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# 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

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*Dasha Ignatova and Katelyn Sears*

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ANNALS OF HEALTH LAW  
Advance Directive

Editors' Note

The Annals of Health Law and Life Sciences is proud to present the second issue of the thirty-fifth volume of our online, student-written publication, *Advance Directive*. This *Spring 2026 Advance Directive* issue focuses on the evolution of healthcare.

The *Spring 2026 Advance Directive* issue examines a broad range of topics within the U.S. healthcare framework, including antitrust, medicine, and regulation. Our student authors provide insightful proposals for regulating consumer substances, narrowing the accountability gap for Private Equity ownership, ensuring fair patent practices, and transitioning from physician-centered care to interdisciplinary care.

This issue's articles explore topics spanning the advancement of modern day medicine, structuring of virtual care and tax-exempt hospitals, and regulating raw-milk sales. These proposals highlight the changing landscape of the healthcare system from its inception and the challenges that arise under growing concerns of regulation, privacy, and monopolization.

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 members of our outgoing *Annals* Executive Board, Matt Padilla, Hyunji Haynes, Grant Higgins, and Christina Ramesh, as well as members of our incoming *Annals* Executive Board, Noelle Tresser, Allison Garcia, Maria Wright, Elizabeth Primrose, Briana Crowley, Taylor Stamm, Yumna Siddiqi, and Taran Stahle, for all their hard work in the technical production process. 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  
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# What Is a Hospital Without Walls? Virtual Care and the Limits of Tax-Exempt Status

*Faye O'Connell*

## INTRODUCTION

Virtual and hybrid hospital models are rapidly changing how healthcare is delivered, particularly for rural and underserved patients and those managing complex chronic conditions.<sup>1</sup> These “hospitals without walls” challenge a foundational assumption embedded in federal tax law: a hospital is, first and foremost, a physical place.<sup>2</sup> Tax-exempt status under Section 501(c)(3) carries significant benefits, including access to tax-exempt bond financing and other public subsidies, yet the IRS’s hospital exemption structure remains rooted in factors such as inpatient beds, emergency rooms, and brick-and-mortar facilities.<sup>3</sup> As a result, virtual hospitals operate in a space of doctrinal uncertainty, where similarly situated providers may receive inconsistent tax treatment based not on how they serve communities, but on whether they resemble a traditional hospital.

Over the past decade, and particularly following the COVID-19 pandemic, healthcare systems have increasingly adopted virtual and hybrid models that deliver hospital-level care without requiring patients to enter a traditional inpatient facility.<sup>4</sup> Hospitals recognized as tax-exempt under Section 501(c)(3) benefit from exemption from federal income tax, access to tax-exempt bond financing, eligibility for charitable contributions, and other

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<sup>1</sup> *Telehealth Services: Exploring Hybrid Models for Improved Access to Care*, DR. KUMO (Nov. 3, 2025), <https://drkumo.com/telehealth-services-exploring-hybrid-models-for-improved-access-to-care/>.

<sup>2</sup> 26 U.S.C. § 501(c)(3) (“Tax-exempt hospital or a cooperative organization created by two or more tax-exempt hospitals providing specific services to other hospitals that have facilities to serve not more than 100 inpatients.”).

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

<sup>4</sup> DR. KUMO, *supra* note 1.



public subsidies.<sup>5</sup> These benefits shape competition in healthcare markets and reflect a judgment that the institution provides sufficient public benefit to justify preferential treatment.<sup>6</sup>

Despite changes in healthcare delivery, the IRS's structure for hospital tax exemption remains grounded in a traditional conception of hospitals as physical institutions. IRS guidance emphasizes factors such as the operation of inpatient facilities, the presence of an emergency room open to the public, and ownership of brick-and-mortar infrastructure.<sup>7</sup> As a result, virtual and hybrid hospitals operate in a space of doctrinal uncertainty. Providers offering comparable services and serving similar patient populations may receive different tax treatment based not on the extent of their community benefit, but on whether their operations resemble a conventional hospital. This emphasis on physical form risks obscuring the core inquiry underlying tax exemption: whether an organization operates for the public benefit.

This Article argues that existing IRS methodology for determining hospital tax-exempt status under Section 501(c)(3) is ill-suited to virtual and hybrid healthcare systems, creating uncertainty and risking inconsistent and inequitable outcomes. Part I outlines the statutory and doctrinal foundations of hospital tax exemption and the evolution of the community benefit standard. Part II examines the emergence of virtual and hybrid hospital models and explains why they strain existing exemption criteria. Part III demonstrates how current IRS tests fail in the virtual care context. Part IV explains why this failure matters for competition, accountability, and

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<sup>5</sup> 26 U.S.C. § 501(c)(3).

<sup>6</sup> Sara Rosenbaum & Ross Margulies, *Tax-Exempt Hospitals and the Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice*, 126 L. & PUB.'S HEALTH 283, 285 (2011).

<sup>7</sup> *Id.* at 284.

healthcare innovation. Part V proposes a functional approach to hospital tax exemption that focuses on access, continuity of care, and measurable community benefit while preserving meaningful limits on exemption. Tax exemption should reflect how care is delivered, not where it occurs.

## I. THE STATUTORY AND DOCTRINAL FOUNDATIONS OF HOSPITAL TAX EXEMPTION

### A. *IRC § 501(c)(3) and the Operational Test*

Section 501(c)(3) of the Internal Revenue Code provides tax-exempt status to organizations organized and operated exclusively for charitable purposes, so long as no part of the organization's net earnings inures to the benefit of private individuals and the organization does not engage in substantial nonexempt activity.<sup>8</sup> Although the statute itself offers little guidance on how these requirements apply to hospitals specifically, Department of Treasury regulations and Internal Revenue Service interpretations have long shaped the hospital exemption.

At the threshold, an organization must satisfy both the organizational test and the operational test.<sup>9</sup> The organizational test examines whether the entity's governing documents limit its purposes to one or more exempt purposes and do not empower it to engage in substantial noncharitable activities.<sup>10</sup> For hospitals, this requirement is generally satisfied through articles of incorporation and bylaws that recite charitable purposes related to

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<sup>8</sup> 26 U.S.C. § 501(c)(3).

<sup>9</sup> *What Are the Organizational and Operational Tests?*, NGOSOURCE (Jan 19, 2022), <https://www.ngosource.org/what-are-the-organizational-and-operational-tests-1>.

<sup>10</sup> *Organizational Test - Internal Revenue Code Section 501(c)(3)*, INTERNAL REVENUE SERVICE (hereinafter "IRS"), <https://www.irs.gov/charities-non-profits/charitable-organizations/organizational-test-internal-revenue-code-section-501c3> (last visited Feb. 2, 2026).

healthcare delivery.<sup>11</sup> The operational test, by contrast, is more substantive and more contested. It requires that an organization actually operate primarily in furtherance of its exempt purposes.<sup>12</sup> An organization that otherwise appears charitable may fail the operational test if it engages in excessive commercial activity or operates in a manner indistinguishable from a for-profit enterprise.<sup>13</sup> This inquiry is particularly salient for hospitals, which routinely charge fees for services, compete in commercial healthcare markets, and generate substantial revenue.<sup>14</sup> Overlaying the operational test is the prohibition on private inurement and private benefit.<sup>15</sup> No portion of a Section 501(c)(3) organization's net earnings may benefit insiders, and any private benefit conferred on non-insiders must be incidental to the organization's charitable purpose.<sup>16</sup> For hospitals, these restrictions have historically focused on physician compensation arrangements, joint ventures, and governance structures.<sup>17</sup> They have also shaped the IRS's concern that

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

<sup>12</sup> *Id.*; NGOSOURCE, *supra* note 9.

<sup>13</sup> See Yuvraj Pathak & David Muhlestein, *Hospital System Market Share and Commercial Prices: A Cross-Sectional Approach Using Price Transparency Data*, HEALTH ECON. REV., Dec. 4, 2024, at 102, <https://doi.org/10.1186/s13561-024-00580-w> (suggesting that hospitals that engage in excessive commercial activity, increase hospital system market share, thus failing the operational test by failing to engage in charitable activities).

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

<sup>15</sup> Mark Hoenig, *Partnering with Nonprofits: Navigating a Tax Law Minefield*, TAXNOTES (May 27, 2019), <https://www.taxnotes.com/special-reports/exempt-organizations/partnering-nonprofits-navigating-tax-law-minefield/2019/05/24/29g68>.

<sup>16</sup> *Inurement/Private Benefit: Charitable Organizations*, IRS, <https://www.irs.gov/charities-non-profits/charitable-organizations/inurement-private-benefit-charitable-organizations> (last visited Feb. 2, 2026).

<sup>17</sup> Nicholas J. Stock II, *Tax-Exempt Hospitals: Community Benefit Requirement and Risks for Hospitals*, FOSTER SWIFT (Oct. 16, 2025), <https://www.fosterswift.com/newsroom/publications/tax-exempt-hospitals-community-benefit-requirement-risks>.

hospitals will function primarily as profit-generating enterprises under the guise of charity.<sup>18</sup>

While these statutory and regulatory principles apply to all charitable organizations, hospitals have been subject to a distinct and evolving set of expectations that reflect their unique role in healthcare delivery. Understanding how the IRS came to define a hospital is essential to understanding why virtual care models pose such a challenge today.

*B. The IRS's Historical Conception of a "Hospital"*

In Revenue Ruling 69-545, the IRS concluded that a nonprofit hospital qualified for exemption despite providing limited charity care, emphasizing instead that the hospital operated an emergency room open to the public, maintained an open medical staff, and served the community without regard to patients' ability to pay.<sup>19</sup> These features were treated as evidence that the hospital served a broad public interest rather than a narrow set of private beneficiaries.<sup>20</sup>

Over time, this reasoning hardened into a set of assumptions embedded in IRS guidance.<sup>21</sup> Hospitals were presumed to be physical facilities that provided inpatient care, operated emergency rooms, and served as community anchors.<sup>22</sup> These assumptions reflected the healthcare landscape of the time, when hospitals were primarily sites of acute, inpatient treatment

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

<sup>19</sup> Rev. Rul. 69-545, 1969-2 C.B. 117.

<sup>20</sup> *Id.*

<sup>21</sup> Erin C. Fuse Brown & Mark A. Hall, *Private Equity and the Corporatization of Health Care*, 76 STAN. L. REV. 527, 530 (2024).

<sup>22</sup> *Id.* at 559.

and emergency services.<sup>23</sup> However, these assumptions were never rooted in the statutory text of Section 501(c)(3).<sup>24</sup> Rather, they emerged as practical proxies for charitable purposes in an era when physical presence and emergency access closely aligned with public benefit. As healthcare delivery has evolved, those proxies have become increasingly strained.

### *C. Hospital-Specific Factors Used by the IRS*

The IRS developed a set of hospital-specific factors that continue to dominate exemption analysis.<sup>25</sup> Among the most significant is the operation of a full-time emergency room open to the public.<sup>26</sup> Emergency room access has been treated as central to a hospital's charitable character, based on the idea that emergency services ensure care regardless of the ability to pay and serve the entire community.<sup>27</sup>

The provision of inpatient services has also played a critical role. Hospitals are expected to maintain beds and admit patients for overnight care, reflecting a traditional understanding of hospitalization.<sup>28</sup> While outpatient services have expanded dramatically, inpatient capacity remains a touchstone

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<sup>23</sup> *Id.* (detailing the pre-telehealth era of private equity in healthcare and how the corporatization of medicine has been implicated by changes to modes of healthcare access).

<sup>24</sup> See 26 U.S.C. § 501(c)(3) (missing specific language indicating requirements of charitable hospitals versus other healthcare providers).

<sup>25</sup> See generally, Mark W. Everson, *Written Statement of the Commissioner of Internal Revenue Before the Committee on Ways and Means*, U.S. HOUSE OF REPRESENTATIVES: A REVIEW OF THE TAX-EXEMPT HOSPITAL SECTOR (May 26, 2005), [https://www.irs.gov/pub/irs-tege/5-26-05\\_hospital\\_sector\\_testimony.pdf](https://www.irs.gov/pub/irs-tege/5-26-05_hospital_sector_testimony.pdf) (detailing the hospital specific factors).

<sup>26</sup> *Id.* at 4.

<sup>27</sup> Eileen Salinsky, *What Have You Done for Me Lately? Assessing Hospital Community Benefit*, NAT'L HEALTH POL'Y F., Issue Brief No. 821 (Apr. 19, 2007), [https://www.ncbi.nlm.nih.gov/books/NBK560012/pdf/Bookshelf\\_NBK560012.pdf](https://www.ncbi.nlm.nih.gov/books/NBK560012/pdf/Bookshelf_NBK560012.pdf).

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

in IRS analysis.<sup>29</sup> Other factors include maintaining an open medical staff, meaning that physicians are admitted based on objective criteria rather than affiliation or exclusivity, and engaging in community benefit activities such as health education, outreach programs, and subsidized services.<sup>30</sup>

Together, these factors function as proxies for charitable purpose. Rather than requiring direct proof of improved community health or access outcomes, the IRS has relied on structural and operational features associated with traditional hospitals. This approach has allowed for relatively predictable administration but has also entrenched a hospital model defined by physical infrastructure and emergency care.

## II. THE EMERGENCE OF VIRTUAL AND HYBRID HOSPITAL MODELS

It is important to distinguish telehealth services, virtual hospitals, and hybrid hospital systems. Telehealth generally refers to discrete services delivered remotely, such as video consultations or remote follow-up visits, often layered onto existing care relationships.<sup>31</sup> These services do not, by themselves, constitute a hospital.<sup>32</sup> Virtual hospitals, by contrast, are organized systems designed to deliver hospital-level care without relying on centralized inpatient facilities.<sup>33</sup> They coordinate diagnosis, treatment,

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<sup>29</sup> Everson, *supra* note 25.

<sup>30</sup> Nancy Zuech Lim, *Community Benefit — Nonprofit Hospital Community Benefit: What Counts and Why It Matters*, CATH. HEALTH ASS'N OF THE U.S (2025), <https://www.chausa.org/news-and-publications/publications/health-progress/archives/summer-2025/community-benefit---nonprofit-hospital-community-benefit--what-counts-and-why-it-matters>.

<sup>31</sup> *What Is Telehealth?*, AM. MED. ASS'N (updated June 12, 2024), <https://www.ama-assn.org/practice-management/digital-health/what-telehealth> (last visited Feb. 2, 2026).

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

<sup>33</sup> Tejaswini Manavi & Derek O'Keeffe, *Virtual Hospital, Real Health Care*, 3 MAYO CLINIC PROC.: DIGIT. HEALTH 100303 (2025), [https://www.mcpcdigitalhealth.org/article/S2949-7612\(25\)00110-5/fulltext](https://www.mcpcdigitalhealth.org/article/S2949-7612(25)00110-5/fulltext).

monitoring, and escalation of care through digital platforms, remote clinical teams, and in-home services.<sup>34</sup> Many operate hospital-at-home programs that substitute inpatient admission with intensive home-based care.<sup>35</sup> Hybrid hospital systems combine virtual infrastructure with limited physical facilities or partnerships with brick-and-mortar hospitals.<sup>36</sup> These systems may centralize physician oversight and monitoring while relying on affiliated hospitals for imaging, procedures, or emergency transfers.<sup>37</sup>

#### *A. How Virtual Hospitals Deliver Care*

Virtual hospitals deliver continuity of care through coordinated, technology-enabled systems rather than physical proximity.<sup>38</sup> Patients are monitored remotely using connected devices, evaluated through virtual consultations, and supported by interdisciplinary care teams.<sup>39</sup> Escalation protocols allow patients to be transferred to partner facilities when higher levels of care are needed.<sup>40</sup> Many virtual hospitals are integrated with brick-and-mortar systems, functioning as extensions rather than replacements.<sup>41</sup>

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

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

<sup>36</sup> Margaret R. Paulson, et al., *Implementation of a Virtual and In-Person Hybrid Hospital-At-Home Model in Two Geographically Separate Regions Utilizing a Single Command Center: A Descriptive Cohort Study*, BMC HEALTH SERVICES RSCH. (2023), <https://doi.org/10.1186/s12913-023-09144-w> (“We describe the implementation of Advanced Care at Home (ACH), Mayo Clinic’s hybrid virtual and in-person hospital-at-home model that combines a single virtual physician-staffed command center with in-home advanced practice provider visits and a vendor-mediated in-person medical supply chain that can deliver care in two diverse settings, urban and rural.”).

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

<sup>38</sup> Alexandre Vallée & Maxence Arutkin, *The Transformative Power of Virtual Hospitals for Revolutionising Healthcare Delivery*, 45 PUB. HEALTH REV. 1606371 (2024), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11221308/>.

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

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

<sup>41</sup> Oscar Boldt-Christmas, Rebecca Kannourakis & Madeline Maud, *Virtual Hospitals Could Offer Respite to Overwhelmed Health Systems*, MCKINSEY & CO. (May 11, 2023),

Others operate independently but maintain formal relationships with local providers.<sup>42</sup> In both cases, physical facilities exist in the background rather than as the defining feature of care delivery.<sup>43</sup> They also play a growing role in post-acute and chronic care management, reducing readmissions and supporting patients outside traditional hospital settings.<sup>44</sup>

*B. Why These Models Challenge Existing Tax Structures*

Virtual and hybrid hospitals do not neatly fit within existing IRS boundaries.<sup>45</sup> Many lack inpatient facilities or operate them only through partners.<sup>46</sup> Emergency care is often handled through transfer agreements rather than in-house emergency rooms.<sup>47</sup> Community benefits are delivered through expanded access, reduced barriers, and continuity of care rather than physical presence.<sup>48</sup> As a result, these models may fail to satisfy hospital-specific factors that were designed around traditional infrastructure, even when they meaningfully promote community health. This mismatch exposes the limitations of relying on form-based criteria to assess charitable purpose.

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<https://www.mckinsey.com/industries/healthcare/our-insights/virtual-hospitals-could-offer-respite-to-overwhelmed-health-systems>.

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

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

<sup>44</sup> Karsten Russell-Wood, *Telehealth's Impact on Rural Hospitals: A Literature Review*, RURAL HEALTH VOICES BLOG (Feb. 6, 2025), <https://www.ruralhealth.us/blogs/2025/02/telehealth-s-impact-on-rural-hospitals-a-literature-review>.

<sup>45</sup> CONGRESS.GOV, *Legal Requirements for Section 501(c)(3) Hospitals* (2026), <https://www.congress.gov/crs-product/R48027>; Rosenbaum & Margulies, *supra* note 6.

<sup>46</sup> Salinsky, *supra* note 27.

<sup>47</sup> *Id.*

<sup>48</sup> Lindsey Culli, *Beyond the Bottom Line: Evaluating Charity Care, Community Benefits, and Tax Exemptions in Nonprofit Hospitals*, JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH (Nov. 26, 2024), <https://publichealth.jhu.edu/2024/evaluating-tax-exemptions-in-nonprofit-hospitals>.



### III. DOCTRINAL BREAKDOWN: WHY CURRENT IRS TESTS FAIL IN VIRTUAL CARE CONTEXTS

Organizations that maintain traditional facilities are more likely to satisfy exemption criteria even if they deliver limited community benefit, while virtual hospitals that expand access and continuity may struggle to qualify solely because they do not resemble legacy institutions.<sup>49</sup> This approach risks freezing the charitable hospital concept in a prior era and discouraging models that decouple care delivery from geography.

More fundamentally, reliance on infrastructure obscures the core inquiry underlying Section 501(c)(3). The statute does not require that charitable organizations own property or operate facilities. It requires that they operate for public benefit.<sup>50</sup> When infrastructure becomes a stand-in for that inquiry, the analysis shifts away from outcomes and toward institutional aesthetics. In the virtual care context, that shift is not merely outdated but distortive.

#### A. *The Emergency Room Requirement and Its Limitations*

Emergency room access occupies a central position in the IRS's hospital exemption analysis, largely due to its role in Revenue Ruling 69-545 and subsequent guidance.<sup>51</sup> The presence of a full-time emergency room open to the public has been treated as evidence that a hospital serves the entire community, including those unable to pay.<sup>52</sup> In traditional settings,

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<sup>49</sup> Steven T. Miller, *Community Benefit and Nonprofit Hospitals: Remarks Before the Office of the Attorney General of Texas, Charitable Hospitals: Modern Trends, Obligations and Challenges*, IRS (Jan. 12, 2009), [https://www.irs.gov/pub/irs-tege/miller\\_speech\\_011209.pdf](https://www.irs.gov/pub/irs-tege/miller_speech_011209.pdf).

<sup>50</sup> 26 U.S.C. § 501(c)(3).

<sup>51</sup> Rev. Rul. 69-545, 1969-2 C.B. 117.

<sup>52</sup> Salinsky, *supra* note 27; Mary Crossley, Elizabeth Tobin Tyler & Jennifer L. Herbst, *Tax Exempt Hospitals and Community Health Under the Affordable Care Act: Identifying and*

emergency departments functioned as gateways to care and safety nets of last resort. Virtual hospitals complicate this need for physical proof. Many do not operate on-site emergency rooms, not because they restrict access, but because they rely on coordinated networks and transfer agreements to deliver emergency care more efficiently.<sup>53</sup> In rural or underserved areas, maintaining a fully staffed emergency department may be economically or logistically infeasible.<sup>54</sup> Virtual models often respond by integrating with local providers, emergency medical services, and regional hospitals to ensure timely escalation when needed.<sup>55</sup>

### *B. Commerciality Doctrine Concerns*

Virtual hospitals also sit uneasily within the IRS's commerciality doctrine.<sup>56</sup> Because they rely heavily on technology, fee-for-service reimbursement, and scalable platforms, they may resemble for-profit telehealth companies in outward form.<sup>57</sup> This resemblance can trigger heightened scrutiny, particularly when traditional markers of charity such as physical facilities or emergency rooms are absent.<sup>58</sup> The commerciality

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*Addressing Unmet Legal Needs as Social Determinants of Health*, 131 PUB. HEALTH REPORTS 195 (2016).

<sup>53</sup> Boldt-Christmas, et al., *supra* note 41.

<sup>54</sup> *Delivery of Emergency Care in Rural Settings: An Information Paper*, AM. COLLEGE OF EMERGENCY PHYSICIANS (2024), <https://www.acep.org/siteassets/sites/acep/blocks/section-blocks/rural/delivery-of-emergency-care-in-rural-settings.pdf>.

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

<sup>56</sup> *Exempt Organizations Technical Guide*, INTERNAL REVENUE SERV., <https://www.irs.gov/pub/irs-pdf/p5833.pdf> (last revised Feb. 1, 2024).

<sup>57</sup> See generally Edward C. Liu, CONG. RSCH. SERV., R48027, *Legal Requirements for Section 501(c)(3) Hospitals* (2024), <https://www.congress.gov/crs-product/R48027> (discussing the requirements for hospital characterization under § 501(c)(3)).

<sup>58</sup> Sandra Feinsmith & Laura Kalick, *Telemedicine and Potential Tax Implications for Tax-Exempt Providers*, BECKER'S HEALTH IT (Aug. 29, 2016), <https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine->

doctrine, however, is meant to assess whether an organization operates primarily for exempt purposes, not whether it uses modern tools or generates revenue.<sup>59</sup> Hospitals have long charged fees, competed in markets, and pursued operational efficiency without forfeiting exemption.<sup>60</sup> The challenge in the virtual care context is that the absence of familiar structural cues makes it harder to distinguish charitable operations from commercial competition using existing heuristics.

Without clearer standards, exemption determinations risk becoming impressionistic. Virtual hospitals may be judged as charitable or commercial based on surface similarities to for-profit platforms rather than on substantive factors, such as patient population served, access expanded, or community health outcomes achieved. This approach undermines predictability and incentivizes organizations to mimic traditional forms rather than optimize care delivery. The commerciality analysis thus exposes a broader problem: existing doctrine relies on visual and organizational proxies that no longer map cleanly onto charitable purpose. In the virtual context, those proxies break down.

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and-potential-tax-implications-for-tax-exempt-providers/<https://www.beckershospitalreview.com/healthcare-information-technology/telemedicine-and-potential-tax-implications-for-tax-exempt-providers/>.

<sup>59</sup> W. Marshall Sanders, *The Commerciality Doctrine Is Alive and Well*, in *Taxation of Exempts* (Mar.–Apr. 2005), <https://www.alston.com/-/media/files/insights/publications/2005/03/the-commerciality-doctrine-is-alive-and-well-itaxa/files/taxation-of-exempts--the-commerciality-doctrine-is/fileattachment/taxation-of-exempts--the-commerciality-doctrine-is.pdf>.

<sup>60</sup> Ahreum Han, Keon-Hyung Lee & Jongsun Park, *The Impact of Price Transparency and Competition on Hospital Costs: A Research on All-Payer Claims Databases*, 22 BMC HEALTH SERV. RSCH. 1321 (2022), <https://pmc.ncbi.nlm.nih.gov/articles/PMC9636618/>.

#### IV. WHY TAX CLASSIFICATION OF VIRTUAL HOSPITALS MATTERS

For-profit virtual care providers may find themselves competing with tax-subsidized nonprofits offering similar services.<sup>61</sup> At the same time, nonprofit virtual hospitals may be denied exemption despite providing comparable or greater community benefit than traditional hospitals.<sup>62</sup> This dynamic raises concerns about exemption creep on one hand and under-inclusion on the other. Without clear standards, tax exemption risks expanding beyond its justification or failing to encompass deserving models.

Forgone tax revenue represents a subsidy justified by the expectation of public benefit.<sup>63</sup> When the exemption criteria fail to align with the actual community benefit, that subsidy becomes untethered from its rationale.<sup>64</sup> For virtual hospitals, accountability concerns are particularly acute.<sup>65</sup> If an exemption is granted based on structural resemblance rather than measurable outcomes, the public has little assurance that subsidies are producing meaningful benefits.<sup>66</sup> Conversely, denying an exemption to access-expanding models because they lack traditional features undermines the

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<sup>61</sup> *Six Key Moments: Hearing on Tax-Exempt Hospitals and the Community Benefit Standard*, U.S. HOUSE COMM. ON WAYS & MEANS (Sept. 22, 2025), <https://waysandmeans.house.gov/2025/09/22/six-key-moments-hearing-on-tax-exempt-hospitals-and-the-community-benefit-standard/>.

<sup>62</sup> *Id.*

<sup>63</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>64</sup> *Id.*

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

<sup>66</sup> Daniel B. Rubin, Simone R. Rauscher Singh & Peter D. Jacobson, *Evaluating Hospitals' Provision of Community Benefit: An Argument for an Outcome-Based Approach to Nonprofit Hospital Tax Exemption*, 103 AM. J. PUB. HEALTH 612, 614 (2013), <https://pmc.ncbi.nlm.nih.gov/articles/PMC3673262/>.

public purpose of the exemption itself.<sup>67</sup> Clear standards are necessary to maintain transparency and legitimacy in the use of public subsidies.

Emerging models may hesitate to invest or expand without clarity on whether they will be eligible for exemption. This uncertainty disproportionately affects models designed to serve rural or underserved populations, where traditional hospital infrastructure is often unsustainable. By privileging legacy forms, existing doctrine may reinforce inequities in access and slow the adoption of care models better suited to contemporary needs.

#### V. UPDATING IRS GUIDANCE

Legislative reform is neither necessary nor desirable in this context. Section 501(c)(3) is deliberately broad,<sup>68</sup> and the IRS has long exercised interpretive authority to adapt exemption standards to changing circumstances. Revenue rulings, notices, and other guidance have historically shaped hospital exemption doctrine in significant ways—most notably through Revenue Ruling 69-545, which itself reoriented the entire field without any statutory amendment.<sup>69</sup> The IRS's authority to issue updated guidance here is well-established and does not require congressional action.

Administrative guidance also offers important practical advantages. It can respond more quickly to evolving care models than legislation, allowing the IRS to refine standards incrementally rather than imposing rigid statutory definitions that may themselves become outdated. Guidance can be issued

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<sup>67</sup> *Id.* at 613.

<sup>68</sup> 26 U.S.C. § 501(c)(3).

<sup>69</sup> Rev. Rul. 69-545, 1969-2 C.B. 117.

in stages, piloted through safe harbors, and revised as the IRS develops expertise with new delivery models. This flexibility is particularly valuable given the pace of change in virtual and hybrid healthcare, where the landscape five years from now may look quite different from today.

Moreover, the tools already exist within the existing doctrinal framework to support a functional reorientation. The community benefit standard, the operational test, and the commerciality doctrine are all sufficiently capacious to accommodate a shift from form-based to function-based analysis. What is needed is not a new law, but an updated interpretation and guidance that translates these existing principles into criteria that reflect how care is actually delivered.

#### *A. Core Elements of a Functional Approach*

Updated guidance should adopt a functional approach to hospital tax exemption that evaluates organizations based on what they do rather than what they look like. The core inquiry should remain unchanged: does the organization operate for public benefit? What must change is the set of criteria used to answer that question. Rather than asking whether a hospital operates an emergency room, maintains inpatient beds, or owns physical facilities, the IRS should ask whether the organization demonstrably improves access to care, integrates with the safety-net system, ensures continuity and coordination of care for patients who need it most, and produces measurable community benefit outcomes.

Access to care is perhaps the most fundamental criterion. A hospital that expands access for rural, low-income, or chronically ill patients—populations that have historically been underserved—is doing exactly what tax exemptions are meant to subsidize. Virtual hospitals that serve these

populations through remote monitoring, hospital-at-home programs, and telehealth consultations are providing access that traditional infrastructure cannot. Guidance should treat demonstrated access expansion, documented through patient population data, geographic coverage, and utilization patterns, as strong evidence of charitable purpose.

Continuity and coordination of care are equally important. One of the core functions that virtual hospitals perform is linking patients to ongoing, coordinated care across settings. Post-acute management, chronic disease support, and care transitions are areas where virtual models often outperform traditional hospitals precisely because they are not constrained by geography. Updated guidance should recognize these functions as evidence of community benefit rather than penalizing their absence of physical infrastructure.

