The appraisal team will then designate how the for-profit entity will ensure the continuation of the defined benefits.<sup>52</sup> Each of the designations will be explicitly stated in the bylaws of the newly formed for-profit entity and voted on for approval by their board of directors. This will ensure that all of the nonprofit's charitable contributions continue to be conferred upon the community in the same amount and in the same essence, when the conversion is complete.

---

<sup>50</sup> See, e.g., CONSUMERS UNION U.S., INC., *supra* note 47 (explaining that an appraisal must be conducted using professional standards to ensure accuracy).

<sup>51</sup> See, e.g., COMMUNITY CATALYST, CONVERSION MODEL ACT 10 (2003) (discussing a proposed act that requires the new entity show "a demonstrated commitment to the mission of the prior charitable organization and the ability to further its charitable purposes").

<sup>52</sup> See, e.g., *id.* at 7 (suggesting a description of how a new entity can plan to continue community benefits).

### *B. Attorney General Approval*

After audit, the for-profit entity would obtain approval from the attorney general of the state where the nonprofit entity is located.<sup>53</sup> The attorney general will ensure that the conversion is in compliance with the proposed uniform federal conversion process through a series of criteria.

The first criteria is that the for-profit entity must have a dedicated purpose in alignment with the nonprofit's original purpose.<sup>54</sup> Additionally, the attorney general must first ensure that "sufficient safeguards are in place to ensure the affected community has continued access to affordable, quality health care" and second, that "the acquiring entity has made a commitment to provide health care to the disadvantaged, the uninsured, and the underinsured at a level comparable to the level historically provided by the converting healthcare entity."<sup>55</sup> In compliance with the designated purpose of the proposal, the for-profit entity would be required to sign a legally binding written agreement committing to provide the community benefits that were audited and memorialized in the bylaws.<sup>56</sup> This proposed criteria addresses the issue that frequently arises in for-profit conversions—when the entity offers communal benefits, but not in the same way or in the same amount that the nonprofit did.

The second criteria is that the for-profit's board must reflect the "geographic, ethnic, gender, age, [and] socioeconomic" demographics of

---

<sup>53</sup> See, e.g., CONSUMERS UNION U.S., INC., *supra* note 47, at 4 (proposing an attorney general's approval for transactions over \$5,000,000, whereas the proposed solution here is recommending an approval requirement regardless of transaction value).

<sup>54</sup> See, e.g., *id.* at 11 (proposing that the mission statement of the nonprofit must be as close to possible as the mission statement of the converting entity).

<sup>55</sup> *Id.* at 8-9.

<sup>56</sup> See, e.g., *id.* at 9 (proposing a legally enforceable agreement to hold entities accountable for their commitment).

the community the hospital will serve.<sup>57</sup> This is important because “[t]rustees who understand the cultures, issues and needs of their patient population can provide deeper insight and make better decisions about how to serve their communities.”<sup>58</sup> A culturally competent board decreases disparities in care and treatment because members are likely to be more aware of the needs affecting the communities they serve.<sup>59</sup> The requirements for a board comprised of the community will be set forth in the hospital’s bylaws.<sup>60</sup> This proposed criteria addresses issues regarding certain demographics being underrepresented during conversion.

The third criteria is that any excess funds resulting from the transaction should be given to the community directly through charity.<sup>61</sup> This is important because one study, conducted by the United States General Accounting Office, showed that in some conversions the proceeds went to the community, but were given to broadly defined charitable organizations that did not align with the nonprofit hospital’s specific mission.<sup>62</sup> The conversion foundations that were formed in this study did not focus solely on providing health care services.<sup>63</sup> Rather, they provided funds for both health and non-health related activities; therefore, the community lost a

---

<sup>57</sup> See, e.g., *id.* at 11 (proposing a diverse board to reflect the entity’s service area).

<sup>58</sup> Mary K. Totten, *How and Why to Increase Board Diversity*, AM. HEALTH ASS’N., <https://trustees.aha.org/articles/916-how-and-why-to-increase-board-diversity> (last visited Oct. 19, 2025).

<sup>59</sup> *Id.*

<sup>60</sup> See, e.g., DERRICK MITCHELL, HOSPITAL BOARD COMPOSITION EFFECT ON HEALTH EQUITY 14 (Med. Univ. of S.C., 2023) (stating that the hospital bylaws required a board reflecting the community demographic).

<sup>61</sup> See, e.g., CONSUMERS UNION U.S., INC., *supra* note 47, at 10-11 (suggesting excess funds be given to nonprofit organization with a similar mission to the converting one).

<sup>62</sup> U.S. GEN. ACCOUNTING OFF., NOT-FOR-PROFIT HOSPITALS – CONVERSION ISSUES PROMPT INCREASED STATE OVERSIGHT 5 (Health Educ. and Hum. Servs. Div., 1997).