Integration with the safety-net system provides another meaningful marker of charitable purpose. A virtual hospital that maintains formal relationships with Federally Qualified Health Centers, critical access hospitals, or community health workers, and that accepts patients regardless of insurance status or ability to pay, is operating in a manner that serves public purposes. Transfer agreements and partnership protocols with safety-net providers should be treated as evidence of community benefit orientation, not as substitutes for missing facilities.

Finally, measurable community benefit outcomes should anchor the analysis. The IRS should require virtual hospitals seeking exemption to document specific, verifiable outcomes, such as reductions in preventable hospitalizations, improvements in chronic disease management, expansion of care to previously underserved areas, or reductions in cost for vulnerable

populations. This approach aligns with a broader trend in health policy toward value-based accountability and ensures that the public subsidy embedded in tax exemption is tied to demonstrated performance.

*B. Applying the Functional Framework to Existing Problem Areas*

The functional approach directly addresses the doctrinal failures identified in Part III. On the emergency room problem, updated guidance should clarify that the relevant inquiry is not whether a hospital operates an on-site emergency room, but whether it ensures that patients have access to emergency care when needed. A virtual hospital that maintains robust transfer agreements with emergency departments, integrates with regional emergency medical services systems, and has documented protocols for emergency escalation should be deemed as providing emergency access in a functionally meaningful sense.

On the commerciality doctrine, the functional framework provides clearer ground for distinguishing charitable operation from commercial competition. The question should not be whether a virtual hospital looks like a for-profit telehealth platform, but whether it operates with a charitable orientation: Does it serve patients regardless of ability to pay? Does it direct resources toward underserved populations? Does it reinvest surplus into access-expanding activities rather than distributing profits to investors? These are the substantive questions that commerciality analysis should answer, and they can be answered just as well for virtual hospitals as for traditional ones.

On enforcement consistency, the functional approach reduces, though does not eliminate, agent discretion by providing clearer criteria tied to observable, verifiable facts. Organizations seeking exemption can document their patient populations, care outcomes, partnership agreements, and



community benefit expenditures. Agents can evaluate those documents against clear standards rather than relying on impressionistic assessments of whether an organization resembles a traditional hospital. This shift toward evidence-based evaluation would improve both consistency and predictability.

*C. Preserving Meaningful Limits on Exemption*

A functional approach does not mean unlimited exemption. Commerciality safeguards and prohibitions on private inurement remain essential. Exemption should remain conditional on genuine public benefit, supported by evidence and subject to ongoing evaluation. A virtual hospital that primarily serves commercially insured, high-income patients while providing little benefit to underserved populations should not qualify for exemption simply because it uses sophisticated technology. The functional framework sharpens, rather than eliminates, the distinction between genuine charitable purpose and commercial enterprise dressed in charitable language.

Additionally, the IRS should retain the authority to revoke exemption when virtual hospitals fail to maintain the community benefit standards on which exemption was granted. This ongoing accountability mechanism is essential to ensuring that the functional approach does not become a one-time certification rather than a continuing obligation. Organizations that receive exemption should be required to report community benefit outcomes periodically and to demonstrate continued compliance with functional criteria. This approach mirrors the accountability mechanisms already

embedded in the community benefit standard for traditional hospitals and can be extended naturally to virtual models.<sup>70</sup>

In sum, the functional approach preserves the core purpose of hospital tax exemption, subsidizing organizations that genuinely serve the public interest, while adapting its administration to the realities of modern healthcare delivery. It does not require abandoning existing doctrine but rather reorienting it around the outcomes that doctrine was always meant to produce.

#### CONCLUSION

Virtual and hybrid hospitals expose a growing mismatch between modern healthcare delivery and the IRS's definition of a "hospital" for tax-exempt status, which still relies on physical infrastructure and emergency room access as stand-ins for charitable purpose. That framework produces inconsistent and often inequitable outcomes: organizations that expand access, improve outcomes, and serve underserved communities can be denied exemption, while legacy institutions may qualify despite offering limited community benefit. The IRS, however, already has the authority to address this without legislative change by adopting a more functional approach, one that evaluates providers based on access, continuity of care, safety-net integration, and measurable community outcomes. Aligning tax exemptions with actual public benefit would improve consistency, limit regulatory arbitrage, and restore confidence in the regime. If a tax exemption is meant to reflect public good, the question should not be whether a hospital

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<sup>70</sup> Rubin, et al., *supra* note 66.

has walls, but whether it meaningfully serves the communities that need it most.

# Anticompetitive Patent Linkage & Evergreening Effectuates High Drug Prices

*Preeta Pavagadhi*

## INTRODUCTION

Drug prices in the United States (“U.S.”) are consistently higher when compared to other similarly situated countries.<sup>1</sup> In 2022, U.S. drug prices were 278% higher than those in 33 comparable countries combined.<sup>2</sup> To put that into perspective, drug prices outside of the U.S. are approximately a third of the cost.<sup>3</sup> Several factors affect drug pricing, including two intellectual property concepts: patent linkage and evergreening in the pharmaceutical industry. These concepts play a major role in delaying market entry of generic drugs that, in turn, perpetuate high prices for brand-name drugs.<sup>4</sup> Generic manufacturers do not need to conduct the same clinical trials as brand-name manufacturers to prove safety and efficacy, such that generic drugs generally cost less than brand-name drugs.<sup>5</sup>

Generic drug approval is prevented by patent linkage if there is one or more active patents that are linked to the brand-name drug.<sup>6</sup> The same is prevented by evergreening, a business strategy of obtaining multiple patents on different aspects or minor modifications of the same product.<sup>7</sup> Evergreening is used to extend patent exclusivity by patenting insignificant

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<sup>1</sup> Andrew W. Mulcahy, Daniel Schwam & Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data*, 11 RAND HEALTH Q., no. 3, 2024, at 1, 5.

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

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

<sup>4</sup> CONG. RSCH. SERV., R46221, *Drug Pricing and Pharmaceutical Patenting Practices* (2020); John R. Thomas, *Revisiting Patent Linkage*, 33 TEX. INTELL. PROP. L.J. 291, 293 (2025).

<sup>5</sup> *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN. (Mar. 16, 2021), <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers>.

<sup>6</sup> CONG. RSCH. SERV., *supra* note 4.

<sup>7</sup> CONG. RSCH. SERV., R40917, *Patent “Evergreening”: Issues in Innovation and Competition*, (2009).

improvements.<sup>8</sup> Both patent linkage and evergreening invoke antitrust principles, sustaining high costs of drugs and delayed generic drug entry.

This article begins by exploring patent linkage, evergreening, and the antitrust laws that pertain to those concepts, while also analyzing the detrimental effects of these practices. This article concludes by proposing potential solutions to promote the market entry of generics and reduce drug costs by mitigating the adverse effects of patent linkage and evergreening on competition and market power, aligning them with antitrust principles.

## I. BACKGROUND INFORMATION

### A. *Hatch-Waxman Act of 1984*

The Hatch-Waxman Act (“Hatch-Waxman”) established the approval pathway for generics by granting the Food and Drug Administration (“FDA”) authority to approve Abbreviated New Drug Applications (“ANDA”).<sup>9</sup> This is an “abbreviated” pathway since generic manufacturers do not have to repeat clinical trials to prove safety and efficacy.<sup>10</sup> The creation of the ANDA process, under section 355(j)(1) of the Federal Food, Drug, and Cosmetic Act, allows generic companies to rely on the FDA’s prior determination of the safety and effectiveness of brand-name drugs.<sup>11</sup> Hatch-Waxman also introduced the “safe harbor” provision, which allows generic companies to develop and test drugs without fear of patent infringement litigation.<sup>12</sup> Generic companies can apply for FDA approval prior to the patent expiration

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<sup>8</sup> Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 491-92 (2020).

<sup>9</sup> JOHN R. THOMAS, CONG. RSCH. SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER (2016).

<sup>10</sup> U.S. FOOD & DRUG ADMIN., *supra* note 5.

<sup>11</sup> THOMAS, *supra* note 9.

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

of the related brand-name drug.<sup>13</sup> However, brand-name drug manufacturers have the benefit of exclusive marketing periods before the FDA can approve a generic drug for market entry.<sup>14</sup>

Hatch-Waxman also developed the Approved Drug Products with Therapeutic Equivalence Evaluations publication, which is referred to as the “Orange Book.”<sup>15</sup> Hatch-Waxman requires approved patent holders to list their patents and exclusivity information relevant to their approved drugs in the Orange Book.<sup>16</sup> The Orange Book plays a critical role in resolving patent disputes under Hatch-Waxman by listing patents associated with approved drugs.<sup>17</sup> Generic applicants filing an ANDA must also file a certification stating which Orange Book patents cover the drug they seek to market.<sup>18</sup> Certifications are filed in one of four categories.<sup>19</sup> The fourth category, a Paragraph IV Certification, is particularly important because the applicant can contend that a certain patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug.<sup>20</sup> This certification initiates a unique legal process and triggers “patent linkage.”

If the patent holder files a lawsuit for infringement within 45 days of receiving notice of the Paragraph IV certification, the FDA is required to impose an automatic 30-month stay (“automatic stay”) on the approval of the

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

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

<sup>15</sup> *Id.*; *Orange Book Preface*, U.S. Food & Drug Admin., <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface> (last visited Apr. 25, 2026). (providing information on FDA-approved drug products, including safety and efficacy ratings and therapeutic equivalence data for generic drugs).

<sup>16</sup> THOMAS, *supra* note 9, at 6-7.

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

<sup>18</sup> *Id.* at 7.

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

<sup>20</sup> *Id.*

ANDA.<sup>21</sup> This pause in the approval process provides time for the court to resolve the patent dispute.<sup>22</sup> However, if no lawsuit is filed within the initial 45-day window, the ANDA may be approved immediately, subject to FDA regulations.<sup>23</sup> Additionally, the first generic manufacturer to file a Paragraph IV certification receives a 180-day market exclusivity period once their drug enters the market.<sup>24</sup> This exclusivity period is an incentive for generic manufacturers to challenge weak or invalid patents.<sup>25</sup> Thus, the Paragraph IV certification process is a critical mechanism for challenging the validity or enforceability of patents, enabling the timely entry of generic drugs while also balancing patent holders' rights.

### *B. Patent Linkage*

The concept of patent linkage was introduced through Hatch-Waxman.<sup>26</sup> Patent linkage is the practice of connecting the regulatory approval of generic drugs to the patent status of their brand-name counterparts.<sup>27</sup> It's the link between the marketing approval of a generic drug and a brand-name drug patent, which covers an aspect of that proposed generic drug.<sup>28</sup> Thus, the

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<sup>21</sup> *Id.* at 7-8.

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

<sup>23</sup> *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1326-27 (Fed. Cir. 2003); *Actavis Lab'ys FL, Inc. v. United States*, 131 F.4th 1345, 1357 (Fed. Cir. 2025).

<sup>24</sup> THOMAS, *supra* note 9, at 9.

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

<sup>26</sup> CONG. RSCH. SERV., *supra* note 4, at 296; K.D. Raju, *Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries*, in *ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW* 329, 331 (Carlos M. Correa & Reto M. Hilty eds., Springer 2022).

<sup>27</sup> Raju, *supra* note 26.

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

generic drug would allegedly infringe upon the brand-name drug if granted market approval.<sup>29</sup>

Patent linkage can occur in two different ways: (1) an automatic bar (“automatic bar system”), or (2) a notice of generic application (“notification system”).<sup>30</sup> Patent linkage could result in an automatic bar to generic approval if the drug has an aspect linked to an active patent in the brand-name drug.<sup>31</sup> It is an automatic bar, meaning the patent holder does not need to take legal action to prevent the approval of the generic drug.<sup>32</sup> Currently, the U.S. operates under the automatic bar system of patent linkage.<sup>33</sup> Alternatively, patent linkage via the notification system does not result in an automatic bar to generic approval, but rather allows the patent holder to initiate legal action, in the form of an injunction, to prevent approval of the generic.<sup>34</sup> This method of patent linkage allows a generic drug to be approved, subject to the condition that the regulatory review agency notify the patent holder of the approval.<sup>35</sup> A notification is sent to the patent holder following the application of a generic, providing them the opportunity to bring an infringement claim against the generic drug manufacturer.<sup>36</sup> The notification system facilitates faster generic approval as it requires legal action by the patent holder to bar approval and is not automatic.

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

<sup>30</sup> Kyung-Bok Son et al., *Moderating the Impact of Patent Linkage on Access to Medicines: Lessons from Variations in South Korea, Australia, Canada, and the United States*, GLOBALIZATION & HEALTH, Oct. 24, 2018, at 1.

<sup>31</sup> CONG. RSCH. SERV., *supra* note 4, at 293.

<sup>32</sup> *Id.* at 309.

<sup>33</sup> 21 U.S.C. § 355.

<sup>34</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105477, *GENERIC DRUGS: STAKEHOLDER VIEWS ON IMPROVING FDA'S INFORMATION ON PATENTS* 10 (2023).

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

<sup>36</sup> *Id.*



### *C. Evergreening*

Evergreening is a business strategy used to ‘life cycle’ manage a company’s income stream by artificially extending the life of a patent by filing additional patents, specifically to extend the drug’s monopoly period.<sup>37</sup> Evergreening can occur in two ways: (1) patenting different aspects of a drug (e.g., new shape or coating), or (2) patenting improvements of a drug (e.g., a new extended-release version).<sup>38</sup> Patenting even minor drug improvements ultimately prevents generic substitution and limits the use of generics.<sup>39</sup> For example, a brand-name drug manufacturer may change its method of administering the drug or make other minor improvements, which impedes the use of generics due to immense market pressure to use the new brand-name version rather than the generic.<sup>40</sup> Brand-name manufacturers influence the market towards their new product through extensive advertising, incentivizing physicians to prescribe the new brand-name drug, or by claiming that the old version of the drug is no longer safe or effective.<sup>41</sup>

These marketing techniques impede the usage of the generic drugs by decreasing their market value, either by labeling the generic as ineffective or the branded drug as far superior. For example, if there is only a generic for an older version of a brand-name drug, consumers are often persuaded to purchase the new and improved brand-name drug. Furthermore, if brand-name companies release new versions into the market before generic companies have a chance to do the same, it may discourage generic

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<sup>37</sup> CONG. RSCH. SERV., *supra* note 7, at 1.

<sup>38</sup> Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 601-02 (2018).

<sup>39</sup> *Id.* at 602.

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

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

companies from producing and releasing their generic drugs.<sup>42</sup> There would be no profit incentive to produce the generic drug if consumers would purchase the new brand-name drug instead.<sup>43</sup> Thus, evergreening delays the market entry of generic drugs, allowing the brand-name manufacturer to charge exorbitant prices for years of additional profits.<sup>44</sup>

#### *D. Relevant Antitrust Principles*

The Federal Trade Commission (“FTC”) is responsible for protecting against anticompetitive behavior and deceptive and unfair trade practices in the marketplace, in part by prosecuting violations of the Sherman Antitrust Act.<sup>45</sup> Section one of the Sherman Antitrust Act provides that any contracts, combinations, or conspiracies that are an unreasonable restraint of trade constitute a felony.<sup>46</sup> Section two of the Sherman Antitrust Act provides that monopolies, or even attempting to form a monopoly, constitute a felony.<sup>47</sup> These provisions provide the legal framework for determining lawful competition and anticompetitive practices in the marketplace.

## II. DETRIMENTS OF PATENT LINKAGE AND EVERGREENING

Patent linkage and evergreening affect competition in the pharmaceutical marketplace by delaying market entry of generic drugs and retaining high

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<sup>42</sup> Hacothen, *supra* note 8, at 522.

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

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

<sup>45</sup> FED. TRADE COMM’N, OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION 1 (2021), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview\\_of\\_ftc\\_actions\\_in\\_pharmaceutical\\_products\\_and\\_distribution.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_of_ftc_actions_in_pharmaceutical_products_and_distribution.pdf).

<sup>46</sup> 15 U.S.C. § 1.

<sup>47</sup> 15 U.S.C. § 2.

drug prices.<sup>48</sup> Patent linkage delays the approval of generics until patent disputes are resolved, while evergreening extends patent protection and thus delays approval of generics.<sup>49</sup> These practices can reduce competition by creating barriers for generic manufacturers, thereby maintaining monopolistic control over the market and keeping the brand-name drug prices elevated.<sup>50</sup> Thus, the use of such tactics can stifle competition, preserve monopoly profits, and produce artificially high prices.<sup>51</sup> The anticompetitive effects of these practices are harmful, especially in the pharmaceutical marketplace that has limited access to affordable drugs.<sup>52</sup> Such practices jeopardize competition, harm consumers' access to drugs, and violate antitrust principles under the Sherman Antitrust Act.

*A. Delayed Approval and Market Entry of Generic Drugs*

Patent linkage is a barrier to generic market entry because it links regulatory approval to patent dispute resolution, allowing brand-name manufacturers to lengthen market exclusivity through automatic stays.<sup>53</sup> This conduct aligns with the improper purpose of excluding competition, as prohibited under the Sherman Antitrust Act.<sup>54</sup> Patent linkage results in prolonged market share and reduced consumer access to affordable

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<sup>48</sup> CONG. RSCH. SERV., *supra* note 4; CONG. RSCH. SERV., *supra* note 7.

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

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

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

<sup>52</sup> DRUGPATENTWATCH, *The Device Patent Wall: How Pharma Buys 4.7 Extra Years of Drug Exclusivity — and What It Costs Everyone*, (March 30, 2026), <https://www.drugpatentwatch.com/blog/is-patent-evergreening-restricting-access-to-medicine-device-combination-products/>.

<sup>53</sup> Raju, *supra* note 26.

<sup>54</sup> CONG. RSCH. SERV., R46679, *The Role of Patents and Regulatory Exclusivities in Drug Pricing* 56-57 (2024).

medications.<sup>55</sup> Thus, patent linkage can delay the approval and market entry of generic drugs, which not only restrains competition and violates antitrust principles but also severely harms consumers.<sup>56</sup>

### *B. Monopolistic Control*

While patents grant lawful exclusivity to their holders, their misuse to restrain competition beyond the scope of the patent's exclusionary rights can result in antitrust violations.<sup>57</sup> Additionally, the improper use of patent linkage to enforce invalid or fraudulently obtained patents, or to extend the patent's monopoly beyond its statutory term, may also violate Sherman Antitrust Act section one.<sup>58</sup> Patent linkage may violate section one of the Sherman Antitrust Act when it is used as part of a scheme to unreasonably restrain trade, such as delaying generic competition or attempting to enforce invalid patents through sham litigation after a stay on approval of a generic drug has been granted. Such practices exceed the lawful scope of patent rights and undermine competition, leading to antitrust liability under federal law.<sup>59</sup>

The FTC defines monopolization as the unreasonable restraint of competition by the creation or maintenance of significant market power by a

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

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

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

<sup>58</sup> *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965); *FTC v. Actavis, Inc.*, 570 U.S. 136, 148-53 (2013).

<sup>59</sup> *See Actavis, Inc.*, 570 U.S. at 157 (concluding that misuse of patent linkage to delay generic competition or enforce invalid patents may exceed the lawful scope of patent rights and trigger antitrust liability).

single company.<sup>60</sup> The practices of patent linkage and evergreening are often used to increase the market power of a single pharmaceutical company. Patent linkage and evergreening can violate section two of the Sherman Antitrust Act when used to unlawfully maintain or extend monopoly power in a relevant market through anticompetitive conduct.<sup>61</sup> There are several ways that patent linkage can violate section two. A patent holder could fraudulently list patents in the Orange Book in an attempt to delay generic competition.<sup>62</sup> Since these actions can trigger an automatic 30-month stay of generic FDA approval, such actions would extend the patent holder's monopoly power in the marketplace for their specific drug. Furthermore, a patent holder's choice to file a baseless patent infringement lawsuit to enforce their fraudulently listed patent can constitute a violation.<sup>63</sup> Such lawsuits are often initiated to delay FDA approval of generic drugs, leveraging the automatic stay provisions of Hatch-Waxman. Courts have held that this type of conduct, when objectively baseless and intended to interfere with competition, constitutes an improper means of maintaining monopoly

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<sup>60</sup> *Monopolization Defined*, FED. TRADE COMM'N, <https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined> (last visited Feb. 19, 2026).

<sup>61</sup> CONG. RSCH. SERV., *supra* note 54.

<sup>62</sup> Press Release, Fed. Trade Comm'n, FTC Issues Policy Statement on Brand Pharmaceutical Manufacturers' Improper Listing of Patents in the Food and Drug Administration's 'Orange Book' (Sep. 14, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-issues-policy-statement-brand-pharmaceutical-manufacturers-improper-listing-patents-food-drug> (noting that courts have interpreted the FTC Act to encompass conduct that also violates the Sherman Antitrust Act).

<sup>63</sup> Mike Cowie et al., *Anticompetitive Unilateral Conduct in the Pharmaceutical Sector in USA*, Dechert LLP (Sep. 6, 2019), <https://www.lexology.com/library/detail.aspx?g=96bfb2d-f51f-4312-9092-d3e6604041d4>.

power.<sup>64</sup> Such conduct undermines competition and promotes monopoly power by delaying generic entry.

Evergreening enables brand-name drug developers to maintain monopolistic control by extending patent protection through minor modifications to existing drugs.<sup>65</sup> These modifications often lack significant therapeutic value but serve to block generic competition. Evergreening is a willful exercise of monopoly power, achieved through unjust enrichment of the patent system rather than the creation of improved products.<sup>66</sup> By preventing market entry of generic drugs, evergreening impairs competition in the marketplace and harms consumers. By extending patent protection without significant innovation, evergreening retains monopolistic control.

### III. PROPOSED SOLUTIONS

A potential solution that addresses the anticompetitive effects of patent linkage and evergreening is enhanced regulatory oversight. Specifically, Congress and other regulatory agencies, such as the FTC and FDA, should implement several policies to help mitigate the anticompetitive effects of patent linkage and evergreening. These policies include having stricter patentability standards, limiting patent linkage to the notification system, and accelerating patent challenges by generic developers. These measures would promote competition, allow faster market entry of generics to reduce drug prices, and align patent practices with antitrust principles.

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<sup>64</sup> *Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.)*, 950 F.3d 1, 14 (1st Cir. 2020); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 367 (D.N.J. 2009).

<sup>65</sup> Feldman, *supra* note 38.

<sup>66</sup> Hacothen, *supra* note 8, at 506.

*A. Stricter Patentability Standards*

Current patentability standards, which require inventions to be useful, novel, and non-obvious, are insufficient to prevent frivolous patents and incremental patent filing that facilitate the practice of evergreening.<sup>67</sup> These patentability standards do not consider whether modifications or improvements have meaningful benefits. Evergreening is a successful tactic largely because brand-name drug manufacturers can file a patent for minor modifications without showing that the change improves therapeutic results for patients. Thus, a proposed reform would be to impose a condition on those seeking to patent changes to an existing product. The condition would be a showing of therapeutic advantage to be eligible for an Orange Book listing of new patent(s) on an existing product. While this proposal would not impede the ability to obtain new patents on modifications, it would prevent the initiation of new 30-month stays for generic drugs under the Hatch-Waxman mechanism. This condition, imposed by the FDA, would require that a modified version of a drug can be listed in the Orange Book only if the applicant can demonstrate that the new formulation has an actual, meaningful clinical advantage over the existing version. This proposal aims to preserve incentives for innovation and intellectual property rights while dismissing the ability to delay generic entry on the basis of minor improvements.

Currently, there are several countries, like India and Brazil, that have similar provisions for assessing the therapeutic advantages of modifications

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<sup>67</sup> 35 U.S.C. §§ 101-103.

before granting secondary pharmaceutical patents.<sup>68</sup> Using similar language from section 3(d) of the Indian Patent Act, the U.S. can implement the following into 35 U.S.C. § 102 - Conditions for patentability; novelty:

(a) Novelty; Prior Art.—A person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

(3) the claimed invention was “a mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”<sup>69</sup>

The goal is brand-name drug manufacturers would not file for additional patents on minor changes because of this proposed condition. If drug manufacturers believe that their modification(s) have a real therapeutic advantage, they need to conduct clinical trials to prove it. Due to their high cost, companies would likely forgo them if there were no significant therapeutic advantage. Thus, tying the implementation of this standard to Orange Book listings itself would deter the practice of evergreening while preserving innovation and the current patent and drug approval mechanisms.

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<sup>68</sup> Bhaven N. Sampat & Kenneth C. Shadlen, *Secondary Pharmaceutical Patenting: A Global Perspective*, 46 RSCH. POL'Y 693, 695 (2017).

<sup>69</sup> The Patents Act, 1970, Section 3 (India).



### *B. Limiting Patent Linkage*

Limiting the patent linkage automatic bar system is another proposed solution to preventing delays of generic entry into the marketplace. Rather, only the patent linkage notification system should exist. While the automatic bar system prevents generic approval completely, the notification system allows patent holders to determine whether to bring a patent infringement claim against a generic developer. If the patent holder chooses to litigate, the generic developer can challenge the patent on its merits. Without an automatic bar and a time limitation on filing suit, generics may still get approved faster than under the automatic bar system.

Currently, the automatic bar system prevents the approval of a generic without regard to patent validity or relevance to the generic drug. Implementing only a notification system for patent linkage would allow the generic drug to be approved for market entry with the condition that the brand-name drug's patent holder is notified of the approval. Upon notification from the regulatory agency, the patent holder may file suit for infringement against the generic manufacturer. This proposal would prevent the automatic bar on generic approval and would require an injunction granted by a court based on the merits of the patent.

Another safeguard to prevent frivolous claims of patent infringement is a good faith certification. Specifically, a patent holder that files suit against a generic manufacturer, based on the notice, must declare a good faith basis by filing a certificate with the court and the opposing party to show a reasonable prospect of success. If the patent holder does not provide such a certification, or the certification is false or misleading, they would be subject to fines, paid to the opposing party. The fines would be determined by a jury during the

patent infringement trial, with a jury instruction from the judge. A proposed jury instruction in relevant part:

In patent infringement cases arising from a Paragraph IV certification and notification to a patent holder, the patent holder who brings a suit against the generic manufacturer must declare a good faith basis for bringing the suit by filing a certificate with the court and serving it to the opposing party. After reviewing the evidence at trial, if you find that the patent holder did not offer such a certification, or if you find that the certification was false or misleading, you shall impose a fine against the patent holder to be paid to the opposing party. To determine the amount of the fine, you should consider (1) the reasoning behind the failure to provide a certification or providing a false or misleading certification and (2) the harm to the opposing party.

Ultimately, this solution aims to preserve the rights of the patent holder while reducing their ability to use weak patents to delay generic entry.

### *C. Accelerating Patent Validity Challenges*

Procedural changes are also needed so generic developers can challenge patent validity more efficiently. This proposal aims to expedite patent validity challenges made by generic developers when a 30-month stay is imposed under the patent linkage system. The proposal is to reform the Inter Partes Review (“IPR”) process overseen by the Patent Trial and Appeal Board (“PTAB”). IPR allows parties to challenge the validity of existing patents before the PTAB, which is quicker than litigation in court.<sup>70</sup> To fast-track patent validity challenges, Congress should amend 35 U.S. Code § 311 to allow generic developers to petition for an Accelerated Inter Partes Review

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<sup>70</sup> 35 U.S.C. §§ 311-319 (governing IPR proceedings); *see also* *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 270 (2016) (describing IPR as a faster, less costly alternative to district court patent litigation).

(“AIPR”) before the PTAB, when a 30-month stay is triggered. The accelerated review would have a statutory deadline of 12 months from the date of the petition filing. If the outcome of the IPR finds the challenged patent invalid or not infringed, the 30-month stay would be lifted, and the generic could proceed with market approval and entry. In relevant part, the amendment would read as follows:

(d) Accelerated Inter Partes Review—

After a generic drug applicant files an ANDA with a Paragraph IV Certification and a 30-month stay is enacted, the applicant may challenge a patent’s validity by requesting an Accelerated Inter Partes Review (AIPR). The Patent Trial and Appeal Board (PTAB) shall decide the case within 12 months of the initiation of the AIPR. Upon a finding of patent invalidity or no infringement, the 30-month stay shall be immediately terminated, and the FDA shall approve the generic application, pursuant to FDA regulations. All parties must submit fees, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.<sup>71</sup>

In terms of funding the PTAB to take on such an enormous task, both generic and brand-name drug companies would provide funding to conduct the review process. The drug companies would be required to pay a filing fee that is proportionate to the commercial value of their drug, and they would pay a percentage of the proceeds of their drug sales. The percentage of proceeds would be the same for all the companies to ensure equity across the market. This approach would benefit the drug companies because they would not have to wait years for their patents to be validated or invalidated and would save on litigation costs that would span over such years. This would also streamline the process of determining whether a patent is valid,

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<sup>71</sup> 35 U.S.C. § 311.

rather than leaving it to a court. This proposal aims to create a self-funding system for an industry that would benefit from it. By accelerating the time it takes to challenge a patent, generics could enter the market earlier, especially if brand-name drug companies are using practices such as patent linkage and evergreening to maintain market exclusivity.

To ensure efficiency within the PTAB in dealing with AIPR and to avoid backlogs of cases, the PTAB can use funding from the AIPR process to increase the number of personnel who can conduct reviews. Allocating that funding to hire additional administrative patent judges can increase efficiency and reduce, if not avoid, backlogs. Additionally, the PTAB can implement artificial intelligence (“AI”) technology to standardize case management and processing. Using AI tools can streamline the administrative aspects of the PTAB and allow for allocating funding to more judges and technical experts to review patents.

Besides funding, several legislative reforms have been proposed to improve the efficiency of the PTAB. For example, several aspects of the Promoting and Respecting Economically Vital American Innovation Leadership (“PREVAIL”) Act propose a standing requirement for petitioners.<sup>72</sup> The requirement would limit who can petition before the PTAB by having to meet certain criteria to have standing. Lastly, to prevent frivolous petitions, the Director of the United States Patent and Trademark Office (“USPTO”) can impose stricter sanctions on parties that engage in unfair practices. The stricter sanctions aim to deter frivolous filings for AIPR. While AIPR proceedings are occurring, patent status would remain

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<sup>72</sup> Dani Kass, *Patent Policy to Watch in 2024*, STERNE KESSLER (Jan. 1, 2024), <https://www.sternekessler.com/news-insights/news/patent-policy-watch-2024/>.

unchanged, as the patent would be considered valid and enforceable until the PTAB issues its decision. This is consistent with 35 U.S.C. § 282(a), which states “[a] patent shall be presumed valid.”<sup>73</sup> Overall, implementing these solutions would allow for AIPR to function efficiently within the PTAB and would promote generic developers to challenge patent validity.

#### CONCLUSION

Patent linkage and evergreening challenge antitrust principles by limiting market competition and maintaining monopolistic market power. Implementation of enhanced regulatory oversight by creating stricter patentability standards, eliminating the automatic bar system of patent linkage, and accelerating patent challenges by generic developers can help realign with antitrust principles of competition and market fairness. Such reforms would ensure that patents serve their intended purpose of promoting innovation without undermining market competition.

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<sup>73</sup> 35 U.S.C. § 282(a).

# Advancing Prehospital Medicine: A Call for a Shift in Industry Standard and for Federal Legislation to Mandate a Degree for Paramedics

*Sara Preziosi*

## INTRODUCTION

Emergency medical services (EMS) is a pillar of public health yet remains an afterthought in the healthcare industry. EMS is comprised of emergency medical responders (EMRs), emergency medical technicians (EMTs), advanced EMTs (AEMTs), and paramedics who are trained in prehospital emergency medicine to respond to emergency calls within the community.<sup>1</sup> EMS was formalized in the 1960s under the National Highway Traffic Safety Administration (NHTSA).<sup>2</sup> States were then granted the authority to determine education and licensure requirements for each level of provider, in consideration of NHTSA recommendations.<sup>3</sup>

Despite the proliferation of EMS through grant funding, accreditation processes, and voluntary national licensing, the Emergency Medical Services Act of 1973 allowed states to maintain discretion over the structure of EMS education and the licensed scopes of practice.<sup>4</sup> This state-based control created inconsistencies and confusion within the profession.<sup>5</sup> The lack of consistency and federal legislation produced exceedingly low wage competition, lack of credibility, poor career advancement, and stunted patient

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<sup>1</sup> NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., NAT'L EMERGENCY MED. SERV. EDUC. STANDARDS 7, 10 (2009), <https://www.ems.gov/assets/National-EMS-Education-Standards-FINAL-Jan-2009.pdf> [hereinafter *The Standards*].

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

<sup>3</sup> NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., NAT'L EMS SCOPE OF PRACTICE MODEL 2019 13 (2019), [https://www.ems.gov/assets/National\\_EMS\\_Scope\\_of\\_Practice\\_Model\\_2019.pdf](https://www.ems.gov/assets/National_EMS_Scope_of_Practice_Model_2019.pdf) [hereinafter *Scope of Practice Model*].

<sup>4</sup> Emergency Med. Serv. Systems Act of 1973, S. 2410, 93rd Cong. (1973), <https://www.congress.gov/bill/93rd-congress/senate-bill/2410>.

<sup>5</sup> *Conn. Paramedic Recertification*, IMPACT EMS TRAINING, <https://www.impactems.com/state-requirements/connecticut-recertification#paramedic> (last visited Mar. 9, 2026).

outcomes within a vital sector of healthcare for the American populace.<sup>6</sup> National EMS organizations have advocated for a uniform reform of prehospital medical care, but have faced perennial resistance from the fire service and others.<sup>7</sup> Before uniform reform can be realized, a degree requirement for paramedics must be legislated.

In the early and mid-twentieth century, nursing education and licensing were decentralized,<sup>8</sup> and nursing was viewed as a pre-marriage activity for women that the nurse would eventually abandon for domesticity.<sup>9</sup> The Nurse Training Act of 1964 was the first substantial step to building a cohesive profession.<sup>10</sup> This legislation promoted wage competition, credibility, career opportunities, and facilitated a research infrastructure to promote better patient outcomes.<sup>11</sup> By shifting nurse education from isolated certification programs to college-accredited degrees, nurses contributed to the field of medicine in tangible, quantifiable, and credible ways.<sup>12</sup>

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<sup>6</sup> COMM ON THE FUTURE OF EMERGENCY CARE IN THE U.S. HEALTH SYS. BOARD ON HEALTH CARE SERV., FUTURE OF EMERGENCY CARE: EMERGENCY MED. SERV. AT THE CROSSROADS, Nat'l Acad. of Sci., Eng'g, and Med. 119 (2007), <https://www.nationalacademies.org/read/11629/chapter/6#120>.

<sup>7</sup> Kevin Sirr, *To Degree or Not to Degree? The Paramedic Question*, J. of Emergency Med. Serv. (Feb. 21, 2024), <https://www.jems.com/ems-training/paramedic-training/to-degree-or-not-to-degree-the-paramedic-question/>.

<sup>8</sup> *Nursing, History and Health Care: Nursing Through Time*, PENN NURSING UNIV. OF PENN., <https://www.nursing.upenn.edu/nhhc/nursing-through-time/1960-1989/> (last visited Feb. 11, 2026) [hereinafter Penn Nursing].

<sup>9</sup> Erin Blakemore, *Why Many Women were Banned from Working during the Great Depression*, History.com (last updated Oct. 30, 2025), <https://www.history.com/articles/great-depression-married-women-employment>.

<sup>10</sup> Nurse Training Act of 1964, H.R. 11241, 88th Cong. (1964), <https://plus.lexis.com/api/permalink/9093df6e-215f-4451-a717-88e190eba1ae> [hereinafter Nurse Training Act].

<sup>11</sup> Joan E. Lynaugh, *Nursing the Great Society: The Impact of the Nurse Training Act of 1964*, 16 Nursing Hist. Rev., no. 1, 2008, at 13–28.

<sup>12</sup> Angela Schnell, et al, *A Bachelor's Degree for Entering the Nursing Pro.: A Scoping Rev. for Supporting Informed Health Care Pol'y*, INT'L J. OF NURSING STUD. ADVANCES 1, 19–20 (2023), <https://pmc.ncbi.nlm.nih.gov/articles/PMC11080422/>.

The fire service has long argued that requiring a degree to become a paramedic will inalterably devastate fire agencies because it is a common grant funding requirement that firefighters hold a paramedic license, but often firefighters do not have genuine interest in providing medical care.<sup>13</sup> Therefore, requiring a degree makes the paramedic license requirement even more difficult to obtain for uninterested employees.<sup>14</sup> Fire service organizations argue that a mandated paramedic degree is not necessary to perform the duties of the job, and will cause increased economic strain on grant-funded services as it will necessitate increased wages and promulgate worsening staffing shortages.<sup>15</sup> However, these criticisms ignore the increasing breadth of curriculum requirements and the expanding scope of practice for paramedics.<sup>16</sup> Therefore, this article argues that EMS must be divorced from the fire service because EMS operates as a public health entity unlike the fire service which operates as a public safety entity, each requiring entirely distinct skillsets, mandates, and objectives.<sup>17</sup>

Mandating more substantial education for EMS clinical providers benefits the community by also addressing staffing shortages through increased

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<sup>13</sup> Clayton Kazan & Hawnwan P. Moy, *The Pros and Cons of Degree Requirements for Paramedics: Kazan and Moy Debate*, NAT'L ASSOC. OF EMS PHYSICIANS (July 22, 2019), <https://naemsp.org/2019-7-21-the-pros-and-cons-of-degree-requirements-for-paramedics>.

<sup>14</sup> Ben Thompson, *Why So Many Firefighters Don't Become Paramedics*, FIRE RESCUE 1 (Apr. 11, 2025, at 10:46), <https://www.firerescue1.com/career-1/articles/why-so-many-firefighters-dont-become-paramedics-vko8qsi6qa7pkewi/>.

<sup>15</sup> *IAFC, IAFF, NFPA, NVFC Oppose Required Degrees for Medics*, EMS1 (February 04, 2019, at 01:39 PM), <https://www.ems1.com/paramedic-jobs-and-careers/articles/iafc-iaff-nfpa-nvfc-oppose-required-degrees-for-medics-nzK9lyQyM2h0kbuI/> [hereinafter *IAFC Oppose*].

<sup>16</sup> Scope of Practice Model, *supra* note 3 at 12.

<sup>17</sup> Sirr, *supra* note 7.



wages commensurate with education.<sup>18</sup> Research repeatedly demonstrates that degree programs, especially those for Science, Technology, Engineering, and Math (STEM), produce higher earning potential which tends to lead to an influx in the workforce, and decreases staffing shortages.<sup>19</sup> In mandating a degree requirement, the resources to fund increased wages may be obtained by shifting a portion of fire funding to EMS.<sup>20</sup> Most fire service calls (64%) are medical (i.e., EMS) in nature, and a significant restructuring of the public safety force is necessary to represent the public health needs of communities and allow for funding reallocation.<sup>21</sup> By combining the lessons from the nursing profession during the 1960s with the support from national EMS agencies today, advocating for education legislation and shifting the industry standard to require a degree for paramedics is both possible and necessary for the advancement of the field of prehospital medicine.<sup>22</sup>

This article will first review the history and structure of paramedic education in the United States, including program accreditation, program deficits, and overarching obstacles prehospital clinicians experience because of the current education structure. Paramedicine and nursing are not identical fields, but are substantially similar in scope of practice, professional

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<sup>18</sup> *Emergency Medical Services (EMS): A Look at Disparities in Funding and Outcomes*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 9, 2024), <https://www.cdc.gov/ems-community-paramedicine/php/us/disparities.html> [hereinafter CDC EMS].

<sup>19</sup> Press Release, N.Y. Univ., Study of 5.8 Million Americans Finds that a College Degree Yields a Significant Return on Investment (Mar. 13, 2024), <https://www.nyu.edu/about/news-publications/news/2024/march/study-of-5-8-million-americans-finds-that-a-college-degree-yield.html>.

<sup>20</sup> *Fire Department Funding: Where It Goes, and Where It Doesn't*, FIREFIGHTERS & EMS FUND (Feb. 20, 2020), <https://www.fireandemsfund.com/fire-department-funding-where-it-goes-and-where-it-doesnt/> [hereinafter FIRE DEP'T. FUNDING].

<sup>21</sup> *Fire Department Overall Run Profile as Reported to the National Fire Incident Reporting System (2020)*, 22 U.S. FIRE ADMIN., no. 1, 2022 [hereinafter Fire Dept. Overall].

<sup>22</sup> Sean M. Caffrey, Leaugeay C. Barnes & David J. Olvera, *Joint Position Statement on Degree Requirements for Paramedics*, 23 PREHOSPITAL EMERGENCY CARE, no. 3, 2019, at 1.

obstacles, and contribution to public health. Therefore, this article will next review the history and structure of nursing education and the parallel problems the nursing industry overcame. This article recommends the EMS profession follow the nursing model for education reform through encouraging national union representation, shifting the EMS industry standard, and separating from the fire service to promulgate a paramedic degree requirement. This article also suggests legislation to reform paramedic education. Critiques against paramedic higher education are then addressed. Finally, this article reviews projected outcomes from paramedic degrees including improved patient outcomes, career advancement, increased wages, decreased staffing shortages, and improved professional credibility.

## I. HISTORY AND STRUCTURE OF PARAMEDIC EDUCATION

### A. EMS Education Legislation

The Highway Safety Act of 1966 was the first effort to formalize emergency response resources for accidents.<sup>23</sup> The original legislation buried a vague reference to emergency services among the other provisions:

In addition such uniform standards shall include, but not be limited to, provisions for an effective record system of accidents . . . accident investigations to determine the probable causes of accidents, injuries, and deaths, vehicle registration, operation, and inspection, highway design and maintenance . . . traffic control, vehicle codes and laws, surveillance of traffic for detection and correction of high or potentially high accident locations, and *emergency services*.<sup>24</sup>

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<sup>23</sup> The Standards, *supra* note 1, at 2.

<sup>24</sup> Highway Safety Act of 1966, 23 U.S.C. § 402(a) (1966) (emphasis added).

The same legislation also authorized the Secretary to allocate funds to develop “emergency service plans.”<sup>25</sup> The Emergency Medical Services Act of 1973 expanded the directive to develop emergency service plans by granting money to the states for research and implementation.<sup>26</sup> Five years later, the first accreditation body was formed to evaluate paramedic education programs and develop uniform standards.<sup>27</sup> However, the accreditation standards formed by the American Medical Association were not mandated by legislation.<sup>28</sup>

### *B. EMS Education Accreditation*

Accreditation was then granted by the Commission on Accreditation of Allied Health Education Programs with a subdivision specific to the EMS community—Committee on Accreditation of Educational Programs for the EMS Professions (CoAEMSP).<sup>29</sup> For a program to be accredited, CoAEMSP requires the program to adhere to the *National EMS Education Standards* (the “Standards”) set by the Department of Transportation.<sup>30</sup> As guidelines, the Standards do not have the force of law, but when coupled with the *National EMS Core Content* (“Core Content”), they provide the structure of paramedic education.<sup>31</sup> Moreover, a paramedic program must be accredited for graduates to qualify to test for their National Registry of EMTs

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

<sup>26</sup> Emergency Med. Serv. Act of 1973, S. 2410, 93rd Cong. § 1202(a)–(b) (1973).

<sup>27</sup> *CoAEMSP History*, CoAEMSP, <https://coaemsp.org/coaemsp-history/> (last visited Feb. 12, 2026).

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

<sup>29</sup> CoAEMSP, <https://coaemsp.org> (last visited Feb. 12, 2026).

<sup>30</sup> *Standards and Guidelines for the Accreditation of Educ. Programs in the Emergency Med. Serv. Pro.*, COMM. ON ACCREDITATION OF ALLIED HEALTH EDUC. PRO. 10 (2023), <https://coaemsp.org/wp-content/uploads/2025/11/CAAHEP-Standards-amp-Guidelines-2023.pdf>.

<sup>31</sup> The Standards, *supra* note 1, at 7.

certifications,<sup>32</sup> on which many states rely to determine individual licensure.<sup>33</sup>

Since program accreditation is optional and national Standards for education and Core Content do not have the effect of law, the structure of paramedic programs varies wildly between states.<sup>34</sup> In Illinois, paramedic programs must achieve a minimum of 500 hours of classroom instruction coupled with a minimum of 500 hours of clinical experience,<sup>35</sup> with many of the programs just one year in length.<sup>36</sup> At Yale New Haven Center for EMS in Connecticut, paramedic students are expected to complete over 1200 hours of training over approximately eighteen consecutive months,<sup>37</sup> while even the accelerated program requires over 1000 hours.<sup>38</sup> Meanwhile, the University of New Haven in Connecticut offers a four-year degree in paramedicine, which requires over 700 clinical hours in addition to classroom instruction requirements to fulfill the standards of a bachelor's degree.<sup>39</sup> Regardless of the length of a paramedic education program, all accredited programs must meet the same learning objectives described in the Standards and Core

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<sup>32</sup> *Paramedic Full Education Program Pathway*, NAT'L REG. OF EMERGENCY MED. TECHNICIANS, <https://nremt.org/Document/Paramedic-Full-Education-Program-Pathway> (last visited Feb. 12, 2026).

<sup>33</sup> *State EMS Agency Map*, NAT'L REG. OF EMERGENCY MED. TECHNICIANS, <https://www.nremt.org/resources/state-ems-offices> (last visited Feb. 12, 2026).

<sup>34</sup> NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., NAT'L EMERGENCY MED. SERV. EDUC. STANDARDS 0 (2021) [hereinafter *The Standards 2021*].

<sup>35</sup> 77 ILL. ADMIN. CODE, § 515.520 (2003).

<sup>36</sup> *Edward Hospital Paramedic Education Program*, ENDEAVOR HEALTH, <https://www.endeavorhealth.org/academics-medical-education/specialized-training-programs/ems-paramedic-education-edward-hospital> (last visited Feb. 12, 2026).

<sup>37</sup> YALE NEW HAVEN HEALTH, YALE NEW HAVEN PARAMEDIC PROGRAM, 3–4 (2025) (on file with author).

<sup>38</sup> YALE NEW HAVEN HEALTH, YALE NEW HAVEN ACCELERATED PARAMEDIC PROGRAM, 2 (2025) (on file with author).

<sup>39</sup> UNIVERSITY OF NEW HAVEN: SCHOOL OF HEALTH SCIENCE, BACHELOR OF SCIENCE PARAMEDICINE, 1 (2018) (on file with author).

Content to maintain accreditation for graduates to become eligible to take the NREMT exam.<sup>40</sup>

### *C. EMS Education Program Deficits*

Students who matriculate from more accelerated programs demonstrate a lack of competency.<sup>41</sup> Even the *EMS Agenda for the Future: A Systems Approach* declared “opportunities for improvement are apparent.”<sup>42</sup> The paramedic scope of practice is perennially increasing,<sup>43</sup> which requires additional education and development of clinical competencies. Average paramedic education models already meet or exceed the hours of instruction required for an associate’s degree but require students to complete the curriculum in half the time.<sup>44</sup> Demanding more hours of lecture and clinical rotations in an abbreviated timeframe puts students and the public health at a disadvantage.<sup>45</sup>

## II. THE PROBLEM WITH NON-DEGREE PARAMEDIC EDUCATION

### *A. Lack of Consistency Between Programs and Subsequent Issues*

The Standards were specifically developed to provide states with flexibility in the development of their paramedic curriculum.<sup>46</sup> However, inconsistent interstate legislation creates barriers between state departments of health, and therefore, many states do not provide license reciprocity for

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<sup>40</sup> The Standards, *supra* note 1, at 7.

<sup>41</sup> Sirr, *supra* note 7.

<sup>42</sup> NATIONAL ASSOCIATION OF EMS PHYSICIANS, *EMS AGENDA FOR THE FUTURE: A SYSTEMS APPROACH* 6 (2000).

<sup>43</sup> Scope of Practice Model, *supra* note 3 at 12.

<sup>44</sup> W. VA. UNIV., *Credit Hours and Time Equivalencies*, <https://provost.wvu.edu/curriculum-development-and-review/course-proposals/credit-hours-and-time-equivalencies> (last visited Feb. 12, 2026) (explaining one credit hour equates to fifteen hours of classroom instruction).

<sup>45</sup> Schnelli, *supra* note 12, at 19.

<sup>46</sup> The Standards 2021, *supra* note 34, at 17.

paramedics unless they hold NREMT certification.<sup>47</sup> Without uniform education and reciprocity, paramedics face licensing obstacles to relocate while states experience paramedic shortages due to a limited candidate pool.<sup>48</sup> Additionally, the disparate education models produce highly variable clinical competencies which reinforce the perception that EMS providers are just “ambulance drivers.”<sup>49</sup> This sentiment manifests among other healthcare providers and drives poor continuity of care for patients.<sup>50</sup> Finally, non-degree paramedics experience low compensation<sup>51</sup> and have limited career advancement options.<sup>52</sup> Not only has data repeatedly proven that workers with a degree have a higher lifetime earning potential<sup>53</sup> and higher per annum earnings,<sup>54</sup> but a two- to four-year degree provides opportunity to develop a

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<sup>47</sup> *State Reciprocity*, EMTRSOURCE.COM, <https://emtresource.com/nremt/state-reciprocity/> (last visited Feb. 12, 2026).

<sup>48</sup> *NREMT to Support National EMS Compact Project*, NAT’L REG. OF EMERGENCY MED. TECHNICIANS (Jul. 29, 2016), <https://www.nremt.org/News/ems-compact-project>.

<sup>49</sup> Marion Renault, *Emergency Medicine’s Original Sin*, THE ATLANTIC (July 12, 2021), <https://www.theatlantic.com/health/archive/2021/07/paramedics-not-just-ambulance-drivers/619395/>.

<sup>50</sup> Andrew J. Torres & Rozalina G. McCoy, *How to Better Value EMS Clinicians as Key Care Team Members*, 24 AM. MED. ASS’N J. OF ETHICS, no. 9, 898, 900 (Sept. 2022).

<sup>51</sup> *Why Are Paramedics Paid So Little?*, J. OF EMERGENCY MED. SERVS. (Feb. 23, 2023) <https://www.jems.com/ems-management/why-are-paramedics-paid-so-little/> [hereinafter *Paid So Little*].

<sup>52</sup> Skip Kirkwood, *A Real EMS Career Ladder for the Paramedic Profession*, EMS1 (Sept. 17, 2024 03:27), <https://www.ems1.com/careers/articles/a-real-ems-career-ladder-for-the-paramedic-profession-dleoepiQvuSKL7NI/>.

<sup>53</sup> *Education and Lifetime Earnings*, SOCIAL SECURITY ADMIN., <https://www.ssa.gov/policy/docs/research-summaries/education-earnings.html> (last visited Feb. 12, 2026).

<sup>54</sup> Chris Muller, *New Research Reveals True Value of College Education*, FORBES (Jan. 03, 2025 at 01:52 ET), <https://www.forbes.com/sites/chris-muller/2024/12/29/new-research-reveals-true-value-of-college-education/>.

well-rounded set of marketable skills, like organizational management, leadership, and public health.<sup>55</sup>

### *B. Poor Union Representation*

Among EMS professionals and physicians, there are many advocates for paramedic degree requirements.<sup>56</sup> However, unlike the fire service, EMS professionals have paltry union representation to advocate for reform,<sup>57</sup> but organizations like EMSPAC developed to promote the advancement of prehospital emergency medicine and paramedic education.<sup>58</sup> Meanwhile, proponents and critics alike recognize the necessity to separate EMS from the fire service to achieve higher education requirements for paramedics.<sup>59</sup> Importantly, even the industry-leading guidance in the *EMS Agenda 2050* recommended a structural shift to degreed curriculum for EMS providers.<sup>60</sup> However, recommendations for how to advance paramedic education remain mixed.<sup>61</sup>

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<sup>55</sup> Greg Friese, *Increasing Your Career Options with More Education*, EMS1 (June 14, 2012 10:37), <https://www.ems1.com/ems-products/education/articles/increasing-your-career-options-with-more-education-l6PES2gZDO5xsneJ/>; The Standards 2021, *supra* note 34, at 19.

<sup>56</sup> The Standards 2021, *supra* note 34, at 19; Kazan, *supra* note 13.

<sup>57</sup> *IAEP at a Glance*, INT'L ASS'N OF EMTs & PARAMEDICS (2022), <https://www.iaep.org/iaep-at-a-glance>; *Membership 101*, INT'L ASS'N OF FIRE FIGHTERS (2026), <https://www.iaff.org/membership-101/>.

<sup>58</sup> *Goal Twelve: Professionalization of EMS*, EMERGENCY MED. SERV. PUB. ADVOC. COUNCIL, <https://emspac.org/bcbo/#recertification-education-licensure> (last visited Feb. 12, 2026).

<sup>59</sup> Sirr, *supra* note 7; Kazan, *supra* note 13.

<sup>60</sup> William Leggio et al., *An Executive Summary of Educational Content from EMS Agenda 2050*, 23 PREHOSPITAL EMERGENCY CARE, no. 5, 10 (Mar. 2019) (summarizing the *EMS Agenda 2050*, of which access has been removed by the current Administration).

<sup>61</sup> Caffrey, *supra* note 22, at 3.

### III. THE NURSING MODEL

#### A. *Nursing Education Legislation*

Beginning in 1960, the federal government reformed the Division of Nursing Resources to prioritize increased education requirements for nurses to produce better patient outcomes.<sup>62</sup> Shortly thereafter, the U.S. Surgeon General submitted a report on the status of the nursing profession, finding:

[A]n inadequate educational system, insufficient numbers of new recruits into the profession, a compensation structure that discouraged people from entering the profession, a lack of research on problems in nursing practice, misutilization of available nursing personnel [sic], and a deficiency in the number of supervisory and teaching nurses. The report recommended the Federal government create massive funding programs to both increase the number of nurses and improve the educational requirements for nursing.<sup>63</sup>

These findings helped catapult the Nurse Training Act of 1964 (the Act), which allocated substantial federal funding for the advancement of the nursing profession and legislated educational requirements.<sup>64</sup> However, the Act permitted that both degree and diploma programs satisfy the education requirement.<sup>65</sup> The American Nurses Association continued to lobby for a federal bachelor's degree requirement.<sup>66</sup> In 1969, the American Association of Colleges of Nursing formed to advocate for the advancement of nursing education.<sup>67</sup> It took another seventeen years before the first state mandated a bachelor's degree to become licensed as a nurse.<sup>68</sup>

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<sup>62</sup> Penn Nursing, *supra* note 8.

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

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

<sup>65</sup> Nurse Training Act of 1964, H.R. 11241 § 805(a).

<sup>66</sup> Penn Nursing, *supra* note 8.

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

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



Ultimately nurse lobbyist groups did not succeed in obtaining federal legislation requiring a degree to become a nurse.<sup>69</sup> However, there are fewer than one hundred diploma programs remaining in the United States, and the current industry standard is for nurses to obtain an associate's or bachelor's degree to practice.<sup>70</sup> Each state maintains a Board of Nursing which determines the state standards, in accordance with each state's Nurse Practice Act.<sup>71</sup> The industry standard to obtain a degree is then reflected in state-specific legislation, like that of Kansas and New York.<sup>72</sup>

*B. Parallel Problems to Paramedicine in Non-Degree Nursing Education*

The nursing profession struggled with the same obstacles EMS providers face now:<sup>73</sup> low wage competition, lack of credibility, poor career advancement, and stunted patient outcomes.<sup>74</sup> The nursing field additionally suffered from staffing shortages which are likewise prevalent today in prehospital medicine.<sup>75</sup> Though, as the Commission on Nursing discovered in the 1980s, higher wages drive employee interest and reduce shortages.<sup>76</sup> Nursing associations' efforts to shift the industry-standard toward degree-level education also increased the credibility of the profession by establishing

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<sup>69</sup> *The Levels of Nursing*, AM. NURSES ENTER. NURSING RES. HUB (Feb. 9, 2024), <https://www.nursingworld.org/content-hub/resources/becoming-a-nurse/levels-of-nursing/>.

<sup>70</sup> *Nursing Diploma Programs*, NURSING DEGREE GUIDE, <https://nursingdegreeguide.com/program-directory/nursing-diploma/> (last visited Feb. 12, 2026).

<sup>71</sup> *Nursing Licensure by State*, NURSING LICENSE MAP, <https://nursinglicensemap.com/states/> (last visited Feb. 12, 2026); *Nurse Practice Act Toolkit*, NAT'L COUNCIL OF STATE BOARDS OF NURSING, <https://www.ncsbn.org/policy-gov/npa-toolkit.page> (last visited Feb. 12, 2026).

<sup>72</sup> KAN. ADMIN. REG. § 60-2-104 (1997); N.Y. EDUC. LAW § 6905.2 (McKinney 2020)

<sup>73</sup> Renault, *supra* note 49; Torres & McCoy, *supra* note 50; *Paid So Little*, *supra* note 51; Kirkwood, *supra* note 52.

<sup>74</sup> Penn Nursing, *supra* note 8; IAFC Oppose, *supra* note 15.

<sup>75</sup> Penn Nursing, *supra* note 8.

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

opportunities for nurses to actively contribute to medical research.<sup>77</sup> Moreover, a degree provides additional transferrable skills for nurses to employ within the medical career ladder or elsewhere, attracting new employees and reducing shortages.<sup>78</sup> Nurses educated to a bachelor's degree level also exhibit fewer medical intervention errors, improving overall patient care and reducing the cost to healthcare systems.<sup>79</sup>

#### IV. RECOMMENDATIONS

##### *A. Representation, Industry Standard, and Separation from Fire*

Federally approved national guidance is the cornerstone of paramedic education.<sup>80</sup> Following in the footsteps of the nursing and fire professions, EMS and paramedics must rally under a national union, like the American College of Paramedics, to persistently lobby for federally mandated degree requirements.<sup>81</sup> They must also work to inspire a new industry standard by producing quantitative and qualitative research analyzing the effects of a degree requirement for paramedics and by bolstering clinician union membership.<sup>82</sup> EMS must also sever from the fire service to escape the restrictions of an entirely separate career field in a way that offers a logical

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

<sup>78</sup> *Id.*

<sup>79</sup> Schnell, *supra* note 12, at 10.

<sup>80</sup> The Standards, *supra* note 1; Scope of Practice Model, *supra* note 3; The Standards 2021, *supra* note 34, at 15.

<sup>81</sup> Press Release, J. of Emergency Med. Serv., American Paramedic Association Announces Formation of American College of Paramedics (July 9, 2024), <https://www.jems.com/ems-management/american-paramedic-association-announces-formation-of-american-college-of-paramedics/>.

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

and smooth transition for the communities that EMS and fire departments serve, which has already been implemented in many locations.<sup>83</sup>

*B. Proposed EMS Education Legislation*

Initial legislation mandating a degree must be vague to accommodate educational differences among states: mandating a degree but not stipulating an associate or bachelor's degree. Section 515.520 of the Illinois Administrative Code (amended using italics), which focuses on paramedic education, provides a basis as potential federal legislation:

- a) An accredited Paramedic program shall be conducted only by *an accredited college or university* whose curriculum has been *approved by the Commission on Accreditation of Allied Health Education Programs: Committee on Accreditation of Educational Programs for the EMS Professions (CoAEMSP)*.
- b) The EMS MD of the EMS System shall attest that the education program will be conducted according to the national EMS education standards. The course hours shall minimally include *750 hours of didactic education specific to paramedicine and the national education standards objectives, and minimally 750 hours* of clinical experience, to include hospitals plus alternate care facilities and field internship experience, including minimum patient care contacts and competency evaluation and measurement as defined in the standards and approved by the EMS MD.
- c) Oversight, quality assurance and outcome measurement for the Paramedic education program shall be the responsibility of the EMS MD and the EMS System Coordinator, with cooperation of the educational institution.
- d) A candidate for a Paramedic degree program *must obtain an active EMT license during the course of the program and work a minimum of 250 hours at that certification level, either through paid, volunteer, or externship*

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<sup>83</sup> Scott Williams, *Wis. Official Presents Plan to Split Fire, EMS into Separate Organizations*, EMS1 (May 14, 2024, 08:04), <https://www.ems1.com/ems-management/wis-official-presents-plan-to-split-fire-ems-into-separate-organizations>.