<sup>63</sup> *Id.* at 20.

portion of their health care benefits.<sup>64</sup> The reported proceeds in the study were \$931 million, so it can be assumed that the loss of those health care services was felt significantly by the community.<sup>65</sup> This exemplifies why it is imperative to ensure the communal benefits align, so the community does not lose the health care services once provided to them. The conversion transaction shall not limit community's accessibility or availability to health care services.<sup>66</sup> This proposed criteria would address the issue of excess funds being given to investors and taken away from the community.

### C. Public Approval

Under the proposed solution, once the attorney general confirms that the three criteria above are satisfied, they will preliminarily approval the conversion transaction.<sup>67</sup> Following the approval, this proposed solution requires that notice of the intent to enter into a conversion transaction be issued to the public through an outlet likely to reach the majority of the community.<sup>68</sup> The notice would contain the value of the transaction, the for-profit's charitable obligation requirement, disclose the members of the

---

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 19-20.

<sup>66</sup> *See* CONSUMERS UNION U.S., INC., *supra* note 47, at 7 (arguing "the transaction must preserve or improve the availability, affordability, and quality of health care of the community").

<sup>67</sup> *See, e.g., id.* at 4 (discussing that after certain criteria are met with clear and convincing evidence, the attorney general may issue approval).

<sup>68</sup> *See, e.g., id.* at 4-5 (suggesting notice be provided "in a newspaper of general circulation in the applicant's service area, at the applicant's place of business in a manner such that anyone walking into the building will see the notice, on the applicant's web site, on the Attorney General's web site, and in papers designated by the Secretary of State").

board, and indicate which foundation the transaction proceeds would go to. Furthermore, the public will have access to these records at no cost.<sup>69</sup>

In addition to the ability to access these records, the proposed solution would allow the community to participate in a public hearing regarding the conversion transaction.<sup>70</sup> At the hearing, members of the community will be able to express concerns or ask questions regarding the conversion. The attorney general will then address concerns by answering questions or directing the question to the appropriate party in the conversion. Once the hearing is complete, the attorney general will provide a final approval through submission of a signed document granting the conversion to proceed as described.

#### *D. Compliance Mechanisms*

After the conversion is complete, with the assurance from the above-mentioned process that community benefits have been maintained, the proposed solution will impose compliance mechanisms to regulate the newly formed entity. To begin, the entity would be required to complete a community health needs assessment every five years.<sup>71</sup> A routine assessment would allow for an understanding of the changing needs of the community and how the for-profit can best support those needs.<sup>72</sup> This would promote greater collaboration between the entity and the

---

<sup>69</sup> See, e.g., *id.* at 6 (suggesting the public have access to information through the attorney general free of charge).

<sup>70</sup> See, e.g., *id.* at 5 (suggesting a public hearing be commenced within 45 days allowing affected members of the community to attend).

<sup>71</sup> SARA ROSENBAUM ET AL., COMMUNITY BENEFIT AND THE ACA A BRIEF HISTORY AND UPDATE I (GEO. WASH. Dep't. of Health Pol'y) (instituting the community health needs assessment required for nonprofit hospitals for for-profit entities as well).

<sup>72</sup> *Id.* (evidencing their application in nonprofit entities).

community, establishing a process where community members are able to have their voices heard and needs met.

The hospital board must either conduct the community health needs assessment itself or appoint a committee to do so in its place. To conduct the assessment, the for-profit hospital must define the community it serves either geographically or by a target population.<sup>73</sup> The for-profit would then assess the health needs of the community through a facts and circumstances analysis.<sup>74</sup> The hospital would also consult individuals who have special information about the healthcare needs of the community, such as individuals who utilize the local healthcare system, government officials, school districts, health insurance companies, and private businesses.<sup>75</sup> The findings of this assessment would then be documented, and the community benefit allocations will be rearranged to best fit the current needs of the community. Subsequently, the hospital would then make the report widely available to the public, allowing them to obtain updates on the status of health in their community, which would also serve as a means of holding the hospital accountable for providing communal benefits.<sup>76</sup>

To ensure compliance with the community health needs assessment, the proposed solution would regulate the hospital by the Department of Health and Human Services (“HHS”). The Centers for Medicare and Medicaid Services (“CMS”) is the best fit agency under HHS to monitor community

---

<sup>73</sup> See, e.g., *Community health needs assessment for charitable hospital organizations - Section 501(r)(3)*, IRS, <https://www.irs.gov/charities-non-profits/community-health-needs-assessment-for-charitable-hospital-organizations-section-501r3> (last visited Oct. 20, 2025) (following the framework used in non-profit entities).

<sup>74</sup> *Id.*

<sup>75</sup> See, e.g., *id.* (recommending receiving input from a broad range of members of the community).