*opportunities*. The candidate must maintain the EMT license through the remainder of the academic program.

e) Paramedic candidates may test for licensure via the NREMT examination (NREMT requires successful completion from an accredited academic institution recognized by NREMT).<sup>84</sup>

#### V. THE CRITICS OPPOSING DEGREE EDUCATION FOR PARAMEDICS

As of 2022, 63% of fire services in the United States provided some degree of emergency medical services.<sup>85</sup> Meanwhile, only 4% of the national fire service call volume is for fires.<sup>86</sup>

However, the fire service is one of the most vocal opponents against requiring degrees for paramedics. Representatives of the fire service claim that a degree is simply not necessary to perform the duties of a paramedic, that current funding streams are insufficient for wage increases, and that a degree requirement worsens staffing shortages.<sup>87</sup>

However, these claims are simply unfounded or easily remedied. As demonstrated by the nursing model of education, a degree requirement has a direct correlation to improved patient outcomes.<sup>88</sup> Studies posit that the additional training produces higher degrees of clinical competency.<sup>89</sup> Therefore, a paramedic degree would improve patient safety and is exceedingly necessary as the scope of practice for a paramedic broadens and

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

<sup>85</sup> Rita Fahy, Ben Evarts & Gary P. Stein, *U.S. Fire Department Profile*, NAT'L FIRE PROTECTION ASS'N (2022), <https://www.nfpa.org/education-and-research/research/nfpa-research/fire-statistical-reports/us-fire-department-profile>.

<sup>86</sup> Fire Dept. Overall, *supra* note 21.

<sup>87</sup> IAFC Oppose, *supra* note 15.

<sup>88</sup> Schnell, *supra* note 12, at 2.

<sup>89</sup> Sirr, *supra* note 7.

the quantity of required curriculum increases.<sup>90</sup> Even the performance of the police, another public safety entity, shows demonstrated improvement with degree attainment.<sup>91</sup>

Furthermore, funding is available for paramedic wage increases by reallocating fire service grants designated for the rare public safety event of a fire to EMS – an expanding pillar of public health.<sup>92</sup> Reallocating fire service grant funding is controversial, and critics are likely correct that fire service staffing will suffer if it becomes necessary to divorce emergency medical services from the fire service to advance the field of paramedicine.<sup>93</sup> Though once emergency medical services is separated from the fire department, the fire service will have a decreased need for volunteers, and likely, a proportionate increase in individuals excited to work in fire suppression rather than obligated by mandate to practice medicine.

## VI. PROJECTED OUTCOMES FROM PARAMEDICS DEGREES

### A. *Improved Patient Outcomes*

The criticism that a degree is not necessary to perform the duties of a paramedic is short-sighted. Rushing students through didactic and clinical work equivalent to an associate's degree, but in half the time, yields poor competency in paramedic graduates.<sup>94</sup> Additionally, parallel studies analyzing patient outcomes in relation to nurse education level provide

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<sup>90</sup> Fintan Feerick et al., *Barriers to Paramedic Professionalisation: A Qualitative Enquiry Across the UK, Canada, Australia, USA and the Republic of Ireland*, 25 BMC HEALTH SERVS. RSCH., 2025, at 4–5.

<sup>91</sup> Caffrey, *supra* note 22, at 2.

<sup>92</sup> CDC EMS, *supra* note 18.

<sup>93</sup> Sirr, *supra* note 7.

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

insight into the necessity and positive effects of a degree for paramedics.<sup>95</sup> Angela Schnelli's research demonstrated "a 10% increase in the proportion of nurses with bachelor's degree was associated with a 7% decrease in patient mortality."<sup>96</sup> Moreover, paramedics' scope of practice continues to broaden, which requires additional training, as evidenced by the increasing number of specializations in which paramedics can become board-certified.<sup>97</sup> Further, the clinical judgments that paramedics are expected to make autonomously and in austere environments require a high level of critical thinking best taught and practiced in the controlled environment of higher education, for the safety of the patient and the provider.<sup>98</sup>

### *B. Transferable Skills and Career Advancement*

Education standardization creates career advancement, as is demonstrated by the EMS systems in the UK, Australia, and other countries.<sup>99</sup> A degree instills transferable and marketable skills, which a paramedic can parlay into leadership or administrative roles in the EMS profession.<sup>100</sup> Degree-educated paramedics are also a source of staffing for lateral transfers into other degree-educated allied health professions during shortages.<sup>101</sup> Furthermore, prehospital emergency medicine is a physically rigorous job, and the

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<sup>95</sup> Schnelli, *supra* note 12, at 19.

<sup>96</sup> *Id.*

<sup>97</sup> INT'L BD. OF SPECIALTY CERTIFICATIONS, <https://www.ibscertifications.org/> (last visited Feb. 12, 2026).

<sup>98</sup> Kazan, *supra* note 13.

<sup>99</sup> Feerick, *supra* note 90, at 2.

<sup>100</sup> Friese, *supra* note 55.

<sup>101</sup> Kazan, *supra* note 13.

transferable and marketable skills a degree provides create a safety net for employment opportunities in non-healthcare fields after a career in EMS.<sup>102</sup>

### C. Increased Wages

Through bolstered union efforts, funding may be reallocated from the fire service to emergency medical services, as representative of public need, and paramedic wages can increase commensurate to the degree held by the provider.<sup>103</sup> Currently, funding for the fire service is derived from the Assistance to Firefighters Grant (AFG) distributed by the National Defense Authorization Act,<sup>104</sup> various additional grants through FEMA,<sup>105</sup> volunteer labor,<sup>106</sup> and property taxes.<sup>107</sup> One method by which fire services maintain this funding is through active lobbying by their substantial union organization, the International Association of Fire Fighters.<sup>108</sup> However, states complain that the majority of taxes allocated for the fire service pay for future pensions rather than for active public safety activities.<sup>109</sup> Funding must shift from preparing for and responding to the rare fire event to the dominant and increasing public health need for prehospital care.<sup>110</sup> By

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<sup>102</sup> Muller, *supra* note 54.

<sup>103</sup> CDC EMS, *supra* note 18.

<sup>104</sup> FIRE DEP'T. FUNDING, *supra* note 20.

<sup>105</sup> *You'd Be Surprised How Simple It Is for Your Fire Department to Get Grant Money*, U.S. FIRE ADMIN. (Mar. 2, 2023), <https://www.usfa.fema.gov/blog/fire-department-grants-are-easy/>.

<sup>106</sup> FireGrantsHelp, *Fueling the Flame: The Vital Role of Grant Funding for Volunteer Fire Departments*, FIRE RESCUE 1 (Dec. 27, 2024, 12:48), <https://www.firerescue1.com/fueling-the-flame-the-vital-role-of-grant-funding-for-volunteer-fire-departments> [hereinafter FireGrantsHelp].

<sup>107</sup> LyLena Estabine, *Illinois Firefighter Pensions Torch Local Finances*, ILL. POL'Y (Nov. 17, 2025), <https://www.illinoispolicy.org/illinois-firefighter-pensions-torch-local-finances/>.

<sup>108</sup> *IAFF-Endorsed Fire Grants and Safety Act Passes Senate*, INT'L ASSOC. OF FIRE FIGHTERS (June 18, 2014), <https://www.iaff.org/news/iaff-endorsed-fire-grants-and-safety-act-passes-senate/>.

<sup>109</sup> Estabine, *supra* note 107.

<sup>110</sup> CDC EMS, *supra* note 18.

reallocating the funding to the more pertinent social need, wages can increase, thereby diminishing EMS staffing shortages.<sup>111</sup> Additionally, recent federal legislation provided increased funding specifically for emergency medical services training and recruitment through the EMT Act of 2025.<sup>112</sup>

#### *D. Decreased Staffing Shortages*

Increased wages produce increased demand for the job, and paramedic staffing shortages will be reduced.<sup>113</sup> Moreover, severing EMS from the fire service will enable targeted recruiting and retention, rather than searching for atypical candidates with a genuine interest in both fields.<sup>114</sup> In shifting the recruitment focus and funding allocation to EMS, the fire service must adapt its operational structure. The separation may look different for individual communities: EMS as a distinct division within the fire department, a complete split in which EMS is entirely removed from fire service operations, or a type of hybrid in which paramedics are contract employees within the fire service. As of 2024, over 80% of fire departments are wholly or partially volunteer-run.<sup>115</sup> The remaining percentage of fire departments must follow the proven operational strategies of their volunteer-based sister departments, while the dispatch of medical calls must pivot from the fire service to EMS providers. The fire service already suffers from significant

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<sup>111</sup> *Paid So Little*, *supra* note 51.

<sup>112</sup> EMT Act of 2025, H.R. 2220, 119th Cong. § 1205(a), (c) (2025).

<sup>113</sup> *Paid So Little*, *supra* note 51.

<sup>114</sup> Marc E. Fitch, *With Shortage of Volunteers, Towns Weigh Costs, Benefits of EMS Hiring Services*, INSIDE INVESTIGATOR (Feb. 12, 2024), <https://insideinvestigator.org/with-shortage-of-volunteers-towns-weigh-costs-benefits-of-ems-hiring-services/>; Kazan, *supra* note 13.

<sup>115</sup> FireGrantsHelp, *supra* note 106.



volunteer shortages because the fire industry continues to ask EMS providers to volunteer their time after months to years of specialized medical training.<sup>116</sup> Therefore, as there is little demand for fire services,<sup>117</sup> the necessity to recruit dual paramedic/firefighters will likely also decrease following the divorce of EMS from the fire service.

#### *E. Increased Professional Credibility*

Finally, a paramedic degree promotes transparency among other allied health professionals through a more uniform education for the paramedic role, as demonstrated by the EMS models in Canada, Ireland, the UK, and Australia.<sup>118</sup> The improved competency of graduates,<sup>119</sup> coupled with opportunities to substantively contribute to medical research, demonstrate that advocating for a change in industry standards and for the legislation of a degree requirement for paramedics advances the industry of EMS in its entirety.

### CONCLUSION

An industry standard shift and federal legislation mandating a degree for paramedic education is necessary to advance the field of prehospital medicine. A required degree is the first step in addressing low-wage competition, lack of credibility, poor career advancement, and stunted patient outcomes within a vital sector of healthcare in the United States. By severing EMS from the fire service, galvanizing under a national union lobbyist organization, and advocating for a legislated degree requirement for

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<sup>116</sup> Fitch, *supra* note 114.

<sup>117</sup> Fire Dept. Overall, *supra* note 21.

<sup>118</sup> Feerick, *supra* note 90, at 4.

<sup>119</sup> Schnell, *supra* note 12, at 19.

paramedics, the EMS profession can shift the industry standard for paramedic education. Like nurses, EMS may fail to promulgate federal legislation for degree requirements, but clinicians can advance the field of prehospital medicine through a unified approach to improving paramedic education and changing the industry standard.



# Balancing Demand and Risk: Regulating Raw Milk Sales

*Elizabeth Primrose*

## INTRODUCTION

In the nineteenth century, milk consumption caused various deadly diseases and triggered many illness outbreaks.<sup>1</sup> Public health concerns spurred milk safety regulations, with pasteurization evolving into a standard practice.<sup>2</sup> The United States Public Health Service (“USPHS”) first recommended milk pasteurization in 1924,<sup>3</sup> and the Food and Drug Administration (“FDA”) prohibited interstate sale of unpasteurized milk in 1987.<sup>4</sup>

Despite the known health risks, consumption of unpasteurized—or “raw”—milk has increased in recent years.<sup>5</sup> While the sale of raw milk across state lines is federally banned, many states permit intrastate sale of raw milk under legal frameworks that vary widely.<sup>6</sup> Outbreaks linked to raw

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<sup>1</sup> Bryn Nelson, *The Lingering Heat over Pasteurized Milk*, SCI. HIST. INST. (Apr. 2, 2009), <https://www.sciencehistory.org/stories/magazine/the-lingering-heat-over-pasteurized-milk/>.

<sup>2</sup> See S.A. Rankin et al., *A 100 Year Review: A Century of Dairy Processing Advancements—Pasteurization, Cleaning and Sanitation, and Sanitary Equipment Design*, 100 J. DAIRY SCI. 9903, 9905 (2017). See also *Milk Pasteurization Process: What Is Pasteurized Milk & Why*, UNDENIABLY DAIRY, <https://www.usdairy.com/news-articles/why-is-milk-pasteurized-4-questions-answered> (last visited Feb. 7, 2026) (defining pasteurization as “the process of applying a certain amount of heat for a set period of time in order to kill harmful bacteria that can be found in raw milk.”).

<sup>3</sup> Rankin et al., *supra* note 2, at 9906.

<sup>4</sup> *Food Safety and Raw Milk*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/buy-store-serve-safe-food/food-safety-and-raw-milk> (last visited Feb. 7, 2026) [hereinafter *Food Safety*].

<sup>5</sup> See Kofi Britwum, *The Rise of Raw Milk: Can Delaware’s New Law Revitalize Small Dairy Farms?*, U. DEL. (Oct. 14, 2024), <https://www.udel.edu/academics/colleges/canr/news/2024/october/the-rise-of-raw-milk/> (describing increase in consumer interest in raw milk and noting known health risks). See also *Raw Milk*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 31, 2025), <https://www.cdc.gov/food-safety/foods/raw-milk.html> (defining raw milk as “milk that has not been pasteurized.”).

<sup>6</sup> See generally *Real Milk Laws by State*, A CAMPAIGN FOR REAL MILK (Feb. 24, 2026), <https://www.realmilk.com/real-milk-legal-map/> (outlining variety of raw milk laws in states).

milk consumption have also risen recently, particularly in states with laws that allow greater availability of raw milk.<sup>7</sup>

This article examines the recent growth in raw milk popularity in the United States. First, this article will give the history of milk regulation in the United States. Then, it will examine the current patchwork of state raw milk regulations. Next, this article will analyze how the relaxation of state raw milk sale laws and the increase in popularity of raw milk have led to public health issues. Finally, this article will propose potential solutions that restrict access to raw milk to reduce foodborne disease and will address criticisms.

## I. HISTORY OF MILK REGULATION

Raw milk contains many dangerous pathogens, which pose risks such as serious illness, kidney failure, and death.<sup>8</sup> Pasteurizing milk eliminates these disease-causing pathogens.<sup>9</sup> Before widespread pasteurization, milk consumption regularly led to illnesses such as tuberculosis, diphtheria, and “summer diarrhea.”<sup>10</sup> Scientists first identified that cow’s milk could transmit disease to humans in the 1870s.<sup>11</sup> In the 1860s, French scientist

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<sup>7</sup> See Lia Koski et al., *Foodborne Illness Outbreaks Linked to Unpasteurised [sic] Milk and Relationship to Changes in State Laws – United States, 1998-2018*, EPIDEMIOLOGY & INFECTION, Oct. 2022, at 1.

<sup>8</sup> See *Raw Milk Misconceptions and the Danger of Raw Milk Consumption*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/buy-store-serve-safe-food/raw-milk-misconceptions-and-danger-raw-milk-consumption> (last visited Feb. 7, 2026) (listing various human pathogens that raw milk can contain, including “*E. coli* O157:H7, *Salmonella*, *Streptococcus* spp. *Yersinia enterocolitica*, *Campylobacter jejuni*, *Staphylococcus aureus*, *Listeria monocytogenes*, *Mycobacterium tuberculosis*, and *Coxiella burnetti*.”) [hereinafter *Raw Milk Misconceptions*].

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

<sup>10</sup> Russell W. Currier & John A. Widness, *A Brief History of Milk Hygiene and Its Impact on Infant Mortality from 1875 to 1925 and Implications for Today: A Review*, 81 J. FOOD PROTECTION 1713, 1713-14 (2018).

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

Louis Pasteur developed pasteurization as a method of heating alcoholic beverages to kill harmful bacteria.<sup>12</sup> In 1870, a Danish professor adopted the pasteurization process to milk.<sup>13</sup>

Pasteurization slowly gained popularity as a way to control milk-borne illness in the early twentieth century.<sup>14</sup> However, milk pasteurization did not become a standardized practice in the United States until later in the 20th century.<sup>15</sup> Cities were the first jurisdictions to require milk pasteurization.<sup>16</sup> In 1908, Chicago passed the first municipal ordinance that required milk pasteurization to combat the transmission of disease from milk to humans.<sup>17</sup> New York City began enforcing its pasteurization ordinance in 1914 after a typhoid epidemic stemming from raw milk.<sup>18</sup>

Due to increased recognition of milk as a cause of illnesses such as typhoid fever and diphtheria, the USPHS developed a model regulation in 1924, which recommended milk pasteurization.<sup>19</sup> While this regulation was not legally binding, it provided guidance for voluntary adoption by local and state milk control authorities.<sup>20</sup>

After more than a decade of legal challenges to its initial proposal to regulate unpasteurized milk,<sup>21</sup> the FDA adopted a final regulation in 1987

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<sup>12</sup> *Id.* at 1714-15.

<sup>13</sup> *Id.* at 1715.

<sup>14</sup> Rankin et al., *supra* note 2, at 9903.

<sup>15</sup> Currier & Widness, *supra* note 10, at 1715.

<sup>16</sup> Kathryn J. Boor et al., *A 100-Year Review: Microbiology and Safety of Milk Handling*, 100 J. DAIRY SCI. 9933, 9934 (2017).

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

<sup>18</sup> Nelson, *supra* note 1.

<sup>19</sup> Leslie C. Frank, *A State-wide Milk Sanitation Program*, 39 PUB. HEALTH REPS. 2765, 2765 (Nov. 1924).

<sup>20</sup> U.S. FOOD & DRUG ADMIN., GRADE “A” PASTEURIZED MILK ORDINANCE, at iv (2023).

<sup>21</sup> *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1231 (D.D.C. 1986); *Food Safety*, *supra* note 4.

requiring the pasteurization of milk moving in interstate commerce.<sup>22</sup> Overall foodborne illness decreased as pasteurization evolved to become a standardized practice in the twentieth century.<sup>23</sup>

## II. CURRENT TREND TOWARD RAW MILK

Despite the known health risks of raw milk consumption and the ban on interstate sales, interest in raw milk has grown in popularity in recent years.<sup>24</sup> In 2024, U.S. sales of raw milk increased by 17.6 percent.<sup>25</sup>

The FDA noted a recent rise in consumer preference for raw milk, with individuals “citing a range of taste, nutritional and health benefits they believe are associated with raw milk consumption.”<sup>26</sup> Raw milk proponents state they believe “that the pasteurization process depletes the milk of important properties that otherwise would confer health benefits.”<sup>27</sup> According to the FDA, these “benefits” are unfounded.<sup>28</sup>

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<sup>22</sup> 17 C.F.R. § 33 (1987).

<sup>23</sup> Meghan Sebastianski et al., *Disease Outbreaks Linked to Pasteurized and Unpasteurized Dairy Products in Canada and the United States: A Systematic Review*, CAN. J. PUB. HEALTH 569, 570 (2022)

(“The ubiquity of pasteurization has reduced the proportion of foodborne illness attributable to unpasteurized dairy products from approximately 25% pre-pasteurization to approximately 2% in the twenty-first century.”).

<sup>24</sup> See *Food Safety*, *supra* note 4 (noting known risks of raw milk consumption and increasing popularity and emphasizing ban on interstate sale of raw milk). See also JoNel Aleccia, *Raw Milk Sales Spike Despite CDC’s Warnings of Risks Associated with Bird Flu*, PUB. BROAD. SERV. (May 14, 2024, 10:40AM), <https://www.pbs.org/newshour/health/raw-milk-sales-spike-despite-cdcs-warnings-of-risk-associated-with-bird-flu> (noting spike in raw milk sales from previous year).

<sup>25</sup> Julia Moskin, *Got Weird? Milk Is Headed for Its Strangest Year Yet*, N.Y. TIMES (Feb. 6, 2025), <https://www.nytimes.com/2025/02/06/dining/milk.html>.

<sup>26</sup> *Food Safety*, *supra* note 4.

<sup>27</sup> Stephanie D. David, *Raw Milk in Court: Implications for Public Health Policy and Practice*, 127 PUB. HEALTH REPS. 598, 598 (2012).

<sup>28</sup> See *Raw Milk Misconceptions*, *supra* note 8 (stating that raw milk “does not cure lactose intolerance,” “does not cure or treat asthma,” and “is not an immune system building food and is particularly unsafe for children.”).

Raw milk has gained popularity on social media. Health influencer Paul Saladino, with an Instagram following of 2.9 million,<sup>29</sup> posted a video encouraging consumption of raw milk, stating: “Do not fear raw milk from good producers. It’s healthy for you. We know this.”<sup>30</sup>

In 2025, social media figures Hannah and Daniel Neeleman opened a farm stand selling raw milk under their social media and brand name “Ballerina Farm.”<sup>31</sup> The opening of Ballerina Farm’s Utah farm stand and grocery store drew significant attention on social media, as the “Ballerina Farm” Instagram account has 10.4 million followers.<sup>32</sup> In January 2026, Ballerina Farm paused raw milk sales after the Utah Department of Agriculture found two health violations.<sup>33</sup>

Social media creators promote raw milk consumption not only to the general adult population, but also to more vulnerable populations.<sup>34</sup> Saladino posted videos alleging that drinking raw milk could help children with

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<sup>29</sup> Paul Saladino (@paulsaladinomd), INSTAGRAM, <https://www.instagram.com/paulsaladinomd> (last visited Mar. 29, 2026).

<sup>30</sup> Paul Saladino (@paulsaladinomd), INSTAGRAM (Apr. 9, 2024), <https://www.instagram.com/reels/C6Wxhfgo3nP/>.

<sup>31</sup> Grace Doerfler, *Ballerina Farm Opens Farm Stand in Kamas*, KPCW (Apr. 7, 2025, 3:11PM), <https://www.kpcw.org/summit-county/2025-04-07/ballerina-farm-opens-farm-stand-in-kamas>.

<sup>32</sup> Grace Doerfler, *Ballerina Farm Lifestyle Arrives in Midway with New Store*, KPCW (May 16, 2025, 5:16PM), <https://www.kpcw.org/wasatch-county/2025-05-16/ballerina-farm-lifestyle-arrives-in-midway-with-new-store>; Hannah Neeleman (@ballerinafarm), INSTAGRAM, <https://www.instagram.com/ballerinafarm/> (last visited Mar. 29, 2026).

<sup>33</sup> Grace Doerfler, *Ballerina Farm Pauses Raw Milk Sales After Samples Fail Health Tests*, KPCW (Jan. 29, 2026, 6:39PM), <https://www.kpcw.org/summit-county/2026-01-29/ballerina-farm-pauses-raw-milk-sales-after-samples-fail-health-tests>.

<sup>34</sup> See *Food Safety*, *supra* note 4 (listing children and pregnant women as “especially vulnerable to the hazards of raw milk consumption.”).



asthma and eczema.<sup>35</sup> According to the FDA, raw milk is “especially” dangerous for children and pregnant women.<sup>36</sup>

Raw milk continues to grow in popularity among conservative groups.<sup>37</sup> Robert F. Kennedy Jr., Secretary of the Department of Health and Human Services (“HHS”),<sup>38</sup> publicly supports raw milk.<sup>39</sup> In an X post in 2024, Kennedy stated that “FDA’s war on public health is about to end,” which he alleged included the FDA’s “aggressive suppression” of a long list of items, such as “raw milk” and “sunshine.”<sup>40</sup> Despite Kennedy’s public support of raw milk, advocates are frustrated by his lack of actual policy changes.<sup>41</sup>

### III. TODAY’S REGULATORY LANDSCAPE

The FDA bans interstate sale of raw milk, but many states permit some form of intrastate raw milk sales, with regulations vastly differing by state.<sup>42</sup> For example, direct-to-consumer sale of raw milk is illegal in Colorado, but consumers can obtain raw milk through cow-share programs, where they

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<sup>35</sup> Paul Saladino (@paulsaladinomd), INSTAGRAM (Oct. 5, 2023), <https://www.instagram.com/reels/CyB5qujuWa1/> (“If you have any of these issues [referring to eczema and asthma], I think you should consider getting them on more raw milk.”).

<sup>36</sup> *Food Safety*, *supra* note 4.

<sup>37</sup> Marc Novicoff, *How Raw Milk Went from a Whole Foods Staple to a Conservative Signal*, POLITICO (Mar. 10, 2024, 7:00AM), <https://www.politico.com/news/magazine/2024/03/10/the-alt-right-rebrand-of-raw-milk-00145625?s=09>.

<sup>38</sup> *Robert F. Kennedy, Jr.*, U.S. DEPT. HEALTH & HUM. SERVS., <https://www.hhs.gov/about/leadership/robert-kennedy.html> (last accessed Feb. 7, 2026).

<sup>39</sup> Suzy Khimm, *Raw Milk Advocates Wonder: Where is Kennedy?*, NBC NEWS (June 19, 2025, 4:00AM), <https://www.nbcnews.com/news/us-news/raw-milk-kennedy-rcna213568>.

<sup>40</sup> See Robert F. Kennedy Jr. (@RobertKennedyJr), X (Oct. 25, 2024, 4:25PM), <https://x.com/RobertKennedyJr/status/1849925311586238737>. See also Robert F. Kennedy Jr. (@RobertKennedyJr), X (July 25, 2024, 1:07PM), <https://x.com/RobertKennedyJr/status/1816535637736227252>.

<sup>41</sup> Khimm, *supra* note 39.

<sup>42</sup> *Map of State Laws on the Sale of Unpasteurized Cow’s Milk, 2012-2019*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (May 16, 2024), <https://www.cdc.gov/phlp/php/publications/unpasteurized-cow-milk.html>.

purchase a portion of a cow or herd and receive a share of milk from that cow or herd.<sup>43</sup> Colorado requires that raw milk from the cow-share programs display a prominent warning statement and requires farms that participate in these programs to be registered with the state.<sup>44</sup> In Pennsylvania, on the other hand, retail sale of raw milk is allowed within the commonwealth, subject to a permit and certain testing and documentation requirements.<sup>45</sup> Notably, in 2025, a Pennsylvania court allowed a preliminary injunction pending a trial on the merits for a family farm to continue to sell raw milk to out-of-state customers as the court reasoned the Pennsylvania Milk Sanitation Law was ambiguous as to if it prohibited the sale of raw milk to-out-of-state customers.<sup>46</sup>

Some states have a complete ban on the sale of raw milk for human consumption.<sup>47</sup> Yet, people have found loopholes in these states by selling raw milk for pets.<sup>48</sup>

Many states have recently passed laws or changed regulations allowing less restrictive intrastate sale of raw milk.<sup>49</sup> In response to the state's

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<sup>43</sup> See COLO. REV. STAT. § 25-5.5-117 (2025) (allowing cow shares).

<sup>44</sup> See *Id.* (requiring registration and warning statements).

<sup>45</sup> See 7 PA. CODE § 59a.402 (2025) (requiring permits and requiring testing and documentation).

<sup>46</sup> Dep't of Agric. v. Miller, 329 A.3d 145, 154-55 (Pa. Commw. Ct. 2025).

<sup>47</sup> See MD. CODE REGS 10.15.06.12 (2026) (banning sale of raw milk for human consumption). See also N.J. REV. STAT. § 24:10-57.17 (2025) (banning sale of milk not pasteurized).

<sup>48</sup> See, e.g., Erika Gonzalez, *It's Illegal in Florida to Sell Raw Milk for Human Consumption, But Why Are More People Drinking It?*, CBS NEWS (Jan. 6, 2025, 11:08AM), <https://www.cbsnews.com/miami/news/raw-milk-trend-in-south-florida/> (describing raw milk for sale being labelled as for pets in a state where sale for human consumption is illegal).

<sup>49</sup> Tony Leys, *More States Legalize Sales of Unpasteurized Milk, Despite Public Health Warnings*, KFF HEALTH NEWS (July 5, 2023), <https://kffhealthnews.org/news/article/more-states-legalize-sales-of-unpasteurized-milk-despite-public-health-warnings/>.

declining dairy industry, Delaware signed the Consumer Milk Choice Act into law, which legalized the sale and distribution of raw milk within the state.<sup>50</sup> Delaware's final regulations, promulgated in 2025, require permits to produce, sell, or distribute raw milk for human consumption.<sup>51</sup> Also in 2025, Arkansas broadened raw milk sales by removing monthly sales limits for farmers and expanding the places where it could be sold.<sup>52</sup>

#### IV. RECENT RAW MILK HEALTH INCIDENTS

Access to unpasteurized milk “continues to result in outbreaks in the United States,” with most raw milk-related outbreaks occurring in states where unpasteurized milk “is expressly allowed by law.”<sup>53</sup> Raw milk illness outbreaks have especially increased in states with legal frameworks that permit broader retail availability of unpasteurized milk.<sup>54</sup>

An illness outbreak linked to raw milk from a California dairy farm in 2024 caused 171 illnesses, 70 percent of which were people younger than

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<sup>50</sup> Sarah Mueller, *Raw Milk Could Save Delaware's Dairy Industry. But the Risks Can Life-Threatening*, WHYY (Oct. 14, 2024, 1:50PM), <https://whyy.org/articles/delaware-raw-milk-legislation-dairy-farmers/>; *Milk Choice*, DEL. DEPT. AGRIC., <https://agriculture.delaware.gov/food-products-inspection/milk-choice/> (last visited Feb. 7, 2026).

<sup>51</sup> 28 Del. Reg. Regs. 871-72 (June 1, 2025); *303 Delaware Raw Milk Regulations*, DEL. DEP'T AGRIC. (June 2025), <https://regulations.delaware.gov/register/june2025/final/28%20DE%20Reg%20871%2006-01-25> (last visited Feb. 7, 2026).

<sup>52</sup> Kristin Higgins, *Arkansas Makes Big Changes to Raw Milk Sales Law*, U. ARK. DIV. AGRIC. (May 27, 2025), <https://www.uaex.uada.edu/business-communities/ced-blog/posts/2025/may/arkansas-makes-big-changes-to-raw-milk-sales-law.aspx>.

<sup>53</sup> Koski et al., *supra* note 7, at 1 (“During 2013–2018, 75 outbreaks with 675 illnesses occurred that were linked to unpasteurised [sic] milk; of these, 325 illnesses (48%) were among people aged 0–19 years. Of 74 single-state outbreaks, 58 (78%) occurred in states where the sale of unpasteurized [sic] milk was expressly allowed.”).