<sup>76</sup> See, e.g., *id.* (suggesting the report be made available via website).

benefit spending because the Schedule H filing is already reported to CMS each year.<sup>77</sup> A new office could be created within CMS, such as the Office of Community Benefit Oversight (“OCBO”). The OCBO would oversee every conversion and ensure that a state’s attorney general is monitoring the in-state conversion activity by meeting the three criteria previously mentioned.<sup>78</sup> Each year, OCBO would be required to review the Schedule H of every hospital who was once a non-profit that converted to a for-profit entity.<sup>79</sup> If the review shows that the hospital is not in compliance with the agreed upon community benefits located in their bylaws, the OCBO will be forced to ensure compliance through a graduated enforcement mechanism.

Under the proposed conversion procedure, the first step in the graduated enforcement mechanism would be to issue a Corrective Action Plan (“CAP”), modeled after CFR § 430.49.<sup>80</sup> The first step of the CAP will be to inform the hospital of how their recorded Schedule H data violated the community benefit guideline set forth in their bylaws.<sup>81</sup> Next, the OCBO would inform the hospital of the corrective action that must be immediately implemented to ensure compliance.<sup>82</sup> These corrective measures would be up to the OCBO’s discretion, but may include processes such as adjustment of the hospital’s budget, new policies, or

---

<sup>77</sup> Zare, *supra* note 45, at 83-84.

<sup>78</sup> The three criteria include (1) assurance that community benefits will be continued in the same amount and essence, (2) a board reflective of the community’s demographic, and (3) assurance that excess conversion proceeds are being given to the community.

<sup>79</sup> See AM. HOSP. ASS’N., *supra* note 16 (requiring that tax exempt entities complete the Schedule H Form 990, but the converted for-profit entity should continue to internally record these numbers for the OCBO’s review).

<sup>80</sup> 42 C.F.R. § 430.49 (2025).

<sup>81</sup> 42 C.F.R. § 430.49(b)(2)(i) (2025).

<sup>82</sup> 42 C.F.R. § 430.49(b)(3)(i) (2025).

operational changes to ensure the community benefit threshold is met.<sup>83</sup> The hospital would also be expected to implement the adjustments indicated in the CAP no later than fourteen days after it is received.<sup>84</sup> Moreover, to ensure continued compliance, a hospital that does not implement the adjustments indicated in the CAP within the fourteen day period will then be put on the OCBO watch list, requiring a monthly review of their community benefit spending.

If the hospital does not properly comply to the CAP in the second year post-violation, the next phase of the graduated enforcement mechanism would be to impose a tax.<sup>85</sup> Meaning, if the hospital fails to correct their spending pursuant to the CAP, thereby failing to meet their community benefit obligation in year two, a \$50,000 tax would be imposed.<sup>86</sup> Although this sanction normally only applies to nonprofit entities in violation of their community benefit spending, it will be used to regulate converted for-profit hospitals.<sup>87</sup> The goal of this tax is to act as a greater penalty for the hospital, incentivizing compliance to their promised community benefit requirements.

Finally, if there is a third year of inadequate community benefit spending, CMS would revoke the hospital's Medicare and Medicaid status. Pursuant to C.F.R. § 424.535, CMS can revoke Medicare or Medicaid enrollment for noncompliance, creating profound effects on hospital systems.<sup>88</sup> Three major consequences of this revocation are the "loss of

---

<sup>83</sup> 42 C.F.R. § 430.49(b)(3)(ii) (2025).

<sup>84</sup> 42 C.F.R. § 430.49(b)(4)(iii) (2025).

<sup>85</sup> 26 U.S.C. § 4959 (2010).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> 42 C.F.R. § 424.535(a)(1) (2023).

Medicare revenue,” “patient disruption,” and “reputational damage.”<sup>89</sup> These consequences, although harsh, are aimed to ensure compliance with the regulations discussed throughout this proposal, aiming to prevent the adverse effects communities are experiencing from the loss of their community benefits due to conversion. This revocation would last until the hospital’s community benefit spending is in compliance with the standard set forth in its bylaws.

#### CONCLUSION

Evidently there are benefits to both nonprofit and for-profit entities, but the communal benefits provided by nonprofit hospitals are both essential and necessary to the overall well-being of a community. In the United States, an issue arises as to whether to prioritize the needs of investors and economic growth, or to prioritize the needs of the community and the benefits it can receive. Rather than choosing between one of the two, a balance can be struck through the implementation of the federal conversion procedure outlined above. The economic benefits derived from a for-profit hospital, along with the communal benefits derived from the nonprofit hospital will increase the overall well-being of the community. The model set forth would be the minimum standard to ensure that community benefits are maintained. Therefore, this solution provides the balance of power and policy needed by the vulnerable members of the communities affected by for-profit conversions.

---

<sup>89</sup> Alicia Shickle, *Navigating Revocation and Preclusion Risks*, AAPC (October 2, 2024), <https://www.aapc.com/blog/91389-navigating-revocation-and-preclusion-risks/>.

# Telehealth Providers: Ensuring Data Remains Private for Virtual Mental Health Patients

*Noelle Tresser*

## I. EMERGENCE OF VIRTUAL HEALTHCARE

Prior to the COVID-19 pandemic, accessing health care services almost certainly required a visit to a physical office space.<sup>1</sup> By the end of 2020 however, approximately 19.6 percent of Americans with private insurance utilized telehealth services in place of traditional in-person visits.<sup>2</sup> Telehealth involves the use of electronic health records, virtual clinical trials, telemedicine, and even AI-based platforms to provide individualized care, allowing providers to evaluate, diagnose, and treat patients from remote locations through video and/or audio calls.<sup>3</sup> In particular, telepsychiatry has emerged as both an important and a routinely used form of care delivery for mental health patients.<sup>4</sup> Alongside this growth in the general use of telepsychiatry are digital mental health startups providing services such as symptom checkers, online and individual group therapy, and access to prescription medications.<sup>5</sup>

Although there are many advantages to having access to mental health care at the touch of a button, ensuring quality care becomes more complicated when corporate concerns are involved.<sup>6</sup> Digital mental health startups have dominated recent investment activity in medicine, and this market is expected to continue growing in upcoming years.<sup>7</sup> In contrast to traditional care methods, digital mental health startups may prioritize profits and can neglect norms established by in-office care to protect

---

<sup>1</sup> Beth Carter et al., *Pandemic-Era Trends in Telehealth Use among Americans with Private Health Insurance*, 2 AARP PUB. POL'Y INST. (2024).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Eric D. Achtyes et al., *Telepsychiatry in an Era of Digital Mental Health Startups*, 25 CURRENT PSYCHIATRY REPS. 263, 263-72 (2023).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

patient health.<sup>8</sup> Data privacy is perhaps the most important norm of in-person therapy, and if laws do not exist to protect patient data, there is a major risk that patients will no longer be motivated to seek online care. Accordingly, digital mental health startups must be wary of business structures that allow for privacy policies to take away from the safe space that therapy visits intend to provide.

This article evaluates the quality of current corporate digital mental health models and emphasizes the need for broad legislative reforms to ensure that patient health is not compromised for the sake of profit motives. Broad legislative reforms are needed, specifically in Illinois, to prevent patient data from being shared with unauthorized individuals or used for reasons that patients do not consent to. This article concludes by providing statutory wording that may be used to shape stronger data privacy protections for online mental health patients.

## II. IMPLICATIONS OF CORPORATE EXPANSION FOR TELEHEALTH

As public interest turns toward the desire for more expansive access to care through telehealth, corporate models are attractive for their potential for rapid growth. Early in the second quarter of 2025, Teladoc Health, the global leader in virtual healthcare, announced its acquisition of UpLift, a virtual mental health provider.<sup>9</sup> This acquisition promises to “remove the traditional barriers to therapy and make mental health care more accessible

---

<sup>8</sup> *Id.*

<sup>9</sup> *Teladoc Health Acquires UpLift, Expanding Consumer Access to Mental Health Care Services Through Covered Benefits*, TELADOC (April 30, 2025), <https://ir.teladochealth.com/news-and-events/investor-news/press-release-details/2025/Teladoc-Health-Acquires-UpLift-Expanding-Consumer-Access-to-Mental-Health-Care-Services-Through-Covered-Benefits/default.aspx>.

to everyone” while also driving revenue growth.<sup>10</sup> Major players in this deal appear optimistic that their profit motives will not impede their ability to offer high quality, private care, but it is unclear whether this is reflected in patients’ actual experiences with the provider.<sup>11</sup> In order for this deal to prove successful, both Teladoc and UpLift must pay close attention to upholding healthcare norms that protect sensitive patient data.

One enormous potential issue for this newly formed telehealth giant comes from the misuse of patient data. In 2024, the Northern District of California allowed BetterHelp, a subsidiary of Teladoc, to continue their use of patient data for advertising, at least temporarily in *In re BetterHelp, Inc. Data Disclosure Cases*.<sup>12</sup> In this consolidated case, plaintiffs alleged that BetterHelp shared users’ email addresses with third parties for advertising, which then used users’ information for their own purposes.<sup>13</sup> The telehealth’s deceptive data privacy practices raised major concerns from patients that their information would be shared and used in an unauthorized manner.<sup>14</sup> Although the plaintiffs did not succeed in this case, it demonstrates that virtual mental health patients are exceptionally interested in knowing exactly when and how their data is used. If consumers of virtual healthcare providers feel that their personal data will be used without their knowledge or consent, they will likely look to the courts and legislators for protection.<sup>15</sup>

---

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *In re BetterHelp, Inc. Data Disclosure Cases*, No. 23-cv-01033-RS 4, 2024 U.S. Dist. LEXIS 124321 (N.D. Cal. July 15, 2024).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