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

eighteen.<sup>55</sup> California allows the retail sale of raw milk by permit holders, but the milk must comply with warning label standards.<sup>56</sup> Idaho also allows retail raw milk sales and has permit and labeling requirements.<sup>57</sup> Between August and November 2025, raw milk caused twenty-six infections in Idaho.<sup>58</sup> Additionally, in New Mexico, where retail sale of raw milk is permitted, a newborn died in February 2026 from contracting an infection linked to the mother's consumption of raw milk during pregnancy.<sup>59</sup>

States with restrictive raw milk regulations have also reported recent outbreaks. Florida, a state with a complete ban on the sale of raw milk for human consumption, saw 21 illnesses related to raw milk in the summer of 2025.<sup>60</sup> In November 2025, Illinois identified 11 illnesses linked to raw milk.<sup>61</sup> Illinois has relatively strict raw milk sale laws, which require that

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<sup>55</sup> Eva Weinstein et al., *Outbreak of Salmonella Typhimurium Infections Linked to Commercially Distributed Raw Milk—California and Four Other States, September 2023—March 2024*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (July 24, 2025), <https://www.cdc.gov/mmwr/volumes/74/wr/mm7427a1.htm>.

<sup>56</sup> See CAL. FOOD & AGRIC. CODE § 33222 (Deering 2025) (requiring permits). See also CAL. CODE REGS. tit. 17 § 11380 (2026) (listing the requirements for warning labels).

<sup>57</sup> See IDAHO ADMIN. CODE r.02.04.13.012 (2026) (prohibiting sale in restaurants or other food service establishments but not limiting retail and not limiting to on-farm sale). See also IDAHO ADMIN. CODE r.02.04.13.020 (2026) (requiring permits to sell raw milk).

<sup>58</sup> DHW Communications, *Idaho Sees Recent Increase in Reported Illnesses Associated with Raw Milk*, IDAHO DEP'T HEALTH & WELFARE (Nov. 25, 2025), <https://healthandwelfare.idaho.gov/news/idaho-sees-recent-increase-reported-illnesses-associated-raw-milk>.

<sup>59</sup> See N.M. STAT. ANN. §25-8-1 (LexisNexis 2025) (allowing for retail sale of raw milk). See also *Health Department Warns Against Consuming Raw Dairy Products*, N.M. DEP'T AGRIC. (Feb. 3, 2026), <https://www.nmhealth.org/news/awareness/2026/2/?view=2315>.

<sup>60</sup> See Press Release, Fla. Dep't of Health, *Florida Department of Health Provides Update on Raw Milk* (Aug. 4, 2025) (on file with author). See also FLA. STAT § 502.091 (2025) (allowing for sale only of pasteurized milk).

<sup>61</sup> IDPH Issues Reminder About Potential Hazards of Consuming Raw Milk, ILL. DEP'T OF PUB. HEALTH (Nov. 7, 2025), <https://dph.illinois.gov/resource-center/news/2025/november/release-20251107>.

raw milk only be sold directly to consumers on the farm within five days of production.<sup>62</sup>

While numbers of raw milk-related illnesses may seem small to some, the disease burden is significant.<sup>63</sup> Raw milk has a greater risk of causing illness than pasteurized milk.<sup>64</sup> For example, of the illnesses caused by dairy in 2015, 96 percent of them were caused by unpasteurized milk.<sup>65</sup>

## V. PROPOSED FRAMEWORK

Access to raw milk should be limited to protect public health. While a federal ban on all raw milk sales would most directly reduce the risks from its consumption, it is not a politically or practically feasible solution.<sup>66</sup> The FDA should continue to specifically ban interstate sale of raw milk, despite calls from raw milk supporters to overturn this.<sup>67</sup> However, to allow proponents of raw milk to access it under more restrictive conditions, Congress should establish a federal agency within the FDA to promulgate and enforce standards regulating raw milk sales within states. This agency would regulate and enforce safety standards governing raw milk sales within states while ensuring that it does not enter interstate commerce. Such regulation is permissible because wholly intrastate activities may be federally

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<sup>62</sup> ILL. ADMIN. CODE tit. 77, § 775.55 (2026).

<sup>63</sup> Solenne Costard et al., *Outbreak-Related Disease Burden Associated with Consumption of Unpasteurized Cow's Milk and Cheese, United States, 2009-2014*, 23 EMERGING INFECTIOUS DISEASES 957, 962 (2017).

<sup>64</sup> Boor et al., *supra* note 16, at 9935.

<sup>65</sup> Costard, *supra* note 63, at 957.

<sup>66</sup> See Jennifer Brown, *Colorado's Long Battle Over Raw Milk is Reenergized by the "Food Freedom" Movement*, COLO. SUN (Sept. 10, 2023, 3:43AM), <https://coloradosun.com/2023/09/10/colorado-raw-milk-food-freedom/> (depicting push for less government interference).

<sup>67</sup> Khimm, *supra* note 39.

regulated when they can collectively exert a substantial effect on interstate commerce.<sup>68</sup>

This federal agency within the FDA should promulgate and enforce raw milk regulations that limit sales to on-farm purchases within five days of production, require prominent warning labels on raw milk, and impose strict permit requirements subject to yearly inspection and regular testing. These standards would limit access to raw milk while allowing states to sell raw milk under controlled conditions.

The first two parts of these standards should restrict raw milk sales to only on-farm sales and limit sales to five days after milk production, modeled after Illinois's law. By keeping distribution small, the risk of widespread illness is limited. The provision should explicitly prohibit retail sale of raw milk and should read as such, with the italics being added:

(1) Raw milk shall be sold or distributed only on the premises of the dairy farm *on which the milk was produced*. Raw milk shall not be sold or distributed in retail environments.<sup>69</sup>

(2) Raw milk shall be offered for sale only within five days after production *on the premises of the dairy farm*.<sup>70</sup>

Section 3 of the regulation should require standardized warning labels on raw milk products to clearly communicate known health risks, especially to vulnerable populations. Modeled exactly after California's warning label regulation, section 3 of the regulation would require warnings that the milk may contain "disease-causing micro-organisms" with a targeted warning to

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<sup>68</sup> Wickard v. Filburn, 317 U.S. 111, 125 (1942).

<sup>69</sup> See ILL. ADMIN. CODE tit. 77, § 775.55(b)(1) (2026).

<sup>70</sup> See ILL. ADMIN. CODE tit. 77, § 775.55(b)(3) (2026).

newborns, children, the elderly, and pregnant women, and specific design requirements to ensure the warning is prominently displayed.<sup>71</sup>

Additionally, the regulation should require persons selling or distributing raw milk to have a permit registered with the federal agency within the FDA, subject to yearly inspection and regular testing by personnel of the agency. Yearly inspections and testing would limit the consumption of contaminated raw milk by detecting harms before they reach consumers. Issuance of a permit should be based on passing an annual inspection. Permits should be valid for one year after issuance. Also, maintenance of the permit should be contingent upon the passing of the regularly required disease tests for dairy livestock. The language, modeled from California's permit requirement, shall read as such, with italics being added:

(4) Every person, before engaging in the business of producing market milk or manufacturing milk, shall obtain a permit from the *federal agency that regulates milk inspection. It is unlawful for a facility to sell or distribute raw milk without a permit. This permit shall be renewed yearly, subject to passing of annual inspection (set out in section 5) and regular disease testing (set out in section 6). Permits will be effective one year after the date of issuance, unless suspended due to failure to pass disease testing, or at the director of the department's discretion.*<sup>72</sup>

Section 5 of this regulation should require yearly inspection by personnel of the federal agency within the FDA for permit issuance or renewal. This inspection would test to ensure that the milk complies with certain bacteria content standards, modeled exactly after California's bacteria content testing requirements.<sup>73</sup>

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<sup>71</sup> See CAL. CODE REGS. tit. 17 § 11380 (2026).

<sup>72</sup> See CAL. FOOD & AGRIC. CODE § 33222 (Deering 2025).

<sup>73</sup> See CAL. FOOD & AGRIC. CODE § 34781 (Deering 2025).

Furthermore, Section 6 of this regulation should outline the regular disease testing requirement. This would require testing dairy livestock for diseases at least once every two months by personnel of the federal agency within the FDA. This testing should be part of the continued requirement for maintaining a permit to sell raw milk. Below is how the language in the regulation should read, adopted from California's law, with modified language italicized:

(6) It is unlawful for any person to sell any milk, or any product of milk, from cows or goats that have not negatively passed a tuberculin *and brucellosis* test applied regularly in accordance with regulations of the department by one of the following:

- (a) A veterinarian in the employ of the department;
- (b) A veterinarian of the United States Department of Agriculture;
- (c) A veterinarian approved by the department and accredited by the

United States Department of Agriculture. In the case of cows or goats which are producing milk that is to be used as raw market milk, "tuberculin test *and brucellosis* applied regularly" means at least *once every two months*. *Failure to comply or positive test results will result in denial or revocation of a permit to sell raw milk.*<sup>74</sup>

Authority to enforce this regulation should be delegated to the director of the newly created federal agency within the FDA. Additionally, inspection of the facilities, issuance of permits, and regular testing of livestock should be completed under the discretion of the newly created agency's director according to promulgated rules and regulations.

Failure of a yearly inspection should result in a permit denial. Failure of a regular disease test of a facility with an active permit should result in

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<sup>74</sup> See CAL. FOOD & AGRIC. CODE § 32903 (Deering 2025) (requiring a negative tuberculin test for milk). See also CAL. FOOD & AGRIC. CODE § 35601 (requiring a negative brucellosis test for milk).



suspension of the permit for one year from the date of suspension. Persons intending to sell or distribute raw milk can apply for a permit one year after the date of denial or suspension. Punishment for selling or distributing raw milk without a valid permit or selling milk across state lines should be either an injunction and or a fine not to exceed \$10,000, or both. The enforcement language should read:

(7) A failure of a yearly inspection results in a denial of a permit to sell raw milk. A person cannot apply for a new permit for one year after the date of a failed inspection.

(8) A failure of a disease test results in a permit suspension for the period of one year from the denial plus the time it takes to get the beginning of the next permit application period. At the beginning of that application period is when a new application for a permit can be sought.

(9) A court of competent jurisdiction may issue an injunction from selling raw milk or a fine not to exceed \$10,000, or both, if a person is found to be selling or distributing raw milk without a valid permit or selling or distributing raw milk across state lines.

Furthermore, the federal agency charged with promulgating these regulations should maintain an easily accessible online list of entities that have valid, denied, and suspended permits. This will educate consumers on if the raw milk they are consuming has passed recent inspections and disease testing.

Finally, the federal agency within the FDA should set up a reporting mechanism for concerned individuals to report possible violations or concerns regarding a seller or distributor of raw milk. The regulation should give the agency authority to investigate valid concerns and suspend licenses based on the agency director's discretion. Suspension will be for one year

after issuance of a suspension decision and a person can apply for a permit again after that period.

## VI. ADDRESSING POTENTIAL CRITICISM

The framework of federally regulating intrastate raw milk sales will likely face criticism. States may feel that it is federal overreach to regulate purely intrastate activity.<sup>75</sup> However, Congress's power under the Commerce Clause can extend to intrastate activity when, in the aggregate, the activity exerts a substantial effect on interstate commerce.<sup>76</sup> While raw milk transactions in a state may appear purely local, the aggregate effect of widespread intrastate sales imposes significant public health costs that extend beyond state borders. A study in 2026 estimated that raw dairy production consumption inflicted a health economic burden of \$4.13 billion between 2000 and 2020.<sup>77</sup> Federally enforcing strict requirements of raw milk sales within states will reduce the spread of disease while still allowing individuals to sell raw milk under regulated conditions to mitigate risks.

Also, raw milk producers may argue that warning labels compel them “to say something that implies that their product is unsafe, which may discourage sales.”<sup>78</sup> However, warning labels with “purely factual and non-

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<sup>75</sup> See Brown, *supra* note 66 (showing push for less government interference).

<sup>76</sup> Wickard v. Filburn, 317 U.S. 111, 125 (1942).

<sup>77</sup> Patricia Hsu & Felcia Wu, *The Unseen Risks of Dairyborne Disease: Disease Burden, Economic Impact, and Regulatory Trends in Raw Milk and Cheese in the US, 2000-2020*, 172 TRENDS IN FOOD SCI. & TECH., June 2026, at 1, 3 (measuring health economic burden with components such as “direct medical costs, hospitalization, outpatient care, medication, and other healthcare expenses.”).

<sup>78</sup> Stephanie D. David, *Raw Milk and the First Amendment: Implications for Public Health Policy and Practice*, 129 PUB. HEALTH REPS. 455, 456 (2014).

controversial” statements about the “safety of a product” would likely be upheld to challenges regarding compelled warnings.<sup>79</sup>

Additionally, raw milk proponents may argue that such a restrictive framework would “unnecessarily limit consumer choice.”<sup>80</sup> However, requiring yearly inspections and regular testing would better empower consumers to know that the raw milk purchased has a reduced risk of contamination. Additionally, the mandatory warning labels would enable consumers to make informed choices about the risks of consuming raw milk.

Finally, the dairy industry may argue that such restrictive regulations would hurt the industry by limiting the sales of independent farmers.<sup>81</sup> While these proposed regulations do limit the scope of raw milk sales, they do so for the benefit of public health. Producing raw milk poses substantial health risks, and even smaller dairy farmers must produce raw milk in ways that minimize the potential for disease and mitigate risk.<sup>82</sup> Establishing effective intrastate regulation would reduce the likelihood of federal intervention that also bans intrastate sales, which many raw milk producers would oppose.<sup>83</sup>

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<sup>79</sup> *Id.*

<sup>80</sup> Travers Koory, *Michigan Republicans Push Raw Milk Access to Boost Consumer Choice, Farm Freedom*, THE MIDWESTERNER (Jan. 15, 2026), <https://www.themidwesterner.news/2026/01/michigan-republicans-push-raw-milk-access-to-boost-consumer-choice-farm-freedom/>.

<sup>81</sup> Mueller, *supra* note 50.

<sup>82</sup> See Doerfler, *supra* note 33 (depicting sellers of raw milk sales stating that “producing raw milk takes careful planning” and that they “[u]nfortunately . . . learned this after the fact.”).

<sup>83</sup> See *Public Citizen v. Heckler*, 653 F. Supp. 1229, 1241 (D.D.C. 1986) (“Assuming the interstate ban is effective without an intrastate ban, it is up to the individual states to decide on such matters of purely local concern. Should it appear that the interstate sale of raw milk continues, it is within HHS’s authority at that time to institute an intrastate ban as well.”).

### CONCLUSION

The existing patchwork of state laws regulating intrastate raw milk sales is not adequate to address public health concerns associated with raw milk. Additionally, the growing number of states relaxing restrictions and expanding permissible methods of raw milk sale increases the risk of the spread of milk-borne illness. Congress should create an agency within the FDA to promulgate and enforce a framework regulating intrastate sales of raw milk. This would balance the preferences of raw milk proponents in states with the goal of limiting the spread of milk-borne disease. The framework would permit the sale of raw milk within state lines while also informing consumers of its risks and limiting its distribution to prevent massive outbreaks. Yearly inspections of raw milk products and facilities and regular testing of dairy-producing livestock under this framework would incentivize producers of raw milk to limit practices that could cause disease. Finally, the FDA should uphold the federal ban on the sale of raw milk across state lines to limit the spread of milk-borne disease by restricting its movement beyond state borders.

As consumer and state preferences regarding raw milk evolve, regulations must prioritize public health by reducing risk, educating consumers about the dangers of consuming raw milk, and ensuring consistent safety standards.



# Parallel Claims, Parallel Power: State Law and Medical Device Litigation

Jason Shih

## INTRODUCTION

The medical device sector is often among the most heavily regulated sectors in the US.<sup>1</sup> Despite the extensive pre-market approval processes conducted by the Food and Drug Administration (“FDA”), consumers who find themselves harmed by these FDA-approved medical devices often still find themselves with little recourse to recoup damages, as federal oversight alone provides little post-market protection.<sup>2</sup> Historically, tort litigation has worked to fill this regulatory gap by providing an outlet in which injured consumers could rely on state common-law claims to recoup damages.<sup>3</sup> However, the passage of the Medical Device Amendments of 1976 (“MDA”), as well as court decisions in cases, such as *Riegel v. Medtronic*, have worked to mold the legal landscape into one that sharply constrains consumers’ ability to pursue state law claims for injuries caused by FDA-approved medical devices.<sup>4</sup> While there are exemptions to this federal preemption, such as the parallel claims exception,<sup>5</sup> these tend to be restrictive and exclusive, often operating more as an illusory remedy rather than a functional and constructive one that works to deter misconduct and vouch for

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<sup>1</sup> *The Essentials of Medical Device Compliance*, VANTAGE MEDTECH, <https://vantagemedtech.com/medical-device-compliance> (last visited Feb. 9, 2026).

<sup>2</sup> *Essure Lawsuit*, ADVOCACY FOR PATIENTS, <https://www.advocacyforpatients.org/devices/essure-lawsuit/> (last visited Apr. 26, 2026) (“Other cases have been dismissed for failing to meet the requirements of the court. For example, in January 2018, Judge Stephen Lambaugh [sic] of Missouri federal court threw 92 out of 95 plaintiffs from an Essure case.”).

<sup>3</sup> *In re* N. Dist. Of Cal. “Dalkon Shield” IUD Prods. Liab. Litig., 693 F.2d 847, 849 (9<sup>th</sup> Cir. 1982).

<sup>4</sup> Medical Device Amendments of 1976, 21 U.S.C. §§ 360c–360k (2018); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

<sup>5</sup> *Riegel*, 522 U.S. at 312 (stating that claims premised on FDA regulations are not additions to federal requirements, but parallel, thus survive federal preemption).

the safety of consumers. In this article, I will be addressing the current state of the medical device approval process and its limitations. Then, I will address how consumers have historically tried to gain compensation for their injuries, as well as contemporary avenues, specifically through the parallel claims exception. Finally, I will address the pitfalls of the parallel claims exception and how policymakers can remodel the parallel claims exception in order to restore power back to injured consumers while still preserving federal regulatory authority and upholding the Supremacy Clause.

### I. MEDICAL DEVICE APPROVAL PROCESS

The foundations for the modern-day medical device approval process is based on the Federal Food, Drug and Cosmetic Act (“FDCA”).<sup>6</sup> When the FDCA was enacted in 1938, it required pre-market approval for drugs, including but not limited to: safeguards from manufacturers about the safety of the drug, labels with adequate directions for safe use, and the prohibition of false therapeutic claims for drugs.<sup>7</sup> In essence, the FDCA increased the FDA’s authority to approve or deny new drugs before they came onto the market.<sup>8</sup> However, it was not until 1962, with the Kefauver-Harris Amendments to the FDCA, that the modern drug approval process was set in motion.<sup>9</sup> The Kefauver-Harris Amendments to the FDCA were significant because they provided the FDA with authority to regulate not only safety standards but also efficacy standards for drugs before they entered the

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<sup>6</sup> *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act> (last updated Nov. 27, 2018).

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

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

<sup>9</sup> *Part III: Drugs and Foods Under the 1938 Act and Its Amendments*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-iii-drugs-and-foods-under-1938-act-and-its-amendments> (last updated Feb. 1, 2018).

market, thereby instituting broader control over the entire drug approval process, especially within a drug's clinical trials.<sup>10</sup>

The FDCA and Kefauver-Harris Amendments laid the foundation for the regulation of medical devices by highlighting the need for the federal government to regulate not just the safety but also the efficacy of drugs and medical devices. However, in comparison to drugs,<sup>11</sup> medical devices were not federally regulated until over a decade later.<sup>12</sup> One of the first legislations surrounding the regulation of medical devices was the Medical Device Amendments of 1976 (“MDA”).<sup>13</sup> The MDA amended the already established FDCA in order to provide benchmarks for assessing the safety and effectiveness of medical devices entering the market.<sup>14</sup>

The medical device pre-market approval cycle is structurally similar to its drug counterpart in that it contains roughly all the same steps: an initial design phase, preclinical phase, approval phase, review phase, and post-market monitoring phase.<sup>15</sup> The medical device process deviates from its drug counterpart in that, instead of a clinical trial phase, it has a “pathway to approval” phase, which occurs after the pre-clinical phase and before the

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

<sup>11</sup> 21 U.S.C. § 321 (2018) (defining “drug” as “articles recognized in the official United States Pharmacopoeia;” “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease;” “[or] intended to affect the structure . . . of the body;” and defining “device” as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article”).

<sup>12</sup> *A History of Medical Device Regulation & Oversight in the United States*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> (last updated Aug. 21, 2023) [hereinafter U.S. FOOD & DRUG ADMIN., *History of Medical Device Regulation*] (“In the 1960s and 1970s, Congress responded to the public’s desire for more oversight over medical devices by passing the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act.”).

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

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

<sup>15</sup> *The Device Development Process*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process> (last updated Jan. 4, 2018).



FDA's review of the device.<sup>16</sup> The medical device approval cycle contains this step because of the wide variety of medical devices the FDA has to approve.<sup>17</sup>

In order to categorize the devices, the MDA created three risk-based classifications for all medical devices: Class I, II, and III.<sup>18</sup> Devices are categorized based on the level of control the FDA believes is necessary to provide to the general public reasonable assurance of their safety and effectiveness.<sup>19</sup>

Class I devices are those that hold low-to-moderate risk and are subject to general controls, which are general device regulations authorized by the FDCA.<sup>20</sup> Because Class I devices tend not to be dangerous, they are also often exempt from pre-market approval processes.<sup>21</sup> The next tier includes Class II devices, which present a moderate to high risk and thus are subject to general controls and special controls.<sup>22</sup> Special controls are usually device-specific, and include additional FDA-monitoring aspects, such as performance standards, patient registries, and special labeling requirements.<sup>23</sup> Additionally, Class II devices may also be subject to subsequent approval requirements, called pre-market notification 510(k)

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<sup>16</sup> *Step 3: Pathway to Approval*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/device-development-process/step-3-pathway-approval> (last updated Feb. 9, 2018) [hereinafter U.S. FOOD & DRUG ADMIN., *Pathway to Approval*]; see also *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> (last updated Jan. 4, 2018).

<sup>17</sup> U.S. FOOD & DRUG ADMIN., *Pathway to Approval*, *supra* note 16.

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

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

<sup>20</sup> *Regulatory Controls*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls> (last updated Mar. 27, 2018) [hereinafter U.S. FOOD & DRUG ADMIN., *Regulatory Controls*].

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

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

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

requirements.<sup>24</sup> A 510(k) is a pre-market approval process that device companies use when the market already contains a substantially equivalent product, allowing the company to bypass some portions of the comprehensive review and clinical process.<sup>25</sup>

When a device is considered high risk, it is categorized as a Class III device and is subject to general controls and Premarket Approval (“PMA”).<sup>26</sup> The PMA process is the most stringent type of device marketing application utilized by the FDA.<sup>27</sup> Devices subject to PMA are often new or previously unmarketed concepts that may present an unreasonable risk of illness or injury, but are frequently used to support or sustain life and prevent impairment of human health.<sup>28</sup> The inherent risks associated with medical devices creates an increased need for regulation: not just prior to market release, but afterwards as well.

Section 522 of the FDCA gives the FDA the authority to conduct post-market surveillance on medical devices.<sup>29</sup> Unlike its drug counterpart, which uses patchwork regulatory mechanisms and statutory language to create authority, § 522 provides the FDA with direct power to conduct post-market surveillance at any time after approval, and describes post-market

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<sup>24</sup> *Class I and Class II Device Exemptions*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions> (last updated July 1, 2025).

<sup>25</sup> *Premarket Notification (510(k))*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k> (last updated Aug. 22, 2024).

<sup>26</sup> U.S. FOOD & DRUG ADMIN., *Regulatory Controls*, *supra* note 20.

<sup>27</sup> *Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma> (last updated May 16, 2019).

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

<sup>29</sup> *Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act> (last updated Oct. 7, 2022) [hereinafter U.S. FOOD & DRUG ADMIN., *Postmarket Surveillance*].

surveillance as the “active, systematic, scientifically valid collection, analysis and interpretation of data or other information about a marketed device.”<sup>30</sup> Essentially, § 522 allows the FDA to require manufacturers to conduct post-market surveillance studies if: the failure of their medical device would reasonably lead to serious adverse health consequences, or their medical device is expected to have substantial use in pediatric populations, will be implanted for over a year, or has life-supporting or life-sustaining use outside the device-user facility.<sup>31</sup> Black letter law<sup>32</sup> outlining the FDA’s roles and surveillance requirements is important because it provides the FDA with certain powers in situations where medical device companies do not comply with said requirements.<sup>33</sup> For example, if companies refuse or fail to comply with § 522, the FDA could label the action or omission a prohibited act, and move to have the device misbranded.<sup>34</sup> Once a company has been found in violation of § 522, or their product has been rendered misbranded, the FDA may be able to utilize enforcement

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<sup>30</sup> *Id.*

<sup>31</sup> INST. OF MED. COMM. ON THE PUB. HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: MEASURING POSTMARKET PERFORMANCE AND OTHER SELECT TOPICS: WORKSHOP REPORT 9 (Theresa Wizemann ed., The Nat’l Acad. Press 2011) (discussing what authority FDA has under Section 522).

<sup>32</sup> *Black Letter Law*, CORNELL LAW SCHOOL LEGAL INFO. INST., [https://www.law.cornell.edu/wex/black\\_letter\\_law](https://www.law.cornell.edu/wex/black_letter_law) (last reviewed June 2022) (defining black letter law as “standard rules that are generally known and free from doubt” and “principles so fundamental in that subject and contained so frequently in hundreds of years of common law that challenging them would be extremely difficult”).

<sup>33</sup> U.S. FOOD & DRUG ADMIN., *Postmarket Surveillance*, *supra* note 29.

<sup>34</sup> *Id.* (“Failure or refusal to comply with a requirement under section 522 of the FD&C Act . . . is a prohibited act under section 301(q)(1)(C) of the FD&C Act, 21 U.S.C. § 331(q)(1)(C), and renders the device misbranded under section 502(t)(3) of the FD&C Act, 21 U.S.C. § 352(t)(3).”).

actions, including seizure of product, injunction, prosecution, and civil money penalties.<sup>35</sup>

However, § 522 is not without its own set of pitfalls, the largest being its utilization by the FDA as a tool to address public health and safety.<sup>36</sup> While § 522 studies are designed for the systematic, population-level surveillance of a device's safety, they are not specifically tailored to identify the injuries of low-frequency or outlier consumers.<sup>37</sup> Thus, injuries from such isolated groups may slip through the cracks, leaving injured consumers without the regulatory attention their injuries deserve. Section 522-backed surveillance data may also fluctuate due to operational challenges or even fall into disuse. For example, a recent study of the history of the FDA's use of § 522 orders shows heavy use from 2011 to 2013 that have since fallen into disuse.<sup>38</sup> Additionally, similar to the FDA's limitations within the post-market drug approval process, § 522 does not do anything to compensate those who have been injured, forcing consumers to pursue other avenues.<sup>39</sup>

## II. STATE TORT LITIGATION AS A SOLUTION

Because the FDA has limited power to rectify consumers' injuries from medical devices, consumers have historically turned towards state tort litigation for remedies.<sup>40</sup> However, this practice has been contested since the MDA's passage in 1976 because it raises the question of whether state courts

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<sup>35</sup> *Id.* ("Note that violations of sections 301(q)(1)(C) or misbranding under section 502(t)(3) may lead to enforcement actions including seizure of product, injunction, prosecution, and/or civil money penalties, as appropriate.").

<sup>36</sup> *Unpacking Averages: Assessing FDA's Postmarket Surveillance Under Section 522*, THE NAT'L LAW REV., <https://natlawreview.com/article/unpacking-averages-assessing-fdas-postmarket-surveillance-under-section-522> (last updated Oct. 1, 2024).

<sup>37</sup> U.S. FOOD & DRUG ADMIN., *Postmarket Surveillance*, *supra* note 29.

<sup>38</sup> THE NAT'L LAW REV., *supra* note 36.

<sup>39</sup> U.S. FOOD & DRUG ADMIN., *Postmarket Surveillance*, *supra* note 29.

<sup>40</sup> *In re Dalkon Shield*, 693 F.2d at 849.

should be allowed to hold manufacturers liable for devices pre-approved by the federal government, essentially undermining the FDA's exclusive authority of pre-market approval.<sup>41</sup> Additionally, the MDA established an express preemption clause under § 360k(a) of the FDCA, which expressly preempts any claim that imposes a state law requirement with respect to a medical device that is "different from, or in addition to" a federal requirement imposed by the FDA.<sup>42</sup>

Consumers have tried to circumvent the MDA's express preemption clause to gain compensation for their damages but are rarely successful. In 1996, *Medtronic v. Lohr* helped to spearhead this movement by creating a narrow pathway for state-tort laws to proceed with litigation.<sup>43</sup> The U.S. Supreme Court held that the MDA does not preempt state common law negligence claims so long as they are not in conflict with or add to federal requirements that are specific to the device.<sup>44</sup> This case laid the foundation for future court cases, as it highlighted the Court's stance at the time, which helped preserve tort law claims for most devices as long as they violated state common law that mirrored federal requirements.<sup>45</sup>

However, not all state laws are in sync with their federal counterparts, as showcased in 2008 through *Riegel v. Medtronic*.<sup>46</sup> The main issue in *Riegel* differed from previous cases because plaintiffs tried to bring state common

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<sup>41</sup> U.S. FOOD & DRUG ADMIN., *History of Medical Device Regulation*, *supra* note 12; *Riegel*, 552 U.S. at 312 (holding that the MDA blocked consumers from seeking remedies via state tort litigation).

<sup>42</sup> Andrew Tauber, Max Heerman & Brian Wong, *A Powerful Tool to Wield Early: How to Argue Medical Device Preemption*, FOR THE DEFENSE 44, 45, <https://www.mayerbrown.com/-/media/files/news/2012/11/how-to-argue-medical-device-preemption/files/how-to-argue-medical-device-preemptionfor-the-defe/fileattachment/how-to-argue-medical-device-preemptionfor-the-defe.pdf> (last visited Apr. 26, 2026).