In a similar complaint by the Federal Trade Commission (FTC) later that year, BetterHelp was exposed for sharing sensitive information about patients' mental health data.<sup>16</sup> Here, BetterHelp asked patients to provide extensive information about their personal history and mental health treatment, while promising consumers that their data would not be used for advertising purposes.<sup>17</sup> Against these promises, however, the company shared patients' private data with third parties like Facebook, Snapchat, and Pinterest.<sup>18</sup> To make matters worse, BetterHelp allowed these third parties to use the patient data for their own internal purposes, such as for research or to improve their own advertising.<sup>19</sup> For multiple years, BetterHelp falsely denied that it had shared personal patient data with third parties, but were still ultimately held accountable for violating California privacy laws.<sup>20</sup> In 2024 the FTC proposed an order requiring BetterHelp to pay \$7.8 million to provide partial refunds for consumers whose data may have been affected.<sup>21</sup>

Furthermore, courts have completely prohibited telehealth providers from sharing user health data with third parties.<sup>22</sup> In *United States of America v. GoodRx Holdings, Inc.*, the FTC prohibited California-based GoodRx from sharing user health data with third parties for advertising

---

<sup>16</sup> *FTC to Ban BetterHelp from Revealing Consumers' Data, Including Sensitive Mental Health Information, to Facebook and Others for Targeted Advertising*, FED. TRADE COMM'N (March 2, 2024), <https://www.ftc.gov/news-events/news/press-releases/2023/03/ftc-ban-betterhelp-revealing-consumers-data-including-sensitive-mental-health-information-facebook>.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *United States v. GoodRx Holdings, Inc.*, No. 4:23-cv-00460 (N.D. Cal. Feb. 1, 2023).

purposes, in addition to a \$1.5 million civil penalty.<sup>23</sup> The proposed order was filed by the Department of Justice on behalf of the FTC, and claimed that GoodRx failed to notify its consumers of its unauthorized disclosures of personal health information.<sup>24</sup> GoodRx, operating a digital health platform offering prescription drug discounts, telehealth appointments, and other health services, had effectively violated its promise to users to never share personal health information with advertisers or other third parties.<sup>25</sup>

According to the complaint, GoodRx shared its patients' health data with Facebook, Google, and other companies, in violation of the FTC's Health Breach Notification Rule.<sup>26</sup> Under the FTC's rule, vendors of personal health records are required to notify consumers following a breach involving unsecured information.<sup>27</sup> In violation of the FTC rule, GoodRx did not notify consumers, the FTC, or the media about the telehealth provider's unauthorized disclosure of individually identifiable health information to Facebook, Google, Criteo, Branch, and Twilio.<sup>28</sup> Prior to this breach by GoodRx, the FTC had already released a statement explicitly warning health applications and similar companies that collect or use consumers' health information that they are required to comply with their Health Breach Notification Rule.<sup>29</sup> As the FTC explained, this Rule

---

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> 16 C.F.R. § 318 (2025).

<sup>28</sup> *United States v. GoodRx Holdings, Inc.*, No. 4:23-cv-00460.

<sup>29</sup> *Statement of the Commission on Breaches by Health Apps and Other Connected Devices*, FED. TRADE COMM'N, (Sept. 15, 2021),

[https://www.ftc.gov/system/files/documents/public\\_statements/1596364/statement\\_of\\_the\\_commission\\_on\\_breaches\\_by\\_health\\_apps\\_and\\_other\\_connected\\_devices.pdf](https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf).

was intended to cover any companies capable of drawing individually identifiable health information that they create or receive from patients.<sup>30</sup>

### III. SAFEGUARDS TO DATA PRIVACY

*BetterHelp* and *GoodRx* make it evident that disclosure of sensitive mental health information without consent may constitute a highly offensive intrusion of privacy.<sup>31</sup> Unfortunately, *BetterHelp* still faces potential legal issues because of their ability to aid third parties in intercepting user communications.<sup>32</sup> Under Section 631 of the California Invasion of Privacy Act (CIPA), businesses may not aid and abet in the use of data by third party vendors in a manner inconsistent with existing data privacy standards.<sup>33</sup> The Northern District of California was not persuaded by *BetterHelp*'s argument that CIPA does not apply to internet communications, meaning that corporate telehealth providers are still on the hook.<sup>34</sup> If a similar claim was brought against *BetterHelp* under the Health Breach Notification Rule, it is likely that a court would find the company liable for a violation of the rule.<sup>35</sup> Thus, there is a major need for virtual mental health providers to be extremely cautious in their handling of user data to avoid penalties under these or similar pieces of legislation.

These instances of FTC sanctions are candid cautionary tales of how the government may restrict the wide mental health care access that these

---

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> CAL. PENAL CODE § 631 (West 2023).

<sup>34</sup> *In re BetterHelp, Inc. Data Disclosure Cases*, 2024 U.S. Dist. LEXIS 124321.