<sup>43</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 470 (1996) [hereinafter *Lohr*].

<sup>44</sup> *Id.* at 498.

<sup>45</sup> *Id.* at 513–14.

<sup>46</sup> *Riegel*, 552 U.S. at 312.

law tort claims that elevated the federal standard for the specific medical device.<sup>47</sup> The U.S. Supreme Court held that these types of state common law tort claims are preempted by federal law, since this is the exact type of scenario the Supremacy Clause is intended to bar.<sup>48</sup> A medical device successfully going through PMA is equivalent to the FDA giving the device its stamp of approval that the device is safe and effective—by allowing consumers to bring state common law tort claims after this stamp would undermine the authority of the federal government.<sup>49</sup> Furthermore, even though the tort action in *Riegel* only alleged that Medtronic violated its legal duty under state law, the Court reasoned that this duty was equivalent to a state-made regulation, since holding a device to a higher safety standard than what the FDA approved would effectively impose additional state requirements on the manufacturer.<sup>50</sup> The Court emphasized, however, that the prior holding in *Lohr* regarding state law claims based on violations of the FDA’s requirements, also known as parallel claims, still held true and are not barred by federal preemption.<sup>51</sup>

Alongside efforts to rely on state tort laws as a basis for compensation, some litigants have also sought to completely circumvent the traditional federal preemption process. In the 2001 case of *Buckman v. Plaintiffs’ Legal Committee*, the U.S. Supreme Court worked to shut down an alternate pathway for state tort cases to litigate against FDA rulings by using fraud-on-the-FDA claims.<sup>52</sup> In *Buckman*, the Court stated that fraud-on-the-FDA

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<sup>47</sup> *Id.* at 322–24.

<sup>48</sup> *Id.* at 322; U.S. CONST. art. VI, cl. 2 (“[The] Constitution, and [federal] laws . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby.”).

<sup>49</sup> *Riegel*, 552 U.S. at 322.

<sup>50</sup> *Id.* at 332–33.

<sup>51</sup> *Id.* at 330.

<sup>52</sup> *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001); Tauber, Heerman & Wong, *supra* note 42, at 46.

claims are impliedly preempted and that the express preemption provision does not “bar the ordinary working of conflict preemption principles.”<sup>53</sup> These types of claims are impliedly preempted specifically in the context of federal regulation of medical devices because there is a statutory “hook” for implied preemption under the FDCA in 21 U.S.C. § 337(a).<sup>54</sup> The Court in *Buckman* interpreted this statute to mean that only the federal government is authorized to file suit for noncompliance with medical device provisions of federal law, and that the MDA and FDCA can only be enforced by the federal government.<sup>55</sup>

### III. PARALLEL CLAIMS IN ACTION

Parallel claims survive federal preemption because they are premised on conduct that violates federal regulatory requirements, without, as the Court held in *Riegel*, imposing obligations that are “different from or in addition to” federal requirements.<sup>56</sup> While parallel claims are a valid pathway for injured consumers to file state law tort claims on paper, in practice, consumers who bring parallel claims oftentimes are still unsuccessful in receiving remedies for their injuries.<sup>57</sup> This narrow exception to the Supremacy Clause is rarely effective or applicable in practice. Rather than functioning as an outlet for injured consumers to pursue tort remedies, the parallel claims exception has largely become a procedural bottleneck,

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<sup>53</sup> *Buckman*, 531 U.S. at 351.

<sup>54</sup> Tauber, Heerman & Wong, *supra* note 42, at 46; *see also* 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”).

<sup>55</sup> *Buckman*, 531 U.S. at 351–52.

<sup>56</sup> *Riegel*, 552 U.S. at 328–29.

<sup>57</sup> *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, No. 08-1905 (RHK/JSM), 2009 U.S. Dist. LEXIS 9236, at \*5–7 (D. Minn. Feb. 5, 2009).

gridlocking claims with court-made procedural requirements before the claimants are able to present the merits of their cases.<sup>58</sup>

A main reason the parallel claims exception does not operate as expected in practice is that courts have often construed its scope inconsistently, interpreting and applying the exception in many decision-altering ways.<sup>59</sup> For example, courts often differ on the pleading standard plaintiffs must utilize when pursuing remedies under the parallel claims exception.<sup>60</sup> Traditionally, courts have applied the pleading standards set forth by the foundational cases of *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*, which stated that pleadings must reach the plausibility standard<sup>61</sup> in order to survive a Rule 12(b)(6) motion to dismiss under the Federal Rules of Civil Procedure (“FRCP”) for failing to state a claim.<sup>62</sup> However, when dealing with parallel claims, many courts apply a different pleading standard, requiring plaintiffs to show specific federal regulatory violations, PMA requirements, and the exact points of noncompliance.<sup>63</sup> Courts may be confused by what the required pleading standard is in these types of cases because higher courts, such as the U.S. Supreme Court and the U.S. Court of Appeals for the First Circuit, have yet to address the overarching question:

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<sup>58</sup> Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U.L.J. 453, 454 (2011) (“[Misinterpretation and misapplication of Buckman, Riegel and Twombly . . . has virtually resulted in jurisprudential tort reform, leaving thousands of patients seriously injured by certain types of medical devices without remedy and denied due process.”).

<sup>59</sup> *Clarifying the Scope of the Parallel Claim Exception to Federal Regulatory Preemption of Medical Devices*, HAUG PARTNERS LLP (Feb. 13, 2023), <https://haugpartners.com/article/clarifying-the-scope-of-the-parallel-claim-exception-to-federal-regulatory-preemption-of-medical-devices>.

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

<sup>61</sup> *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (providing that a complaint must include more than just conclusory statements; it must include enough factual allegations and overall be plausible on its face); *see also* *Ashcroft v. Iqbal*, 556 U.S. 662, 697 (2009).

<sup>62</sup> HAUG PARTNERS LLP, *supra* note 59; FED. R. CIV. P. 12(b)(6).

<sup>63</sup> HAUG PARTNERS LLP, *supra* note 59.



What is the requisite level of pleading specificity applicable in the context of medical device preemption?<sup>64</sup>

Courts' confusion on this topic is most evident through the lens of appellate courts. In *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, the Eighth Circuit dismissed the plaintiff's motion for reconsideration, stating that plaintiffs needed to identify specific federal requirements that were violated by the medical device.<sup>65</sup> In 2011, the Eleventh Circuit held a similar decision in *Wolicki-Gables v. Arrow International, Inc.*, upholding the notion that pleadings must meet a heightened specificity requirement.<sup>66</sup> The Eleventh Circuit reasoned that because the "allegations do not set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged," the district court was correct in concluding that the state tort law claims were preempted by the MDA.<sup>67</sup> Furthermore, the *Wolicki-Gables* court explained that plaintiffs must identify these specific points because a lower pleading threshold would allow plaintiffs to bypass federal preemption by "simply incant[ing] the magic words '[Appellees] violated FDA regulations.'"<sup>68</sup>

Other courts, such as the Seventh Circuit, have held differently. In *Bausch v. Stryker Corp.*, the Seventh Circuit rejected the idea that plaintiffs must plead the exact federal requirements that were violated by the medical device.<sup>69</sup> Here, the court stated that because the plaintiff's complaint included factual details that corroborated their injury and established a link between the device and their injury, there was no need to include the federal

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

<sup>65</sup> *In re Medtronic, Inc.*, 2009 U.S. Dist. LEXIS 9236, at \*5–7.

<sup>66</sup> *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301–02 (11th Cir. 2011).

<sup>67</sup> HAUG PARTNERS LLP, *supra* note 59; *Wolicki-Gables*, 634 F.3d at 1301.

<sup>68</sup> *Wolicki-Gables*, 634 F.3d at 1301.

<sup>69</sup> *Bausch v. Stryker Corp.*, 630 F.3d 546, 560–61 (7th Cir. 2010).

requirements that were violated.<sup>70</sup> *Bausch* also indicated how it would be “unreasonable to expect that [plaintiff] could have pled more specifically without access to the failed [device] itself, but accessing the [device] outside of a discovery process would risk charges of spoliation of evidence,” highlighting the unrealistic standards plaintiffs are often held to in order to prove their cases.<sup>71</sup> Moreover, *Bausch* noted that a plaintiff may not be able to reach the plausibility pleading standard set forth by *Twombly* and *Iqbal* because of the inaccessibility of the completed versions of these documents, and that with the abundance of evidence already provided by plaintiffs, their complaints could still survive a Rule 12(b)(6) motion.<sup>72</sup>

#### IV. REFORM PROPOSAL: RECALIBRATION OF THE PARALLEL CLAIMS EXCEPTION

The central issue that parallel claims face in modern-day litigation is twofold: the original intent of parallel claims exception has been lost, and due to the lack of precedent, courts are confused about the pleading standards to which parallel claims must be held.<sup>73</sup> Reforms to the parallel claims exception must address both points in order to ensure the maximum coverage of remedies provided to consumer-plaintiffs.

##### *A. Revisiting the Intent of the Parallel Claims Exception*

The precursor to addressing the pleading conundrum is to establish the intent behind the parallel claims exception. Courts have long referenced the

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<sup>70</sup> HAUG PARTNERS LLP, *supra* note 59.

<sup>71</sup> *Bausch*, 630 F.3d at 561.

<sup>72</sup> HAUG PARTNERS LLP, *supra* note 59 (“Because some of the PMA materials are confidential, and there is ‘no public access to complete versions of these documents,’ the court suggested that complaints containing conclusory allegations about Class III devices can nevertheless survive 12(b)(6) motions.”); FED. R. CIV. P. 12(b)(6).

<sup>73</sup> See HAUG PARTNERS LLP, *supra* note 59.

holdings in *Lohr* and *Riegel* as to what a consumer's claim must be to be categorized into the parallel claims exception.<sup>74</sup> However, *Riegel*'s judicial interpretation of this exception seems to narrow the exception, as it essentially dampens the original congressional intent of the parallel claims exception recognized in *Lohr*.<sup>75</sup> Because of this, courts must recalibrate their fundamental understanding of the parallel claims exception by interpreting *Riegel* expansively in light of the congressional intent recognized in *Lohr*.<sup>76</sup> In the interest of justice, courts must come to understand that it is not enough to mechanically apply the "different from, or in addition to" requirement; we must also not ignore Congress's intent to preserve state tort remedies for injured consumers.<sup>77</sup>

State tort laws co-exist with federal regulations such as the FDCA. While both serve similar purposes, state tort laws are aimed specifically at protecting the state's own population. Thus, while federal regulations necessarily inform state tort laws, they should not be used to confine their state counterparts, and certainly not alter or create them. The act of disregarding the congressional intent does exactly this, resulting in courts inadvertently transforming federal regulations into both the floor and ceiling for medical device liability. This is in direct violation of the principles of federalism and should be alarming, not just to the judicial system, but to the legislative system as well. Therefore, reform in this area should reinforce the

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<sup>74</sup> *Lohr*, 518 U.S. at 495–97; *Riegel*, 552 U.S. at 312.

<sup>75</sup> See generally *Riegel*, 552 U.S. (redefining parallel claims as more of a narrow exception to federal preemption); *Lohr*, 518 U.S. at 484–85 ("First, because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action.").

<sup>76</sup> *Lohr*, 518 U.S. at 484–85.

<sup>77</sup> *Riegel*, 552 U.S. at 328; *Lohr*, 518 U.S. at 484–85.

congressional intent set forth in *Lohr*, in order to uphold the value and utility of state tort doctrines.<sup>78</sup>

*B. Establishing A Pleading Framework*

The second reform that should be made to the parallel claims exception is the establishment of a coherent pleading framework for parallel claims. As previously mentioned, courts of all levels struggle to apply a consistent pleading framework for parallel claims. Having mixed pleading standards is detrimental not only to the consumer-plaintiff's livelihood, but also to the judicial system in the long run as it does nothing to establish a proper foundation and precedent for future, and possibly more complicated, issues that may arise from the parallel claims exception.<sup>79</sup> Thus, reformation in this area should focus on treating claims that fall into this narrow exception as state tort law claims first, using noncompliance with federal regulations as evidence, rather than an element, to the parallel claims exception. By allowing courts to acknowledge the existence of a state tort law duty, establishing a factual basis for the claim, and providing a causal connection between the noncompliance with a federal regulation and an injury, courts will be able to bypass the confusion of whether a standard deviates from the *Twombly-Iqbal* standard, as well as allow consumer-plaintiffs to have a fair chance to present and advocate for themselves.

Reforming the pleading standard of parallel claims in this way will still uphold the foundations of federal preemption provided by the Supremacy Clause and § 360(k) of the FDCA because courts will still be bound to the

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<sup>78</sup> *Lohr*, 518 U.S. at 484–85.

<sup>79</sup> See generally Adam N. Steinman, *The Rise and Fall of Plausibility Pleading?*, 69 VAND. L. REV. 333 (2016) (discussing the negative effects that unclear pleading requirements can have).

strict exceptions carved out by the parallel claims exception, forcing courts to dismiss claims that contradict federal regulations. Additionally, consumer-plaintiffs will remain barred from asserting fraud-on-the-FDA theories, as courts will still uphold precedent from cases, such as *Buckman*.<sup>80</sup> This reform would ensure that plaintiffs pursuing parallel claims are not only given the proper opportunity to assert their case, but are still bound to the existing limitations of the parallel claims exception.

### *C. Addressing Reformation Criticisms*

While these reforms may be beneficial to consumer-plaintiffs seeking remedies, one major criticism the federal government may have regarding the expansion of the parallel claims exception is that granting a wide berth to private litigation in this field could effectively transform the narrow exception from one that provides remedies into one that allows for de facto FDA enforcement.<sup>81</sup> For example, by allowing increased discovery to uncover regulatory violations by medical device manufacturers, state courts may be undermining the FDA's power as the primary regulator that is responsible for monitoring and enforcing compliance with its laws.

However, construing the expansion of the parallel claims exception as de facto FDA enforcement misinterprets the purpose of the expansion: the goal here is not to undermine or remove the power of the federal government, but to supplement it. The *Riegel* requirements<sup>82</sup> and proposed pleading framework make it clear that the FDA's enforcement of medical devices

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<sup>80</sup> *Buckman*, 531 U.S. at 351–52.

<sup>81</sup> *Id.* at 349 n.4 (clarifying that, in the Court's view, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with medical device provisions" thereby acknowledging its concern that an expansion of private litigation would result in de facto FDA enforcement).

<sup>82</sup> *Riegel*, 552 U.S. at 321.

remains the overarching regulatory obstacle that all manufacturers must navigate to be initially placed on the market. Additionally, not only has the FDA historically been underfunded, but the FDA has often been unable to provide consumers with appropriate remedies for their injuries.<sup>83</sup> Supplementing the FDA's enforcement power with state tort litigation avenues will allow state and federal judicial systems to work in tandem towards the FDA's goal of ensuring the safety and efficacy of medical devices.

Another potential criticism is that expanding the parallel claims exception could lead to abuse by consumer-plaintiffs, who use the now-expanded process as a method to "check" whether medical device manufacturers are meeting FDA requirements. Specifically, private litigators could potentially utilize this pathway to open claims based on injury, without providing a concrete factual basis, in an effort to fish and hope for a deviation from FDA compliance. While the fear of bad faith or speculative claims is a common one within the arena of product liability and health law,<sup>84</sup> this criticism relies on the assumption that courts will allow litigants to proceed without providing a factual, evidentiary basis for their claim. This is rebutted by the fact that courts already have the power to deny claims they believe have not met the pleading requirements, as well as other procedural tools to address bad faith claims, such as Rule 11(b), which requires all pleadings and motions to be backed with factual contentions, evidentiary support, and to not be

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<sup>83</sup> INST. OF MED., CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY: WORKSHOP SUMMARY 13 (Leslie Pray & Sally Robinson eds., The Nat'l Acad. Press 2007); ADVOCACY FOR PATIENTS, *supra* note 2.

<sup>84</sup> Thomas Feore & Ana Nizharadze, *Court of Appeal Cuts Off Speculative Product Liability Claims*, JD SUPRA (May 28, 2025), <https://www.jdsupra.com/legalnews/court-of-appeal-cuts-off-speculative-6249126/>.

presented for any improper purpose.<sup>85</sup> Moreover, violating such requirements may result in sanctions per Rule 11(c).<sup>86</sup> In short, any attempt by litigants to “check” medical device manufacturers will be quickly shut down if they do not provide a breach of a specific parallel violation alongside a proper evidentiary basis.

#### CONCLUSION

As it currently stands, the parallel claims exception operates as more of a theoretical safeguard to the liberties of injured consumers than as a meaningful avenue for pursuing remedies. Although viable in theory, the current state of the parallel claims exception provides little meaningful relief, since the current legal framework often tilts against injured consumers. Reforms to this already narrow exception of federal preemption is much needed, not only to ensure fairness for those injured by medical devices, but also to recalibrate the power balance between state and federal government.

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<sup>85</sup> FED. R. CIV. P. 12(b)(6); FED. R. CIV. P. 11(b).

<sup>86</sup> FED. R. CIV. P. 11(c).

# When Healthcare Ownership Evolves Faster Than Health Law: Private Equity and the Accountability Gap

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## INTRODUCTION

In recent years, the ownership structure of healthcare in the United States has undergone significant changes, yet legal accountability has not kept pace with this fundamental shift. Private equity (“PE”) firms play an increasingly central role in acquiring and managing hospitals and other healthcare facilities, demonstrating a profound shift in how healthcare institutions are governed.<sup>1</sup> Even as PE firms exert significant influence over entire networks of affiliated providers, enforcement of health law remains centered on individual providers even when key decisions originate at the PE ownership level.<sup>2</sup> This creates a growing misalignment between the locus of operational control and the allocation of legal accountability.

Because enforcement mechanisms attach primarily to individual healthcare providers, regulatory responsibility does not extend upstream to PE ownership, even if it may be the source of downstream noncompliance. Provider-focused legal frameworks are ill-suited to address systemic risks that could exist across multiple facilities operating under the same PE firm. This concern is heightened in regions where PE ownership has disproportionate market saturation, as shared governance by a dominant PE firm can expose a local healthcare market to consistent patterns of

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<sup>1</sup> *Market Trends in Private Equity-Backed Healthcare, with Insights from Home Health*, TRILLIANHEALTH (Sep. 22, 2025), <https://www.trillianthealth.com/market-research/studies/market-trends-in-private-equity-backed-healthcare-with-insights-from-home-health>.

<sup>2</sup> See, e.g., Erin C. Fuse Brown & Mark A. Hall, *Private Equity and the Corporatization of Health Care*, 76 STAN. L. REV. 527, 574 (2024).



noncompliance and quality issues with no meaningful alternatives for healthcare.

This article argues that federal and state health law compliance frameworks have failed to address the evolving role of PE ownership in healthcare and must narrow this growing “accountability gap” to align regulatory responsibility where there is actionable functional control. For purposes of this article, “accountability” refers to the expectation that an entity will be subject to compliance enforcement mechanisms under federal or state health laws and ongoing oversight. Part I provides a background on PE healthcare ownership, including typical structural and functional characteristics. Part II analyzes whether developments in federal False Claims Act lawsuits involving PE firms constitute a meaningful shift in PE accountability through liability exposure. Part III addresses state Corporate Practice of Medicine laws and presents one state’s leading model for bridging the accountability gap. Part IV synthesizes the preceding analyses to propose a coordinated federal and state framework for imposing meaningful PE accountability.

## I. THE RISE OF PE IN HEALTHCARE: OWNERSHIP, STRUCTURE, AND INFLUENCE

### *A. Expansion of Private Equity Ownership in Healthcare*

Recent market data illustrates the growing prevalence of PE ownership across the healthcare sector. As of 2026, 9% of all private hospitals and 23% of all for-profit hospitals are owned by PE firms with a disproportionate concentration in rural areas, where they account for nearly 30% of hospital

ownership.<sup>3</sup> Late 2025 saw an uptick of approximately 445 PE healthcare buyouts, signaling that acquisition activity shows no signs of slowing.<sup>4</sup> Aside from hospitals, PE firms acquire nursing homes, specialty clinics, and behavioral health facilities, among others.<sup>5</sup>

### *B. The MSO Structure and the Illusion of Formal Separation*

Because most jurisdictions restrict the Corporate Practice of Medicine (“CPOM”), a doctrine prohibiting non-physicians from owning, controlling, or directly employing doctors, PE firms structure their healthcare acquisitions to maintain formal separation between business and clinical operations.<sup>6</sup> To comply, PE firms establish a Management Services Organization (“MSO”) structure that acquires all non-clinical assets such as real estate, equipment, and branding.<sup>7</sup> Meanwhile, physicians affiliated with the entity separately manage a Professional Corporation (“PC”) responsible for staffing and licensure of clinicians.<sup>8</sup> Both entities execute a Management Services Agreement (“MSA”), allocating non-clinical functions to the MSO and clinical operations to the PC.<sup>9</sup> In theory, this “friendly MSO model” should satisfy CPOM doctrine, but in practice, non-clinical governance often exerts significant influence over clinical operations.

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<sup>3</sup> PRIV. EQUITY STAKEHOLDER PROJECT, *PESP Private Equity Hospital Tracker* (last rev. Apr. 2025), <https://pestakeholder.org/private-equity-hospital-tracker/>.

<sup>4</sup> Jay Asser, *Healthcare Private Equity Deal Value Hits Record \$191B in 2025*, HEALTHLEADERS (Jan. 22, 2026), <https://www.healthleadersmedia.com/ceo/healthcare-private-equity-deal-value-hits-record-191b-2025>.

<sup>5</sup> Elizabeth Montgomery, *Private Equity in Health Care*, ARK. CTR. FOR HEALTH IMPROVEMENT (Oct. 2, 2025), <https://achi.net/publications/private-equity-in-health-care/>.

<sup>6</sup> SOVDOC, *A Deep Dive into Private Equity Deal Structures for Healthcare Practices* (June 16, 2025), <https://sovdoc.com/private-equity-deal-structures-healthcare>.

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

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

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

### *C. PE Impact on Clinical Care and Patient Outcomes*

The influence of non-clinical PE governance can lead to functional control over clinical care by shaping operational, financial, and organizational decisions that materially influence healthcare delivery.<sup>10</sup> This control is a necessary feature of the PE business model's profit-driven structure.<sup>11</sup> PE acquisition is typically financed through significant debt in a leveraged buyout, which uses the entity's assets and projected revenue as collateral.<sup>12</sup> This results in debt-fueled pressure for the acquired entity to quickly generate returns through aggressive cost-cutting and revenue-maximizing strategies; meanwhile, the PE seeks to maximize its profit upon exit following a brief period of targeted facility investments and financial restructuring.<sup>13</sup> Although proponents argue that PE acquisition can offer struggling rural and safety net facilities an opportunity for capital and revitalization rather than closure, the PE model has widely been criticized for prioritizing profit over quality, patient-centered care.<sup>14</sup>

In practice, this profit-driven PE model shapes healthcare delivery through budget constraints, staffing reductions, and resource cuts.<sup>15</sup> The most common cost-cutting measure involves staffing; not only staff reduction, but

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<sup>10</sup> See generally, Christopher Cai & Zirui Song, *A Policy Framework for the Growing Influence of Private Equity in Health Care Delivery*, 329 JAMA 1545 (2023), <https://jamanetwork.com/journals/jama/fullarticle/2804025> (explaining how PE's non-clinical governance can effectively shape and influence clinical care).

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

<sup>12</sup> Rai Hasen Masoud, *Medicine in the Age of Private Equity: The Ethics of Profit in Patient Care*, GEO. L. (Oct. 21, 2025), <https://www.law.georgetown.edu/denny-center/blog/medicine-private-equity>.

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

<sup>14</sup> Maya Brownstein, *Private Equity's Appetite for Hospitals May Put Patients at Risk*, HARV. SCH. OF PUB. HEALTH (Dec. 16, 2024), <https://hsph.harvard.edu/news/private-equitys-appetite-for-hospitals-may-put-patients-at-risk/>.

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

also replacement of expensive licensed professionals with less credentialed staff—for instance, hiring a nursing assistant to a role formerly filled by a nurse.<sup>16</sup> Healthcare delivery is adversely affected because understaffing and scarcity of highly-skilled clinical providers often results in measurably worse patient outcomes.<sup>17</sup> PE firms may also critically compromise patient care if they neglect to invest in medical equipment, rendering it outdated, faulty, or not readily available.<sup>18</sup> Another harmful trend involves eliminating less profitable services, such as OB-GYN and pediatrics, in favor of more lucrative ones such as cardiology and orthopedics, which further exacerbates healthcare access inequities.<sup>19</sup>

## II. THE ACCOUNTABILITY GAP FOR PRIVATE EQUITY

The structural and operational realities discussed in Part I demonstrate the ways in which PE ownership substantially influences healthcare, yet existing frameworks are designed to regulate individual providers rather than the PE firms directing them. The following discussion evaluates whether federal or state health law mechanisms are equipped to close this gap.

### *A. Federal Accountability Under the FCA: A Promising Start Followed by Retreat*

The False Claims Act (“FCA”) has emerged as a promising but judicially inconsistent mechanism for narrowing the accountability gap, with courts

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<sup>16</sup> Brian Keyser, Alexandra Thornton & Claire Koyle, *5 Consequences of Private Equity’s Expansion in Health Care Services*, CTR. FOR AM. PROGRESS (Oct. 30, 2025), <https://www.americanprogress.org/article/5-consequences-of-private-equitys-expansion-in-health-care-services/>.

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

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

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

extending PE liability on a case-by-case basis without establishing clear or uniform standards. Recent PE lawsuits are based on the FCA's prohibition against a party that "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."<sup>20</sup> PE liability therefore requires showing that the PE knowingly caused or was sufficiently involved in submitting false claims to the government.<sup>21</sup> In 2010, The Affordable Care Act further added that violations under the Anti-Kickback Statute ("AKS") are *per se* false claims under the FCA, meaning that any claim in violation of the AKS—the federal statute against offering or receiving remuneration to induce referrals for federally reimbursed services—automatically qualifies as a false claim under the FCA.<sup>22</sup> The government may also use the FCA to hold providers broadly liable for noncompliance because submitting claims for reimbursement inherently implies compliance with applicable laws, which notably includes another fraud statute known as Stark Law ("Stark"), the federal prohibition against certain physician self-referrals.<sup>23</sup> Because healthcare regulation centers on noncompliance and fraud, which is often enforced through AKS and Stark, the FCA's broad enforcement reach makes it a promising mechanism for advancing PE accountability. As the following case law demonstrates, however, that promise has proven difficult to fulfill.

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<sup>20</sup> David R. Hazelton et al., *Private Equity Firm Faces FCA Liability for Portfolio Company's Alleged Misconduct*, 2318 CLIENT ALERT COMMENT. 1, 1 (May 11, 2018), <https://www.lw.com/admin/upload/SiteAttachments/Alert%202318v4.pdf>.

<sup>21</sup> Lori L. Pines, Kristen M. Murphy & Nadya Salcedo, *Understanding the False Claims Act*, WEIL, GOTSHAL, & MANGES LLP WITH PRAC. L. LIT. 2 (last visited Mar. 9, 2026), [https://www.weil.com/~media/files/pdfs/understanding-the-false-claims-act-\(75611346\).pdf](https://www.weil.com/~media/files/pdfs/understanding-the-false-claims-act-(75611346).pdf).

<sup>22</sup> See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(g)).

<sup>23</sup> Pines et al., *supra* note 21.

In 2018, the Department of Justice (“DOJ”) intervened in an FCA lawsuit against a PE firm for the first time in *United States ex rel. Medrano v. Diabetic Care Rx, LLC*.<sup>24</sup> An amended complaint named Riordan, Lewis, & Haden, Inc. (“RLH”) as a defendant alongside its portfolio company, Patient Care America (“PCA”), formerly known as Diabetic Care Rx LLC.<sup>25</sup> PCA was accused of submitting false claims under the AKS based on allegations that it provided kickbacks in the form of commissions to marketing companies in order to induce prescriptions for its products.<sup>26</sup> RLH was also implicated because it allegedly “conspired with, approved, and bankrolled” PCA’s plan through its continued payment of these commissions.<sup>27</sup> The allegations emphasized RLH’s involvement, showing that RLH’s board chairman was on PCA’s Executive Team, that principals of both entities were in constant communication, and that RLH described itself as “not a passive investor” on its website.<sup>28</sup> The case was settled in 2019 without a determination of liability, but still served as a primary indication of the government’s intent to subject PE firms to FCA exposure when they are actively involved in advancing fraud for their portfolio company.<sup>29</sup> *Medrano* did not specify a minimum required level of PE involvement for establishing

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<sup>24</sup> WHITE AND WILLIAMS LLP, *The Long Arm of the Law Lengthens: What the U.S. ex rel. Medrano v. Diabetic Care RX, LLC Settlement Means for Private Equity Investors*, JD SUPRA (Oct. 8, 2019), <https://www.jdsupra.com/legalnews/the-long-arm-of-the-law-lengthens-what-35912/>.

<sup>25</sup> First Amended Complaint and Demand for Jury Trial at 8, *United States ex rel. Medrano v. Diabetic Care Rx, LLC*, No. 0:15-cv-62617-BB (S.D. Fla. Mar. 4, 2016), [hereinafter *Medrano* Complaint].

<sup>26</sup> *Id.* at 2.

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

<sup>28</sup> *Id.* at 8.

<sup>29</sup> *Id.*; Maria Durant, Katy Forsstrom & Clara Troyer, *FCA Considerations for Private Equity Firms Investing in Health Care Companies*, HOGAN LOVELLS (last visited Mar. 5, 2026), <https://fca-2024.hoganlovellsabc.com/2023-and-the-road-ahead/fca-considerations-for-private-equity-firms-investing-in-health-care-companies#>.

exposure, only that significant involvement in governance, whether directly connected to the fraudulent conduct or not, could suffice.<sup>30</sup>

Some clarity as to liability was provided in 2021 in *United States ex rel. Martino-Fleming v. South Bay Medical Health Centers*. South Bay, a mental health facility, was found liable under the Massachusetts FCA statute for providing and billing Medicaid for mental health services through individuals who were not properly qualified, licensed, or supervised to provide these services.<sup>31</sup> South Bay was a portfolio company of H.I.G. Capital, LLC (“HIG”), a PE firm which was named in the amended complaint for its “knowing ratification” and refusal to prevent South Bay’s fraudulent activity.<sup>32</sup> Similar to the leadership in *Medrano*, HIG had significant control over the portfolio company because its employees and executives formed a majority of South Bay’s Board.<sup>33</sup> Additionally, the whistleblower and others had expressly informed the Board of their concerns relating to the violations, but they were ignored.<sup>34</sup> HIG was found liable and reached a record healthcare fraud settlement.<sup>35</sup> *Martino-Fleming* therefore demonstrates that both exposure and liability are possible under a state FCA statute when a PE

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<sup>30</sup> Hazelton, *supra* note 20, at 2.