<sup>35</sup> 16 C.F.R. § 318.

telehealth businesses seem to provide. With moves like Teladoc's acquisition of BetterHelp, it should remain a top priority for these providers to maintain ethical healthcare practices. Legal issues relating to the mishandling of patient data are likely to fall under violations of 15 U.S.C. § 45, which bans unfair or deceptive acts or practices affecting commerce.<sup>36</sup> Violation of this provision is grounds for large civil penalties that could amount to insurmountable losses for liable companies.<sup>37</sup> With their seemingly ever-increasing expansion of clientele in combination with shoddy data privacy practices, Teladoc, BetterHelp, and similar providers face huge risks for consequences on their current trajectory.<sup>38</sup> While some of these mistakes may be attributable to the experimental nature of the COVID-19 era, these corporate telehealth entities must carefully evaluate the legal aids and parameters available to them already.

Legislation like CIPA and the Health Breach Notification Act highlight the need for strict laws when sensitive personal information is collected by businesses. With the high volume of personal data that corporate telehealth firms may collect, they may be at a high risk of failing to comply with privacy laws. In combination with expansion efforts like the acquisition of BetterHelp by Teladoc, personal health data of huge numbers of people are the responsibility of a vast array of employees and practitioners.<sup>39</sup> BetterHelp announced in 2025 that it had surpassed five million online therapy patients from over a hundred countries.<sup>40</sup> The

---

<sup>36</sup> 15 U.S.C. § 45.

<sup>37</sup> *Id.*

<sup>38</sup> FED. TRADE COMM'N, *supra* note 29.

<sup>39</sup> TELADOC, *supra* note 9.

<sup>40</sup> *BetterHelp Surpasses 5 Million People Benefiting from Online Therapy Service*, BUSINESSWIRE (Jan. 22, 2025),

online therapy platform employs over 35,000 licensed therapists, all of whom are required to comply with local privacy laws when handling patient data.<sup>41</sup> BetterHelp clearly prioritizes corporate growth, but data privacy rules are still imperative for businesses of any size.<sup>42</sup>

The case of *Giles v. Brookwood Health Services* exemplifies these concerns surrounding the reasonable standard of care in medical practices.<sup>43</sup> In *Giles*, the Alabama Supreme Court held that Brookwood Health Services could be held liable for negligence when it failed to provide appropriate standards of care.<sup>44</sup> This case established that healthcare entities owe a mandatory, nondelegable duty of care to their patients.<sup>45</sup> This duty of care establishes that healthcare providers must exercise caution as they handle patient data, especially when it is attributable to their mental health challenges.<sup>46</sup> If a court can find a health provider liable for failing to abide by the applicable duty of care, the company is likely to face serious penalties, including monetary damages and orders to halt their business.<sup>47</sup>

Although *Giles* does not involve telehealth directly, it is highly relevant in setting a precedent for holding healthcare businesses accountable for lapses in care, regardless of whether services are delivered in person or

---

<https://www.businesswire.com/news/home/20250122456222/en/BetterHelp-Surpasses-5-Million-People-Benefiting-from-Online-Therapy-Service>.

<sup>41</sup> *Id.*

<sup>42</sup> TELADOC, *supra* note 9.

<sup>43</sup> *Giles v. Brookwood Health Serv.*, 5 So.3d 533 (Ala. 2008).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> FED. TRADE COMM'N, *supra* note 16.

virtually.<sup>48</sup> For telehealth companies, this means they cannot evade responsibility by blaming individual providers or technological limitations.<sup>49</sup> Businesses like BetterHelp must ensure that adequate training, attention to detail, and strong privacy protections are constantly a norm for their practice.<sup>50</sup> If a corporate telehealth provider fails to uphold the standard of care expected in the profession, they could still face legal repercussions under the rule established in *Giles*.<sup>51</sup> Even though online mental health providers are admired for their ability to cut corners by providing easily accessible care to large numbers of clients, the area of data privacy is no place for shortcuts.<sup>52</sup>

#### IV. THE RISE IN ONLINE MENTAL HEALTH PROVIDERS IS OUTPACING PATIENT PRIVACY PROTECTIONS

In Illinois, data privacy laws must be strict enough to ensure compliance with statewide standards, particularly as they relate to corporate telehealth providers. The state has been successful at enacting proactive legislation in some areas of digital privacy law, such as with the Biometric Information Privacy Act (BIPA).<sup>53</sup> BIPA, enacted in Illinois in 2008, is a comprehensive set of data privacy laws that regulates how private entities collect, use, and store, and biometric identifiers, which may include fingerprints, facial scans, and voiceprints.<sup>54</sup> For telehealth providers,

---

<sup>48</sup> *Id.*

<sup>49</sup> *In re BetterHelp, Inc. Data Disclosure Cases*, No. 23-cv-01033-RS 4, 2024 U.S. Dist. LEXIS 124321 (N.D. Cal. July 15, 2024).

<sup>50</sup> *Giles*, 5 So.3d at 533.

<sup>51</sup> *Id.*

<sup>52</sup> FED. TRADE COMM'N, *supra* note 16.

<sup>53</sup> 740 ILL. COMP. STAT. 14 (2025).

<sup>54</sup> *Id.* at § 14/10.

BIPA is incredibly important in placing boundaries on the amount of data that can be obtained, and how that data may be utilized.

Under BIPA, companies must obtain informed, written consent before collecting or sharing a patient's biometric data, and they must establish publicly available policies detailing data their retention and destruction policies.<sup>55</sup> BIPA also provides individuals with a private right of action which allows patients to sue companies for violations, even in the absence of actual harm.<sup>56</sup> For healthcare providers using facial recognition, voice authentication, or other biometric tools, BIPA serves as a powerful regulatory framework. Its principles could be further expanded, however, to encompass broader categories of sensitive health data in the realm of telehealth patient data.<sup>57</sup>

Even with legislation like BIPA in place, current Illinois laws do not go far enough to address the unique vulnerabilities present in mental health telehealth services. Mental health records, in particular, contain deeply personal data that, if leaked or misused, can result in serious psychological and social, in addition to legal, consequences for patients.<sup>58</sup> Under current Illinois law, there are insufficient mechanisms to hold telehealth businesses accountable for breaches that result from weak internal safeguards or negligent vendor management.<sup>59</sup>

One of the most significant gaps in Illinois law is the lack of explicit, comprehensive regulations targeting corporate data practices in healthcare

---

<sup>55</sup> *Id.* at § 14/15.

<sup>56</sup> *Id.* at § 14/20.

<sup>57</sup> *Id.*

<sup>58</sup> FED. TRADE COMM'N, *supra* note 29.

<sup>59</sup> *Id.*

technology. Unlike some other states such as California, which enacted CIPA, Illinois lacks a broad consumer data protection framework that applies across all healthcare sectors, including telehealth.<sup>60</sup> Accordingly, telehealth providers have been able to share user data expansively with third parties.<sup>61</sup> As a result, patients using online mental health services may unknowingly have their data shared with third parties for marketing, advertising, or training purposes without obtaining consent.<sup>62</sup> Illinois lawmakers must address this gap by introducing legislation that expands the definition of covered entities and strengthens consent, disclosure, and enforcement provisions.

#### V. EXPANDING ILLINOIS' CURRENT DIGITAL PRIVACY LAW AND FEDERAL OVERSIGHT FOR PATIENT PRIVACY

Moreover, enforcement of existing privacy obligations is inconsistent and lacks the teeth necessary to deter corporate noncompliance. Even under BIPA, enforcement has largely relied on private litigation rather than proactive state oversight.<sup>63</sup> A more robust regulatory approach would involve clearer authority and resources to investigate telehealth privacy violations and impose penalties for noncompliance. Illinois should also mandate transparency reports from telehealth providers, require privacy impact assessments for digital health tools, and offer patients greater control over how their mental health data is used and retained. In an era where corporate telehealth is becoming a primary avenue for mental

---

<sup>60</sup> CAL. PENAL CODE § 631 (West 2023).

<sup>61</sup> FED. TRADE COMM'N, *supra* note 29.

<sup>62</sup> *Id.*

<sup>63</sup> 740 ILL. COMP. STAT. § 14/20.

healthcare, Illinois has both a moral and a legal obligation to lead in protecting its patients' most sensitive information.<sup>64</sup>

Section 10 of BIPA defines what constitutes biometric information. Under this Section, “biometric identifiers do not include information captured from a patient in a health care setting or information collected, used, or stored for health care treatment, payment, or operations.”<sup>65</sup> BIPA does, however, include confidential and sensitive information, which is personal information that can be used to uniquely identify an individual or an individual's account or property.<sup>66</sup> These two definitions within BIPA appear to be inconsistent with current telehealth trends because the information being obtained by telehealth providers most likely constitutes confidential and sensitive information, yet it is not protected under this statute because it goes beyond the definition of biometric information.<sup>67</sup>

To expand BIPA's protections for data obtained in the telehealth context, these two definitions should be aligned under a new subchapter of the statute. The following includes the current definitions provided in Section 14 of BIPA with proposed additions italicized:

Biometric information' means any information, regardless of how it is captured, converted, stored, or shared, based on an individual's biometric identifier used to identify an individual. *Included under the protection of this Act is 'confidential and sensitive information,'* which means personal information that can be used to uniquely identify an individual or an individual's account or property. Examples of confidential and sensitive information include, but are not limited to, a genetic marker, genetic testing information, a unique identifier number to locate an account or

---

<sup>64</sup> Eric D. Achtyes et al., *supra* note 4.

<sup>65</sup> 740 ILL. COMP. STAT. § 14/20.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

property, an account number, a PIN number, a pass code, a driver's license number, or a social security number.