<sup>31</sup> *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, No. 15-cv-13065-PBS, 2021 WL 2003016 (D. Mass. May 19, 2021), [hereinafter *Martino-Fleming* Memorandum].

<sup>32</sup> HERBERT SMITH FREEHILLS KRAMER, *Investors Beware: Private Equity Firms Continue to Face Potential Liability Under the False Claims Act for Their Portfolio Companies’ Conduct* (Aug. 2, 2022), [https://www.hsfkramer.com/en\\_US/insights/2022-08/investors-beware-private-equity-firms-continue-to-face-potential-liability-under-the-false-claims-act-for-their-portfolio-companies-conduct](https://www.hsfkramer.com/en_US/insights/2022-08/investors-beware-private-equity-firms-continue-to-face-potential-liability-under-the-false-claims-act-for-their-portfolio-companies-conduct).

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

<sup>34</sup> *Martino-Fleming* Memorandum, *supra* note 31, at 6.

<sup>35</sup> Mary Inman & Ronny Valdes, *\$25 Million Medicaid Settlement Reached over Violations of False Claims Act in Massachusetts*, ICD10MONITOR (Nov. 4, 2021), <https://icd10monitor.medlearn.com/25-million-medicaid-settlement-reached-over-violations-of-false-claims-act-in-massachusetts/>.

firm demonstrates knowing and willful indifference to fraud in its portfolio company, combined with deliberate inaction.<sup>36</sup>

Around the same time in 2021, *Ebu-Isaac v. Insys Therapeutics, Inc.* found that a PE firm was liable under the FCA for the actions of its portfolio company because they were sufficiently integrated to be viewed as a single entity for purposes of FCA liability.<sup>37</sup> *Ebu-Isaac* considered factors reflecting a joint effort, such as the overlap of corporate leadership, and emphasized that communications by senior PE officers to the portfolio company's members used collective language indicating that the entities shared common objectives.<sup>38</sup>

Together, these initial PE-FCA cases established a pattern where courts considered not only a PE firm's direct role in the fraudulent conduct, but also its broader level of control and involvement in the portfolio company's operations when determining FCA liability. In each case, the courts expressly referenced these factors in their decisions but provided limited guidance. This is crucial because many PE firms will claim to have a limited role in the portfolio company's operations to support that they could not cause or have knowledge of violations leading to a false claim; clarifying which facts illustrate adequate integration or control to rebut this claim could be dispositive for finding liability.<sup>39</sup> These PE-FCA cases ultimately fell

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<sup>36</sup> Durant et al., *supra* note 29.

<sup>37</sup> Kirk Ogrosky et al., *Whistleblower Lawyers Use False Claims Act to Target Private Equity Firms Invested in Healthcare and Life Sciences*, GOODWIN L. (Jun. 29, 2022), [https://www.goodwinlaw.com/en/insights/publications/2022/06/06\\_29-whistleblower-lawyers-use-false-claims-act](https://www.goodwinlaw.com/en/insights/publications/2022/06/06_29-whistleblower-lawyers-use-false-claims-act).

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

<sup>39</sup> Valerie Cohen, Chuck Morton & Pat Dunbar, *Rounding out 2023: Health Care Enforcement Trends in Private Equity*, WESTLAW TODAY 2 (Dec. 7, 2023), <https://www.venable.com/-/media/files/publications/2023/12/roundingout2023healthcareenforcementtrendsinprivat.pdf>.



short of imparting clear guidance—particularly regarding the extent of PE control and collaboration—a significant factor given that many PE firms have controlling stakes and board representation in their portfolio companies.<sup>40</sup> *Panowicz v. Charter Health Holdings, Inc.* subsequently provided some clarity on which facts may indicate that a PE firm and its portfolio company are sufficiently integrated to constitute a single entity for purposes of FCA liability. However, in doing so, it represents a notable retreat from the more permissive approach of finding FCA exposure applied in prior cases.

A federal court in October 2025 dismissed PE firm Pharos Capital from *Panowicz*, a qui tam whistleblower lawsuit under the FCA’s antiretaliation provision.<sup>41</sup> The whistleblower alleged that his employer, Charter Health, had unlawfully retaliated against him in violation of the FCA by terminating him after he identified \$15 million in potential overpayments and subsequently recommended disclosure and corrective actions.<sup>42</sup> Pharos Capital was named in an amended complaint one year after Charter Health filed for bankruptcy, presumably to secure damages from an alternative, capital-rich source.<sup>43</sup> The complaint alleged that because Pharos held majority ownership of Charter Health, it also qualified as the whistleblower’s

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<sup>40</sup> Alexander M. Owens, *DOJ Scores First Homegrown FCA Settlement Against a Private Equity Firm*, WESTLAW TODAY (Aug. 20, 2025), [https://www.falseclaimsact.com/wp-content/uploads/2025/09/WLT\\_Owens.pdf](https://www.falseclaimsact.com/wp-content/uploads/2025/09/WLT_Owens.pdf).

<sup>41</sup> Bance Pachuca et al., *Private Equity Firm Avoids Potential False Claims Act Liability in Dismissal from Whistleblower Suit Brought by Healthcare Portfolio Company Executive*, WINSTON & STRAWN LLP (Oct. 30, 2025), <https://www.winston.com/en/blogs-and-podcasts/government-program-fraud-false-claims-act-and-qui-tam-litigation-playbook/private-equity-firm-avoids-potential-false-claims-act-liability-in-dismissal-from-whistleblower-suit-brought-by-healthcare-portfolio-company-executive/>.

<sup>42</sup> *Panowicz v. Charter Health Holdings, Inc.*, No. 8:23CV483, slip op. at 5 (D. Neb. Oct. 15, 2025) (memorandum and order), [hereinafter *Panowicz* Memorandum].

<sup>43</sup> Pachuca et al., *supra* note 41.

employer for purposes of liability under the FCA.<sup>44</sup> The court disagreed, finding instead that Pharos and Charter Health were separate corporate entities.<sup>45</sup> This determination was based on the fact that they had separate geographically distant headquarters, were engaged in different businesses with distinct purposes and functions, and generally did not share common management despite the presence of three Pharos partners on Charter Health's Board and its CEO being a former executive at Pharos.<sup>46</sup>

Evaluating *Panowicz* in light of the preceding cases, it appears that the groundbreaking implications of a shift toward heightened PE accountability following *Medrano* were overstated. Prior to *Panowicz*, the presence of current and former PE executives on the board of its portfolio company was consistently a dispositive factor in determining whether the PE exercised sufficient control over the portfolio company to constitute FCA exposure.<sup>47</sup> *Panowicz* now clarifies that this is not enough.<sup>48</sup> Although *Medrano* identified various other factors to demonstrate the PE's control over the portfolio company's operations, it did not indicate that all must be met. Meanwhile, *Martino-Fleming* found PE liability despite offering limited control-based analysis beyond significant PE board representation.<sup>49</sup> *Ebu-Isaac* similarly emphasized the overlap of board members and officers, treating collective communication language as additional support for

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<sup>44</sup> *Panowicz* Memorandum, *supra* note 42, at 9.

<sup>45</sup> *Id.* at 12.

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

<sup>47</sup> D. Jacques Smith et al., *Private Equity Firm Not Liable for Alleged FCA Retaliation Claims by Former Employee of Portfolio Company*, ARENTFOX SCHIFF LLP (Oct. 27, 2025), <https://www.afslaw.com/perspectives/investigations-blog/private-equity-firm-not-liable-alleged-fca-retaliation-claims>.

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

<sup>49</sup> HERBERT SMITH FREEHILLS KRAMER, *supra* note 32.

inferring that the fraudulent activities arose out of a joint effort.<sup>50</sup> Even if *Ebu-Isaac* were to be interpreted as requiring at least one additional supporting factor beyond PE board representation, this was arguably satisfied in *Panowicz* by the whistleblower's description of Pharos' active role in Charter Health's operational, financial, and employment decisions.<sup>51</sup>

It would also be a mistake to distinguish *Panowicz* from previous PE-FCA cases on the basis that the PE firm was named under the anti-retaliation provision of the FCA rather than for the submission of false claims.<sup>52</sup> If elements that would normally be used in support of a PE's exposure to FCA liability under the prohibition against false claims are deemed insufficient for determining liability under the antiretaliation provision, then dismissal substantially narrows the factual and legal basis upon which future FCA claims against the PE could be pursued.<sup>53</sup>

The PE firm's dismissal in *Panowicz* ultimately reflects judicial reluctance to extend FCA accountability to PE firms, even when prior case law provided adequate justification to permit, at minimum, a finding of potential exposure. The facts in *Panowicz* that were found to be insufficient for purposes of FCA exposure are typical of most healthcare PE structures, suggesting the decision's limiting effect extends well beyond the facts of that case. As such, *Panowicz* represents a significant setback to prior judicial progress toward tightening PE accountability through the FCA. However, as the following

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<sup>50</sup> Ogrosky et al., *supra* note 37.

<sup>51</sup> *Panowicz* Memorandum, *supra* note 42, at 4.

<sup>52</sup> *Id.* at 1.

<sup>53</sup> JONES, SKELTON, & HOCHULI, P.L.C., *Claim Preclusion Applies Where Second Suit Addresses Different Issues Than the First Suit as Long as they Arise from the Same Nucleus of Facts* (May 12, 2009), <https://www.jshfirm.com/claim-preclusion-applies-where-second-suit-addresses-different-issues-than-the-first-suit-as-long-as-they-arise-from-the-same-nucleus-of-facts/>.

discussion demonstrates, more meaningful progress toward PE accountability has emerged from state law than from federal enforcement mechanisms.

*B. State CPOM Laws: Limitations, Loopholes, and an Effective Model*

State CPOM statutes are enacted with the goal of preventing non-physician influence over clinical care, typically through prohibitions on non-physician ownership or control of medical practices and direct employment of physicians.<sup>54</sup> Evaluating a non-physician entity's influence on medical judgment is part of its regulatory inquiry, suggesting that CPOM laws might serve as meaningful regulation against PE firms.<sup>55</sup> However, though CPOM statutes attempt to address the issue of corporatization in healthcare, they generally have little practical effect in preventing it.<sup>56</sup>

1. The “Friendly MSO” Loophole

PE firms consistently avoid CPOM enforcement through the “friendly MSO model” as discussed in Part I.<sup>57</sup> This model allows PE firms to maintain clinical influence over the acquired entity by assigning their own medically-licensed employees to executive positions of the affiliated physician PC.<sup>58</sup> PE firms then reinforce their influence by requiring physicians to sign

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<sup>54</sup> SovDOC, *supra* note 6.

<sup>55</sup> Jane M. Zhu, Hayden Rooke-Ley & Erin Fuse Brown, *A Doctrine in Name Only - Strengthening Prohibitions against the Corporate Practice of Medicine*, 389 N. ENGL. J. MED. 965, 967 (2023).

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

<sup>57</sup> SovDOC, *supra* note 6.

<sup>58</sup> Hayden Rooke-Ley et al., *The Corporate Backdoor to Medicine: How MSOs Are Reshaping Physician Practices*, MILBANK MEM'L FUND (Apr. 28, 2025), <https://www.milbank.org/publications/the-corporate-backdoor-to-medicine-how-msos-are-reshaping-physician-practices/>.

restrictive covenants that suppress their professional independence.<sup>59</sup> This loophole remains effective even in states with strict CPOM laws; PE firms still own 6% of private hospitals in California, despite being one of the strongest CPOM jurisdictions in the country.<sup>60</sup>

## 2. A Flawed Doctrine

The aforementioned MSO loophole exposes a significant flaw in CPOM doctrine—it inherently assumes that when physician autonomy is structurally ensured, physicians will prioritize the best interests of their patients rather than those of the PE firm. Yet PE firms exploit this loophole precisely to ensure that physicians placed in PC leadership are firmly aligned with the PE's objectives.<sup>61</sup> Physician independence therefore should not be conflated with patient-centered care when a PE firm finds ways to direct clinical governance. Beyond this flaw, CPOM laws also evaluate a non-physician entity's liability narrowly on the basis of its control over medical judgment.<sup>62</sup> This focus on the singular act of clinical decision-making renders CPOM laws unequipped to address indirect pressures often imposed by PE firms that diminish the quality of healthcare delivery, including short-staffing, medical equipment deficiencies, or reduced service availability.<sup>63</sup> These realities

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

<sup>60</sup> PERMITHEALTH, *The Corporate Practice of Medicine 50-State Guide* (Dec. 23, 2025), <https://www.permithealth.com/post/the-corporate-practice-of-medicine-50-state-guide/>; *Private Equity in Health Care: Prevalence, Impact and Policy Options for California and the U.S.*, CAL. HEALTH CARE FOUND. (May 7, 2025), <https://www.chcf.org/resource/private-equity-in-health-care-prevalence-impact-and-policy-options-for-california-and-the-u-s/>.

<sup>61</sup> Rooke-Ley, *supra* note 58.

<sup>62</sup> Xusong Du, *Enforcing the Corporate Practice of Medicine Doctrine Through False Claim Liability*, 125 COLUM. L. REV. 837, 846 (2024).

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

suggest that strict CPOM statutes function more as structural formalities than as meaningful regulation, with the critical exception of one state.

### 3. The Nation's Strictest CPOM Statute: Potential Benefits and Disadvantages

Oregon has recently taken significant legislative action to directly address loopholes commonly exploited by PE firms under the MSO model. Oregon's Senate Bill 951 ("SB 951"), effective as of June 2025, comprehensively targets PE governance over healthcare by precluding all individuals affiliated with the PE or its MSO structure ("MSO-PE" individuals)—whether licensed physicians or not—from owning or controlling a physician PC.<sup>64</sup> It also prevents MSOs from having discretionary authority over the narrowly-defined services they are permitted to assist in, and prohibits restrictive covenants such as noncompetition agreements that limit physician independence.<sup>65</sup> Overall, SB 951 significantly empowers state enforcement mechanisms, enabling Oregon to pursue direct civil penalties, injunctive relief, and punitive damages directly against PE firms that acquire healthcare facilities.<sup>66</sup> Introduced as the strongest CPOM statute to date, SB 951 signaled the possibility of heightened state-led regulatory scrutiny to PE firms nationwide.<sup>67</sup>

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<sup>64</sup> S.B. 951, 83d Leg. Assemb., Reg. Sess. (Or. 2025).

<sup>65</sup> Timothy M. McCrystal et al., *Key Takeaways Related to Oregon's New CPOM Law*, ROPES & GRAY (Jun. 12, 2025), <https://www.ropesgray.com/en/insights/alerts/2025/06/key-takeaways-related-to-oregons-new-cpom-law>.

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

<sup>67</sup> DECHERT, *New Oregon Law Leads Nation in Restricting Healthcare Investment* (Jun. 26, 2025), <https://www.dechert.com/knowledge/onpoint/2025/6/new-oregon-law-leads-nation-in-restricting-healthcare-investment.html>.

Although SB 951 represents a significant step forward in PE accountability, there are notable criticisms of strong CPOM enforcement. A primary concern is that strict CPOM laws discourage PE investment in healthcare markets that substantially depend on outside capital to survive.<sup>68</sup> This is especially true for rural and safety-net facilities where, despite well-documented operational shortcomings, PE acquisition has nonetheless helped prevent closure and preserve access to care for underserved populations.<sup>69</sup> Additionally, the patchwork nature of state CPOM laws means that PE firms can simply prioritize acquisition in permissive states.<sup>70</sup> Critics also argue that strong regulation imposes compliance burdens that could discourage physician participation in PE-affiliated practices altogether, further exacerbating provider shortages.<sup>71</sup>

Despite these criticisms, Oregon's passing of SB 951 represents the most intentional model currently available to bridge the accountability gap. Its impact, however, is inherently constrained by its jurisdictional scope. Meaningful national change depends on state-by-state replication that is not likely, underscoring a need for the coordinated federal-state response proposed in Part III.

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<sup>68</sup> Testimony in Opposition to S.B. 951, 82d Leg. Assemb., Reg. Sess., at 1 (Or. 2025).

<sup>69</sup> Janet Gao, Yongseok Kim & Merih Sevilir, *Private Equity in the Hospital Industry*, 171 J. FIN. ECON. 1, 2 (2025).

<sup>70</sup> Dilani Logan & Katherine L. Gudiksen, *The Corporate Practice of Medicine: Time for a Reevaluation?*, THE SOURCE ON HEALTHCARE PRICE & COMPETITION (March 2025), <https://sourceonhealthcare.org/profile/the-corporate-practice-of-medicine-time-for-a-reevaluation/>.

<sup>71</sup> Testimony in Opposition to SB 951, *supra* note 68.

### III. BRIDGING THE ACCOUNTABILITY GAP

As discussed in Part II, the accountability gap cannot be meaningfully closed through incremental judicial development or isolated state reform alone. Building on the need for a coordinated federal-state response, this Part will proceed in developing a two-pronged approach: first, by addressing judicial inconsistency through FCA reform; and second, by targeting structural loopholes exploited by PE firms through a federal CPOM framework.

#### *A. Strengthening Federal Enforcement Mechanisms*

Congress should amend the FCA to establish a presumption of PE liability when it holds majority ownership and board representation in a portfolio company that submits false claims, subject to rebuttal based on evidence that the PE firm implemented reasonable compliance oversight commensurate with its financial and operational involvement. This unambiguous statutory basis not only rewards proactive compliance infrastructure, but also removes the inconsistent, fact-specific analysis currently used for determining PE integration and control.

Below is proposed language for a new subsection of the FCA, 31 U.S.C. § 3729(f)—Liability of Controlling Entities:

(1) **Presumption of Liability.** A controlling entity shall be presumed liable under subsection (a) for any false or fraudulent claim submitted by an entity in which it holds majority ownership and board representation, to the same extent as if the controlling entity had knowingly presented, caused to be presented, or knowingly made or used a false record or statement material to such claim.

(2) **Rebuttal.** The presumption established under paragraph (1) may be rebutted by clear and convincing evidence that the controlling entity



implemented compliance oversight reasonable and commensurate with its degree of financial and operational involvement in the entity that submitted the claim.

(3) Definition. For purposes of this subsection, the term “controlling entity” means any private equity firm, parent company, or other entity that holds majority ownership and board representation in a healthcare provider that submits claims for reimbursement under a federal healthcare program.

Regardless of legislative outcome, the DHHS Office of Inspector General (“OIG”) should issue compliance guidelines that directly address PE-owned healthcare entities, identifying the most relevant factors to FCA exposure in the PE context, providing specific details on board composition, shared executives, and the impact of PE-led financial directives on any fraudulent or non-compliant conduct by the portfolio company. OIG guidance could clarify the government’s approach for interpreting the FCA’s “knowingly caused” standard in the context of the PE ownership model, particularly in how it determines a minimum threshold of PE integration and control. This would provide whistleblowers and enforcement authorities with a clearer framework for pursuing FCA claims against PE firms.

#### *B. Closing the MSO Loophole Through a Federal-State Framework*

Oregon’s SB 951 represents the most intentional legislative effort toward upstream PE accountability currently available, but its impact is jurisdictionally limited to healthcare facilities located within Oregon. The optimal solution is a federal CPOM framework that establishes a uniform national baseline to close the MSO loopholes most frequently exploited by PE firms, with some enforcement flexibility conceded for state implementation. SB 951’s prohibition on all MSO-PE individuals from exercising ownership or control over a physician PC, regardless of their

medical licensing status, is a critical provision to include in this framework because it limits a mechanism that PE firms frequently use to assert clinical control through a physician-agent.<sup>72</sup> This loophole defeats the purpose of the MSO-PC model, which is originally intended to keep business and clinical operations of a healthcare entity independent from each other in accordance with CPOM doctrine.<sup>73</sup> SB 951's prohibition on restrictive covenants is also necessary, as these agreements often serve to suppress physician autonomy in favor of ownership interests.<sup>74</sup> A national CPOM statute could include federal language based on SB 951:

No individual employed by, contracted with, or otherwise affiliated with a Management Services Organization shall hold an ownership interest in or exercise control over a physician professional corporation, regardless of licensure status. No management services agreement shall include any provision restricting a physician's right to practice medicine, including noncompetition, non-solicitation, or no-hire clauses. Violations of this section shall subject the management services organization and any controlling entity to civil penalties, injunctive relief, and other remedies the court finds appropriate.

While the SB 951-inspired federal CPOM framework may impose significant restrictions on the existing MSO model, states would retain meaningful discretion over enforcement intensity, including penalty severity, investigative resource allocation, and the availability of private rights of action. States where access to outside capital is critical for sustaining care may calibrate enforcement accordingly, without compromising the national baseline. Although restrictive, this proposed framework is not intended as

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<sup>72</sup> Rooke-Ley et al., *supra* note 58.

<sup>73</sup> SovDOC, *supra* note 6.

<sup>74</sup> Rooke-Ley et al., *supra* note 58.

an outright prohibition on PE acquisition. It merely requires PE firms to comply with the same standards already imposed on healthcare providers.

#### CONCLUSION

The legal frameworks governing healthcare accountability were not designed with PE ownership in mind, and their failure to evolve alongside this growing ownership reality has created a structural gap that existing federal and state mechanisms have struggled to address. As PE firms assume an increasingly dominant role in healthcare governance, the misalignment between functional control and legal accountability will only deepen, perpetuating a system where profit increasingly takes precedence over patient care. Without meaningful reform, the patients who depend on these institutions will bear the consequences of a system that holds everyone accountable except those who increasingly control it.

# The Opioid You Can Buy with a Slushie: Kratom, 7-OH, and Federal Regulatory Limbo

*Annemarie Whalen*

## INTRODUCTION

Kratom (*Mitragyna speciosa*) is a tree native to Southeast Asia whose leaves contain over 40 alkaloids, including 7-hydroxymitragynine (7-OH).<sup>1</sup> In its natural form, 7-OH is present in trace amounts and acts as a partial agonist at  $\mu$ -opioid receptors, producing mild analgesic, stimulatory, and anti-anxiety effects.<sup>2</sup> Kratom's widespread use in the U.S. began around 2016, largely used for self-treating chronic pain, opioid dependence, and mental health conditions.<sup>3</sup> Kratom is not regulated or controlled federally, although the Food and Drug Administration (FDA) has consistently maintained that it has no approved medical use and is an unlawful dietary supplement.<sup>4</sup>

The market has since evolved beyond the natural leaf. Concentrated 7-OH products have emerged as a discrete product, with effects and risks that more closely resemble traditional opioids.<sup>5</sup> These concentrated products are often characterized as New Psychoactive Substances (NPS), a class of chemically modified substances designed to mimic controlled drugs while evading regulation through misleading labeling and perceived legality.<sup>6</sup> The result is a demand-side expansion of opioid risk that operates largely outside

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<sup>1</sup> *Kratom: Summary of State Laws*, LEGIS. ANALYSIS & PUB. POL'Y ASS'N (Jan. 2026), <https://legislativeanalysis.org/wp-content/uploads/2026/02/Kratom-Summary-of-State-Laws.pdf>.

<sup>2</sup> Rhiannon Bath et al., *Self-reported Health Diagnoses and Demographic Correlates with Kratom Use: Results from an Online Survey*, 14 J. ADDICTION MED. 2, 2 (2020).

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

<sup>4</sup> *FDA and Kratom*, U.S. FOOD & DRUG ADMIN. (Dec. 2, 2025), <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>.

<sup>5</sup> *Id.*; Watford, *Kratom faces increasing scrutiny from states and the feds* (Aug. 11, 2025), <https://stateline.org/2025/08/11/kratom-faces-increasing-scrutiny-from-states-and-the-feds/>.

<sup>6</sup> *NPS Snapshot: Kratom-Derived Semi-Synthetic Opioids*, CAYMAN CHEMICAL, (OCT. 2025); Peter Reuter & Bryce Pardo, *New Psychoactive Substances: Are There Any Good Options for Regulating New Psychoactive Substances?* 40 INT'L. J. OF DRUG POL'Y 117, 117-122 (2016).

public awareness.<sup>7</sup> Kratom products are marketed as novelty food and wellness items, frequently displayed alongside sodas and snacks, and are widely accessible to adolescents, health-conscious consumers, and overworked professionals, often without meaningful notice of their opioid dependence profile.<sup>8</sup>

Market indicators confirm accelerating normalization. By 2024, the capsule segment was valued at \$218 million and is projected to reach \$376 million by 2032.<sup>9</sup> North America accounted for 82.05% of global extract sales, with e-commerce driving distribution.<sup>10</sup> Reported U.S. kratom use rose to about two million in 2024, though survey methodology suggests this is an undercount.<sup>11</sup>

The risks are not theoretical.<sup>12</sup> Synthetic 7-OH can be up to 13 times more potent than morphine and is linked to significantly greater respiratory

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<sup>7</sup> 34 *Kratom Ecommerce Statistics: Market Growth, Consumer Behavior, and Digital Commerce Infrastructure*, SWELL (Jan. 2, 2026), <https://www.swell.is/content/kratom-ecommerce-statistics>.

<sup>8</sup> Amanda Watford, *Kratom Faces Increasing Scrutiny from States and the Feds*, STATELINE (Aug. 11, 2025), <https://stateline.org/2025/08/11/kratom-faces-increasing-scrutiny-from-states-and-the-feds/>; Kristen Smith et al., *The Rise of Novel, Semi-synthetic 7-hydroxymitragynine Products*, 120 ADDICTION 387, 387 (2024).

<sup>9</sup> SWELL, *supra* note 7.

<sup>10</sup> *Id.* One US based retailer achieved \$3.5 million in kratom extract sales in 2024 (over 50% growth from 2023). See [shopcbdkratom.com](https://shopcbdkratom.com).

<sup>11</sup> SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE U.S.: RESULTS FROM THE 2021 NAT'L SURVEY ON DRUG USE AND HEALTH, NSDUH Series H-57, HHS Pub. No. PEP22-07-01-005 at 24 (2022) [hereinafter SUBSTANCE USE AND MENTAL HEALTH 2021]. Alternative survey methods estimate up to fifteen million US users. See Oliver Grundmann et al., *Presence of Kratom in Opioid Overdose Deaths: Findings from Coroner Postmortem Toxicological Report* 15 FRONTIERS IN PSYCHIATRY 1, 1-3 (2024). Estimating the prevalence of 7-OH users is difficult because kratom experts do not synonymize 7-OH with natural kratom and there are few metrics dedicated solely to 7-OH. Smith et al., *supra* note 8.

<sup>12</sup> Shaunna Devitt, *Health Advisory: Serious Illnesses Associated with 7-OH*, AMS. POISON CTRS. (Aug. 12, 2025), <https://poisoncenters.org/newsalerts/13531044>.

depression.<sup>13</sup> Between January and July 2025, U.S. Poison Centers received 1,690 kratom-related exposure reports, surpassing the total for 2024, driven in part by the rise of 7-OH products.<sup>14</sup> From 2023 to 2025, emergency medical services recorded over 4,000 kratom or 7-OH-related encounters, and multiple states have documented kratom-related fatalities since 2020.<sup>15</sup> This data indicates a foreseeable and escalating pattern of harm, rather than speculative risk.

This article proceeds in four parts. Part II sets forth the federal and state regulatory landscape governing kratom and 7-OH, examining the oscillation between attempted federal scheduling and fragmented state responses that together create a regulatory gray area. Part III explains why current federal tools, such as FDA enforcement authority, drug approval pathways, and the Controlled Substances Analogue Enforcement Act (Analogue Law) are structurally insufficient to govern consumer substances that pose opioid-like

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<sup>13</sup> Marty Makary, *Beware: Synthetic Kratom — 7-OH — is Powering a New Opioid Crisis*, N.Y. POST (July 29, 2025), <https://nypost.com/2025/07/29/opinion/beware-synthetic-kratom-7-oh-powers-a-new-opioid-crisis/>.

<sup>14</sup> Devitt, *supra* note 12. It's relevant to note that in some cases where 7-OH was linked to fatalities, other substances, such as fentanyl, heroin, cocaine, or prescription opioids were also present. Jeffrey Singer, *When 7-OH Fears Drive Policy by Anecdote*, CATO INST. (Mar. 5, 2026), <https://www.cato.org/commentary/when-7-oh-fears-drive-policy-anecdote>.

<sup>15</sup> *7-OH (7-Hydroxymitragynine): The Dangerous "Legal" Drug Sold at Gas Stations*, NOVA TRANSFORMATIONS (Nov. 22, 2025), <https://novatransformations.com/7-oh-7-hydroxymitragynine-the-hidden-danger-in-gas-station-kratom-products-charlotte-nc/>; *Classification of Mitragynine-Related Compounds as Schedule I Controlled Substances*, OHIO BD. OF PHARMACY, <https://www.pharmacy.ohio.gov/documents/pubs/special/kratom/classification%20of%20mitragynine-related%20compounds%20as%20schedule%20i%20controlled%20substances%20-%20emergency%20rule.pdf#> (last visited Feb. 10, 2025); *Additional Fatal Overdoses Tied to Synthetic Kratom in Los Angeles County*, LOS ANGELES CNTY. DEP'T. PUB. HEALTH (Oct. 10, 2025), <http://publichealth.lacounty.gov/phcommon/public/media/mediapubhpdetail.cfm?prid=5156>; *Attorney General Knudsen Warns of Dangers of the Commercially Sold Opioid: 7-hydroxymitragynine*, MONT. DEP'T OF JUST. (Sep. 3, 2025), <https://dojmt.gov/attorney-general-knudsen-warns-of-dangers-of-the-commercially-sold-opioid-7-hydroxymitragynine/>.

dependence risks yet fall outside both approval and scheduling regimes. Part IV proposes a new federal framework, titled "Regulation of Psychoactive Consumer Substances Posing Opioid Dependence Risk" (PCSOD) as a provisional, risk - triggered amendment to the Federal Food, Drug, and Cosmetic Act (FDCA). The framework draws on the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) and introduces key modifications, including affirmative market authorization, a tiered evidentiary standard to account for product potency, and anti-evasion provisions. Part V anticipates and responds to objections, including those grounded in harm reduction concerns and regulatory overreach.