*A private entity in possession of confidential and sensitive information must develop a written policy, made available to the public, establishing a retention schedule and guidelines for permanently destroying confidential and sensitive information when the initial purpose for collecting or obtaining such information has been satisfied.*

By updating BIPA's protective measures to also cover confidential and sensitive information, there may be direct recourse for individuals who are experiencing misuse of their data. Additionally, this updated language allows patients seeking telehealth mental health resources to feel confident that the private information they share will actually remain private. Critics of more stringent data privacy laws may argue that patient privacy is already protected enough when telehealth providers share information with third parties. However, absent this updated legislation, corporate telehealth providers would remain incentivized to continue using patient data for business reasons that do not reflect the best interests of their users.<sup>68</sup> For these providers, it is imperative that high quality care is not ignored for profit motives, and enacting this type of legislation places a reasonable boundary that still allows for further corporate expansion maneuvers.<sup>69</sup>

For legislation to be successful, it needs to thoroughly protect vulnerable information being shared by mental health patients, while not preventing existing and future providers from seeking a vaster patient network. This ensures that corporate telehealth providers may continue to provide much-needed care to patients from across the country. With some

---

<sup>68</sup> FED. TRADE COMM'N, *supra* note 16.

<sup>69</sup> TELADOC, *supra* note 9.

changes to current BIPA protections, mental health patients utilizing platforms like BetterHelp can feel more confident that the information they share will only be used for authorized purposes. Critics may argue that this balance will be difficult to achieve, but Illinois already offers reasonable protections for the use of biometric information by business entities, so this proposed legislation is merely an extension of that protection.<sup>70</sup>

In addition to expanding BIPA's coverage of patient data privacy to corporate telehealth providers, there is a need for the FTC and local governments to closely monitor these companies' practices. First, all telehealth providers should be notified of any expansions to BIPA and any applicable limitations imposed by the Health Notification Breach Act or similar laws. BIPA helps to ensure that corporate telehealth providers comply with the Health Notification Breach Rule, but it still may be possible for companies to evade liability even once they have been notified of these laws.<sup>71</sup> Accordingly, it is important for the FTC to regularly audit corporate telehealth companies and similar providers that promise to only share confidential and sensitive patient information with third parties for specifically disclosed purposes. Although it is helpful and necessary for companies to state that confidential and sensitive data will be safe, federal and state governments can still use their power to ensure that these policies are enforced.

---

<sup>70</sup> 740 ILL. COMP. STAT. § 14/20.

<sup>71</sup> 16 C.F.R. § 318.

The FTC, for example, has broad investigative authority to become informed of potentially harmful business practices.<sup>72</sup> Under Section 5(b) of the FTC Act, the FTC has the authority to challenge any unfair or deceptive acts or practices or other violations of applicable laws.<sup>73</sup> The FTC can issue a complaint setting forth its charges whenever it has reason to believe that a law violation has occurred.<sup>74</sup> This policy allows the FTC to identify potentially harmful practices of companies like corporate telehealth providers, which can disrupt how these businesses operate.<sup>75</sup> Because they have this capacity to directly enforce instances where telehealth providers engage in practices that go against data privacy laws, the FTC needs to consistently keep track of these businesses' actions. Corporate telehealth providers and similar businesses need to remain aware that they may not engage in any kind of practice that violates BIPA, the Health Notification Breach Act, or similar applicable laws.

In this realm, governmental authority can remain broad without interfering too much with the day-to-day operations of corporate mental telehealth providers. Whether this means that these providers are audited by state and federal governments annually, or that their data usage must be reported as it occurs, there is room for growth in how data privacy laws are enforced. If telehealth providers disclose where patient data will be used and actually stick to their policies, administrative enforcement should not hinder their ability to provide quality care. Moving forward, these

---

<sup>72</sup> *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority*, FED. TRADE COMM'N, <https://www.ftc.gov/about-ftc/mission/enforcement-authority#top> (Revised July 2025).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

solutions will protect the needs of Americans seeking virtual care from corporate providers for mental health treatment, while allowing for comprehensive care. With these solutions in place, mental health patients can still opt for telehealth businesses to treat even their most deeply personal health concerns.

#### CONCLUSION

For the foregoing reasons, Illinois should implement the proposed legislation to protect its virtual mental health patients, and enforcement must be upheld by local and state governments. Telehealth has proven to be an excellent option for individuals to receive more efficient care through a huge variety of provider options. As these providers make business decisions to reach even larger numbers of users, they also must remain cautious that these expansion efforts do not impede on patients' data security. By utilizing BIPA to expand the protection of virtual patient data, corporate telehealth providers will have built-in safeguards to uphold the long-established norms of traditional healthcare services. Once further policies are implemented to ensure that these safeguards are regularly enforced by governmental authority, patients can rest assured that their sensitive information will remain private. Altogether, the proposed legislation prioritizes safety for virtual mental health patients, while still allowing corporate telehealth providers to continue expanding their patient population.