#### I. FEDERAL ACTION AND STATES' POSITIONS

Federal drug regulation is structured around two primary pathways: FDA approval as a lawful drug or Drug Enforcement Administration (DEA) scheduling as a controlled substance.<sup>16</sup> Substances that fall outside both categories lack any affirmative mechanism for governing their presence in consumer markets.<sup>17</sup> The FDA regulates products through medical-use determinations, marketing and labeling standards, and post-market enforcement, while the DEA classifies substances into one of five schedules based on their accepted medical use, potential for abuse, and safety, and must obtain a formal recommendation from the FDA before scheduling determinations are made.<sup>18</sup>

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<sup>16</sup> JASON HEFLIN, CONG. RSCH. SERV., LSB11082, KRATOM REGULATION: FEDERAL STATUS AND STATE APPROACHES (2023), <https://www.congress.gov/crs-product/LSB11082>.

<sup>17</sup> See Clara Turnage, *Despite Federal Warnings, Kratom Still Readily Available Across US*, THE UNIV. OF MISS., (Nov. 14, 2024), <https://olemiss.edu/news/2024/11/kratom-availability-2024/index.html>.

<sup>18</sup> CONG. RSCH. SERV., REP. NO. LSB11082; 21 U.S.C. § 301; 21 U.S.C. § 812.

Kratom fits neither framework. In 2016, the DEA attempted to schedule 7-OH as a Schedule I substance, citing rising abuse, deaths, and evidence of opioid-like dependence.<sup>19</sup> However, the action was withdrawn due to public backlash.<sup>20</sup> In 2025, the FDA again recommended scheduling 7-OH and initiated targeted enforcement actions against manufacturers.<sup>21</sup> This oscillation has left kratom in a regulatory gray area defined by reactive FDA enforcement and fragmented state law.<sup>22</sup>

As of 2026, state regulation remains uneven, reflecting kratom's contested legal status and the market's capacity to outpace. Several states regulate kratom in some form, with many using different variations of the Kratom Consumer Protection Act (KCPA) to regulate manufacturing, age restrictions, and potency limits while allowing natural kratom to remain on the market.<sup>23</sup> Fewer states classify 7-OH as a controlled substance, effectively banning kratom.<sup>24</sup> This patchwork cannot meaningfully constrain product potency, online distribution, or youth access without coordinated federal action.

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<sup>19</sup> Gerald Gianutsos, *The DEA Changes Its Mind on Kratom*, U.S PHARMACIST (Mar. 17, 2017), <https://www.uspharmacist.com/article/the-dea-changes-its-mind-on-kratom>.

<sup>20</sup> *Id.*

<sup>21</sup> *FDA Issues Warning Letters to Firms Marketing Products Containing 7-Hydroxymitragynine*, U.S. FOOD & DRUG ADMIN. (July 15, 2025) [hereinafter *FDA Issues Warning Letters*], <https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-firms-marketing-products-containing-7-hydroxymitragynine>.

<sup>22</sup> *Kratom Summary of State Laws*, *supra* note 1.

<sup>23</sup> *What Is the KCPA? The Kratom Consumer Protection Act Explained*, KATS BOTANICALS (2025 Update), <https://katsbotanicals.com/what-is-the-kcpa-the-kratom-consumer-protection-act-explained/> (last visited Feb. 10, 2026); CONG. RSCH. SERV., REP. NO. LSB11082.

<sup>24</sup> *Kratom Summary of State Laws*, *supra* note 1, at 6.



## II. WHY EXISTING FEDERAL TOOLS ARE INSUFFICIENT

Existing federal authority is insufficient for comprehensively regulating kratom. The FDA's determination that kratom products marketed as food or dietary supplements are adulterated enables only violation-based enforcement against specific products, not categorical oversight.<sup>25</sup> Enforcement proceeds firm-by-firm and product-by-product at a pace that cannot realistically scale consumer markets.<sup>26</sup> Warning letters invite drug reformulation rather than compliance, and injunctive relief requires proof of irreparable harm that the government cannot always establish amid rapid product innovation.<sup>27</sup> As a result, enforcement removes individual products while new, often higher-potency variants emerge in response.<sup>28</sup>

Current drug approval pathways offer no broader solution. FDA oversight requires either disease claims or approval through an Investigational New Drug Application (IND) or a New Drug Application

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<sup>25</sup> 21 U.S.C. § 342(f)(1)(B); *FDA and Kratom*, *supra* note 4; *FDA Takes Steps to Restrict 7-OH Opioid Products Threatening American Consumer*, (July 29, 2025) [hereinafter *FDA Takes Steps*], <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-restrict-7-oh-opioid-products-threatening-american-consumers>.

<sup>26</sup> *FDA and Kratom*, *supra* note 4 (explaining that enforcement is complicated by kratom's fragmented supply chain, including unregistered online sellers, mislabeled mail, and shipments operating out of private residences).

<sup>27</sup> See FDA, *Letters to Industry*, U.S. FOOD & DRUG ADMIN. (Feb. 20, 2020), <https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry> (Feb. 20, 2020); 21 C.F.R. § 10.85. Federal courts consistently treat FDA warning letters as informal, non-final actions lacking binding or precedential authority. See *Holistic Candles & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 942 (2012); *Reid v. Johnson & Johnson*, 780 F.3d 952, 965 (2015).

<sup>28</sup> Michael White, *Kratom's Use and Impact on Pediatric Populations*, 30 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS (2025) (finding that many of 68 tested kratom products contained excessive amounts of heavy metals); Chad J. Reissig et al., *7-Hydroxymitragynine (7-OH): An Assessment of the Scientific Data and Toxicological Concerns Around an Emerging Opioid Threat*, U.S. FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION RSCH. (July 29, 2025), <https://www.fda.gov/media/187899/download> (observing from social media sources that users acknowledge higher potency kratom products marketed as "candy like" increase overconsumption risks).

(NDA), both of which have foundered for safety concerns.<sup>29</sup> Vendors evade this framework by forgoing approval and using general wellness language rather than disease treatment claims, such as claiming kratom “helps with occasional anxiety and stress” rather than “treats anxiety.”<sup>30</sup> This leaves the FDA without authority to impose category-wide controls such as age limits, retail restrictions, or online sales requirements.<sup>31</sup>

Kratom also falls outside Analogue Law, which targets chemical innovations intended to evade drug controls.<sup>32</sup> Analogue law covers substances with both substantially similar chemical structures and pharmacological effects to those in Schedules I or II; kratom’s indole alkaloids fail to meet the latter requirement.<sup>33</sup> Consequently, neither FDA consumer-product authorities nor federal drug control laws provide a viable regulatory framework for kratom.

Scheduling alone is insufficient to address the risks associated with the market because it targets individual compounds rather than the market conditions that drive their proliferation.<sup>34</sup> Tianeptine, colloquially known as “gas station heroin,” demonstrates the relative limits and strengths of scheduling.<sup>35</sup> As a fully synthetic  $\mu$ -opioid receptor agonist, it fits existing

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<sup>29</sup> 21 U.S.C. § 321(g)(1); Stephen Daniells, *Sixth Time Still Not a Charm: FDA Again Rejects NDIN for Kratom*, NUTRAINGREDIENTS (July 8, 2022), <https://www.nutraingredients.com/Article/2022/02/02/Sixth-time-still-not-a-charm-FDA-again-rejects-NDIN-for-kratom/>.

<sup>30</sup> *FDA Issues Warning Letters*, *supra* note 21.

<sup>31</sup> 21 U.S.C. § 342(f).

<sup>32</sup> 21 U.S.C. § 813.

<sup>33</sup> 21 U.S.C. § 802(32)(A); *Kratom*, NAT’L. INST. OF HEALTH (Mar. 11, 2026), <https://nida.nih.gov/research-topics/kratom#kratom-compound>.

<sup>34</sup> See Reuter & Pardo, *supra* note 6.

<sup>35</sup> Tharwat El Zahran et al., *Characteristics of Tianeptine Exposures Reported to the National Poison Data System — United States, 2000–2017*, MMWR 67, 815 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/mm6730a2.htm>.

controlled substances paradigms and states have responded almost exclusively through scheduling and produces classic opioid dependency.<sup>36</sup>

Kratom, however, is not a single-compound problem.<sup>37</sup> Its complex alkaloid profile and adaptable market design limit scheduling's effectiveness, as evidenced by varying state responses.<sup>38</sup> This dynamic reveals a structural gap between innovative markets and outdated regulation—one Congress has both the authority and precedent to implement through a market-level framework that targets harm before it becomes entrenched.<sup>39</sup>

### III. A PROPOSED FRAMEWORK

Kratom exposes the same regulatory problem that once defined tobacco.<sup>40</sup> Prior to the TCA, the FDA played no role in regulating tobacco products, and the Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, confirmed that regulatory authority did not reach the agency.<sup>41</sup> Congress responded by granting the FDA tailored authority to regulate tobacco under

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<sup>36</sup> *Id.*; See *Regulation of Tianeptine – State by State Overview*, N.C. GEN. ASSEM., <https://webservices.ncleg.gov/ViewDocSiteFile/84838> (last visited Feb. 13, 2025).

<sup>37</sup> *Kratom: Summary of State Laws*, *supra* note 1.

<sup>38</sup> *Id.*; See source cited *supra* note 23 and accompanying text.

<sup>39</sup> 2009 Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387a; See generally Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), ch 42, 123 Stat. 1776 (2009) (codified as amended at 21 U.S.C. §§ 21 U.S.C. 387-387u) (stating that FDA premarket review authority for tobacco products is the only effective way to protect the public health).

<sup>40</sup> See generally *Kratom's Rise to Prominence: The Evolution of Kratom*, GLOBAL KRATOM COALITION, <https://globalkratomcoalition.org/the-evolution-of-kratom> (last visited Feb. 10, 2026) [hereinafter *Kratom's Rise*].

<sup>41</sup> See INST. OF MED., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION, 273-290 (Robert Wallace et al. eds., 2007) (explaining how tobacco oversight was characterized by state control subject to federal preemption of health warnings and regulations absent FDA regulation); *FDA v. Brown & Williamson Tobacco Corp. et al.*, 529 U.S. 120, 161 (2000) (holding the FDA cannot regulate tobacco under the FDCA absent Congressional authority).

a public health standard, including market restrictions, premarket review for new products, and access controls.<sup>42</sup> The TCA demonstrates Congress's ability to create a tailored framework to regulate substances that fall outside traditional drug approval and controlled substances regimes, pose documented dependence risks, and is present in consumer markets.<sup>43</sup> Each condition applies to kratom, but at a significantly earlier point in the normalization curve than tobacco had reached when Congress acted.<sup>44</sup>

#### A. The "PCSOD" Framework

To address this gap, Congress should add a new subchapter to the FDCA titled "Regulation of Psychoactive Consumer Substances Posing Opioid Dependence Risk" (PCSOD). This subchapter would apply to any substance that (1) is not an approved drug under Subchapter V and tobacco products under Subchapter IX (2) is not currently scheduled under the Controlled Substances Act (CSA) or Analogue Law; (3) produces pharmacological effects at the  $\mu$ -opioid receptors when consumed by humans, as determined by the Secretary of Health and Human Services (HHS) based on available pharmacological evidence; and (4) is sold or offered for sale directly to consumers other than pursuant to a valid prescription. Designation would

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<sup>42</sup> 21 U.S.C. § 387a.

<sup>43</sup> See Wallace, *supra* note 41, at 279 (describing how FDA regulation of tobacco products would enable a public health balancing standard, accounting for initiation, cessation, substitution and black-market risks, rather than a binary approval or ban approach).

<sup>44</sup> See *Kratom's Rise*, *supra* note 40 (kratom extract distribution in the U.S. began in 2013); *Compare SUBSTANCE USE AND MENTAL HEALTH 2021* *supra* note 11, at 24 (estimating 1.7 million people above age twelve used kratom in the past year) and NSDUH 2021, *supra* note 11, at 10 (estimating 43.6 million people above age twelve smoked cigarettes in the past month). When Congress acted in 2009, tobacco use was deeply entrenched and the leading preventable cause of death in the U.S, with 3200 kids trying cigarettes for the first time and many facing premature death. See *FDA Regulation of Tobacco Products: A Common Sense Law to Protect Kids and Save Lives*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 25, 2016), <https://assets.tobaccofreekids.org/factsheets/0352.pdf>.

follow a notice-and-comment rulemaking consistent with 5 U.S.C. § 533,<sup>45</sup> with an expedited procedure available where the Secretary finds a reasonable probability of public health harm.<sup>46</sup>

*B. Tobacco Regulation as a Reference and Required Adjustments*

The TCA provides the closest regulatory model for kratom, but kratom requires key modifications to adequately address kratom’s risks of opioid dependence: an expanded public health calculus, a tiered evidentiary framework, and the elimination of any presumed market legality.<sup>47</sup>

1. Public Health Calculus

Under the TCA, tobacco manufacturers must obtain premarket authorization before introducing new products into consumer markets, requiring the Secretary to determine whether a product is “appropriate for the protection of the public health,” weighing the risks and benefits to the population, including the likelihood that existing users will quit and the likelihood nonusers will start.<sup>48</sup>

The PCSOD should retain this framework but require a more demanding health calculus to account for downstream opioid effects. Because kratom and its derivatives can produce pharmacological effects and withdrawal symptoms clinically comparable to prescription opioids, the PCSOD would require the agency to additionally assess whether a product’s continued market availability increases demand for illicit opioids, including among

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<sup>45</sup> 5 U.S.C. § 533.

<sup>46</sup> 21 U.S.C. § 387j(d)(3).

<sup>47</sup> 21 U.S.C. § 387j(c)(4).

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

users who lose access through supply disruption or enforcement action.<sup>49</sup> The relevant inquiry would not only be whether a product's standalone risk profile is acceptable, but also whether its continued availability would contribute to the broader reservoir of opioid dependency. This factor would apply to both the initial authorization determination and to expedited designation.

## 2. Market Access and Provisional Authorization

The TCA's premarket review regime reflects the reality that it was enacted against a deeply entrenched and politically accepted market, largely preserving existing products and primarily focusing review on new or modified ones.<sup>50</sup> As a result, the TCA regulates at the margins, and this design has produced well-documented enforcement challenges, particularly in the context of e-cigarettes, where unauthorized products have proliferated despite formal premarket requirements.<sup>51</sup> Because kratom has not reached the level of market entrenchment that constrained tobacco regulation,<sup>52</sup> the PCSOD should require affirmative authorization of all PCSOD products as a condition of market access. New Zealand's Psychoactive Substances Act model is instructive: no psychoactive substance may enter the consumer

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<sup>49</sup> See Letter from Brett P. Giroir, Assistant Secretary for Health, Senior Advisor for Opioid Policy, to Uttam Dhillon, Acting Administrator, Drug Enforcement Administration (Aug. 16, 2018),

<https://www.rilegislature.gov/Special/comdoc/House%20Corporations%202024/03-14-2024--H7231--US%20Dept%20of%20Health%20Human%20Services%20-%20Dr.%20Brett%20Giroir.pdf>.

<sup>50</sup> See Wallace, *supra* note 41; 21 U.S.C. § 387j(a)(1); 21 U.S.C. § 387(g)(d)(3).

<sup>51</sup> *FDA Regulation of Tobacco Products: Premarket Review Requirements*, AM. CANCER SOC'Y ACTION NETWORK, <https://www.fightcancer.org/sites/default/files/FDA%20Regulation%20of%20Tobacco%20Products%20Premarket%20Review%20FINAL%2010.6.20.pdf> (last visited Apr. 25, 2026).

<sup>52</sup> See *supra* note 44 and accompanying text.

market unless approved as a low-risk harm product.<sup>53</sup> Federal adoption in the U.S. could use a time-limited sponsor requirement narrowly tailored to psychoactive consumer substances with opioid or opioid-like dependence risk, while preserving FDA drug approval and DEA scheduling as ultimate regulatory endpoints.

Existing PCSOD products commercially marketed as of the date of designation may continue under provisional authorization, but unlike the TCA's grandfathering approach, that authorization would be strictly conditional.<sup>54</sup> This approach preserves short-term market stability while ensuring continued participation depends on affirmative approval, rather than regulatory delay.

### 3. Application Process and Deadlines

Like the TCA, the PCSOD should require the Secretary to affirm or deny market entry within 180 days of a complete application.<sup>55</sup> However, to avoid the congestion that plagued tobacco premarket review and ultimately led to de facto authorization, the PCSOD should impose application caps during the provisional period prioritized by market share, deny excess applications, and require all provisional authorizations to expire within 24 months.<sup>56</sup>

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<sup>53</sup> *Id.*; *Psychoactive Substances Act*, MINISTRY OF HEALTH (July 3, 2024), <https://www.health.govt.nz/regulation-legislation/psychoactive-substances/psychoactive-substances-act>. New Zealand's model is also instructive for its failures, as its primary failure was a moratorium on processing applications for product approvals, ultimately freezing the market.

<sup>54</sup> 21 U.S.C. § 387j(a)(2)(B).

<sup>55</sup> *See* 21 U.S.C. § 387j(c)(1)(A).

<sup>56</sup> 21 U.S.C. § 387j. In 2020, the FDA received nearly 7 million premarket tobacco applications and failed to complete review within the allotted one year, leaving over 53,000 products on the market pending review. *See* OFF. OF INSPECTOR GEN., A-06-22-01002, THE FOOD AND DRUG ADMINISTRATION NEEDS TO IMPROVE THE PREMARKET TOBACCO

The PCSOD should adopt the TCA's application requirements, including health risk investigations, dependence and withdrawal profiles, substitution risk, ingredient and concentration disclosures, and manufacturing standards.<sup>57</sup> These requirements are well-suited to kratom products, where labeling is unreliable, key pharmacological risks remain undeveloped, and production is often inconsistent and contaminated.<sup>58</sup> Adopting these baseline disclosures would help bring a largely opaque market into a uniform and supportive environment for informed use.<sup>59</sup>

A PCSOD substance would be exempt from this subchapter only if (1) the Secretary approves the substance as a new drug under 21 U.S.C. § 355; (2) Congress enacts explicit legislation authorizing the substance's continued consumer market sale under defined conditions; or (3) the substance is scheduled under the CSA.<sup>60</sup> This exit mechanism would ensure the PCSOD operates as a transitional regulatory category rather than a permanent classification while requiring eventual resolution.

#### 4. Tiered Evidentiary Standard

Unlike the TCA's uniform authorization standard across tobacco products,<sup>61</sup> the PCSOD should adopt a tiered standard based on potency and product type to reflect the risk gradient between natural kratom leaf and 7-

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APPLICATION REVIEW PROCESS FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS TO PROTECT PUBLIC HEALTH, (2023).

<sup>57</sup> 21 U.S.C. § 387j(b)(1)(A)-(G).

<sup>58</sup> See generally *FDA Takes Steps*, *supra* note 25 (warning that concentrated 7-OH products may not be clearly labeled regarding their content); White, *supra* note 28 and accompanying text.

<sup>59</sup> Peter Grinspoon, *Kratom: Fear-worthy foliage or beneficial botanical?* HARV. HEALTH PUBL'G. (Sep. 9, 2024), <https://www.health.harvard.edu/blog/kratom-fear-worthy-foliage-or-beneficial-botanical-201908071936>.

<sup>60</sup> 21 U.S.C. § 812.

<sup>61</sup> 21 U.S.C. § 387e(j).



OH.<sup>62</sup> A federal standard aligned with state-level precedent would likely be more resistant to industry challenge than a uniform one applied across the full PCSOD product spectrum.<sup>63</sup>

Thus, synthetic or higher-potency PCSOD products would carry a heightened evidentiary burden. These products would not be authorized absent a finding that they do not produce opioid-like dependence or harm at proposed concentrations. This approach would ensure the most dangerous products face the strictest scrutiny and would curb the availability of substances most likely to drive dependence and harm.<sup>64</sup> Consistent with this heightened risk profile, the PCSOD should expand the TCA's suspension authority.<sup>65</sup> The TCA permits suspension only after a finding of "reasonable probability" of serious harm exceeding that of comparable products, and requires an informal hearing.<sup>66</sup> The PCSOD would instead permit immediate suspension upon a finding of acute withdrawal risk or probable illicit substitution. This departure reflects the heightened urgency and risks specific to opioid-like substances.

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<sup>62</sup> See Reissig et al., *supra* note 28.

<sup>63</sup> *FDA Takes Steps*, *supra* note 25; *Kratom: Summary of State Laws*, *supra* note 1 (43 states allow natural kratom in some form, while only 6 ban it); See generally JAMES T. O'REILLY & KATHARINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION 1 FOOD AND DRUG ADMIN. § 10:87 (2025-1) (4th ed. Nov. 2025 update) (Westlaw) (noting that, in the NDI context, courts are more likely to uphold FDA guidance against commercial speech challenges when grounded in express congressional delegation and defined categories).

<sup>64</sup> See generally Reissig et al., *supra* note 28, at 3 (finding that 7-OH is a potent opioid agonist with significant potential for abuse and harm).

<sup>65</sup> 21 U.S.C. § 387j(d)(3).

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

## 5. Anti-Evasion Provisions

To prevent manufacturer circumvention, the PCSOD should also include an anti-evasion provision modeled on 21 U.S.C. § 813(c).<sup>67</sup> Labeling or marketing disclaimers including “not for human consumption” would not control where objective evidence indicates intended human use,<sup>68</sup> including where the Secretary finds that (1) the substance is chemically capable of producing such effects when consumed by humans; (2) the substance is distributed through retail channels in which consumer purchase for personal use is the primary commercial purpose; or (3) the substance is marketed, packaged, or presented in a manner consistent with consumer use, including through flavoring, youth marketing appeals, such as the use of bright colors, mimicking novelty food items, or consumer facing retail display, notwithstanding any contrary label.<sup>69</sup>

A regulatory structure capable of overseeing consumer substances that pose opioid-like dependency risks is the appropriate response to a foreseeable and escalating public health problem, rather than the familiar cycle of forced tolerance followed by prohibition.

## IV. ANTICIPATED OBJECTIONS AND RESPONSES

The PCSOD framework will likely face objections from kratom advocates and those concerned with harm reduction and regulatory overreach. First, critics may argue that the scheduling 7-OH is sufficient and enacting additional legislation is burdensome. However, scheduling alone removes a

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<sup>67</sup> 21 U.S.C. § 813(c).

<sup>68</sup> 21 U.S.C. § 813(c).

<sup>69</sup> 21 U.S.C. § 813(b)(4); 21 U.S.C. § 802(48); 21 U.S.C. § 813(b)(1).

single product while leaving an unregulated supply chain intact.<sup>70</sup> Because kratom's products are easily reformulated and remarketed, this replacement cycle would likely repeat itself at the compound level under a scheduling-only approach.<sup>71</sup>

Relatedly, state-level efforts reinforce this limitation.<sup>72</sup> Existing bans show high rates of noncompliance, in part because regulators lack rudimentary market knowledge of what products exist, who manufactures them, at what concentrations, and through what distribution channels.<sup>73</sup> Federal scheduling would likely replicate these deficiencies by imposing prohibition without the necessary foundation to enforce it in an evolving market.<sup>74</sup> Further, cannabis illustrates how Schedule I status does not mean governability once widespread normalization and demand are established.<sup>75</sup> Kratom is earlier on that normalization curve, which supports the need to intervene now with a conditional, market-level framework rather than waiting for its dependency to become entrenched and then attempting to eject it through scheduling.

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<sup>70</sup> See JOANNE LAMPE ET AL., CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): FOR THE 119TH CONGRESS (2025) (noting that when states legalize or decriminalize a federally controlled substance, the legal change is the removal of state prohibition, while federal enforcement authority potentially may be utilized).

<sup>71</sup> See Reuter & Pardo, *supra* note 6.

<sup>72</sup> Teresa Perry & Sayorn Chin, *The Unregulated Rise of Kratom Drinks: Emerging Challenges and Policy Recommendations*, PUB. HEALTH REPS., 1, 3 (2025).

<sup>73</sup> *Id.*; FDA and Kratom, *supra* note 4.

<sup>74</sup> Perry & Chin, *supra* note 72 (suggesting noncompliance may stem from the absence of a preregistration process); See generally, Smith et al., *supra* note 8 (describing the proliferation of synthetic 7-OH products); See generally Reuter & Pardo, *supra* note 6.

<sup>75</sup> See *Drug Scheduling*, U.S. DRUG ENF'T AUTH., <https://www.dea.gov/drug-information/drug-scheduling> (last visited Feb. 10, 2026); *Marijuana Legality Map*, DISA, <https://disa.com/marijuana-legality-by-state/> (last updated Feb. 3, 2026); 21 U.S.C. § 903 (expressly disclaims field preemption, allowing federal prohibition to coexist with divergent state regimes).

Second, critics may contend that the PCSOD would function as a de facto ban on kratom products, endangering harm reduction and opioid recovery.<sup>76</sup> Advocates argue that kratom and 7-OH have higher success rates of long-term opioid abstinence than FDA-approved treatments, citing wider access, affordability, and lower social stigma.<sup>77</sup> Relatedly, critics argue that restricting 7-OH will drive dependent users toward illicit markets.<sup>78</sup> These concerns are serious but mischaracterize both the market's nature as a recovery pathway and the PCSOD's goals.

The current market is not a stable recovery mechanism. It markedly reflects the characteristics of illicit supply; kratom products are systematically mislabeled, manufacturing is not standardized, and evidence reveals that such synthetics can be as addictive as opioids.<sup>79</sup> The need for more affordable, accessible FDA-approved treatment for opioid addiction cannot be overstated. However, an unregulated market that induces opioid-like dependency under the guise of harm reduction while simultaneously creating new addiction pathways is antithetical to recovery and presents an independent public health risk. Further, the PCSOD is a transitional

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<sup>76</sup> See *supra* p. 9.

<sup>77</sup> Geoffrey Lawrence, *What is 7-OH and Why Did the FDA Seize This Potentially Life-Saving Substance*, REASON FOUND (Dec. 31, 2025), <https://reason.org/commentary/what-is-7-oh-and-why-did-the-fda-seize-this-potentially-life-saving-substance/>.

<sup>78</sup> Claims that synthetic kratom-derived products constitute an “international cartel poisoning Americans” correctly identifies misconduct by certain actors, but it mischaracterizes the regulatory failure at issue. See *The Fourth Wave of the Opioid Epidemic is Here, STOP GAS STATION HEROIN*, <https://stopgasstationheroin.com/> (last visited Feb 11, 2026); See Letter from Jeffrey Singer, Senior Fellow, Dept. of Health Pol’y Studies to the Joint Comm. on Pub. Health (Sep. 10, 2025), <https://www.cato.org/sites/cato.org/files/2025-09/Written%20Testimony%20for%20MA%20Joint%20Committee%20on%20Public%20Health%20%28S.%201609%29%20.pdf>.

<sup>79</sup> *Kratom: Unsafe and Ineffective*, MAYO CLINIC (June 18, 2024), <https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/kratom/art-20402171>; See Watford, *supra* note 5.

framework that aims to bring an unregulated market towards greater uniformity when PCSOD substances occupy a regulatory gray area.

The concern for black markets, cross-border leakage, and illicit substitution are legitimate risks, but are materially worse in the current regulatory gray area.<sup>80</sup> The PCSOD aims to improve the status quo by stabilizing access to lower-risk products while removing the most dangerous ones.<sup>81</sup> A framework that accounts for proactive enforcement is better at serving harm-reduction goals than a market that lacks product controls, manufacturer registries, or potency standards.

#### CONCLUSION

Federal drug law was designed for a prior era and lacks the tools to address consumer products that pose an opioid dependency risk. An affirmative authorization framework, such as the PCSOD, that incorporates a pharmacological trigger resistant to labeling evasion and potency standards that limit escalation incentives would address this gap. Congress has demonstrated the capacity to create a tailored regulatory regime under which the FDA has authority. Such a framework should be implemented before kratom's harms become irreversible.

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<sup>80</sup> See Grinspoon, *supra* note 59.

<sup>81</sup> See *supra* p. 13.

# From Physician-Centered Care to Interdisciplinary Care: How Federal Student Loan Reclassification Will Setback Health Care Evolution

Maria Wright

## INTRODUCTION

As the United States health care system developed into modern-day medicine, the model of care evolved from a physician-focused system of care to an interdisciplinary, patient-centered system of care.<sup>1</sup> This transition led to better patient outcomes, improved care efficiency, and comprehensive care.<sup>2</sup> However, the benefits of interdisciplinary care may soon be gone. Under President Trump's *One Big Beautiful Bill Act*, the Trump Administration established new federal loan limits for graduate students beginning on July 1, 2026.<sup>3</sup> These federal loan limits will reduce the maximum amount of graduate loans certain aspiring health professionals may borrow from \$200,000 to \$100,000 based on the reclassification of

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<sup>1</sup> LINDA McCAULEY ET AL., IMPLEMENTING HIGH-QUALITY PRIMARY CARE: REBUILDING THE FOUNDATION OF HEALTH CARE 71-73 (2021); Mary Ifner Dobbins et al., *Integrated Care and the Evolution of the Multidisciplinary Team*, 43 PRIMARY CARE: CLINICS IN OFF. PRAC. 177, 178-80 (June 2016).

<sup>2</sup> Ruttanaporn Kongkar et al., *The Impact of Interdisciplinary Team-Based Care on the Care and Outcomes of Chronically Ill Patients: A Systematic Review*, 18 J. MULTIDISCIPLINARY HEALTHCARE 445, 453-54 (Jan. 2025) (discussing how interdisciplinary team-based care can lead to better outcomes for chronically ill patients, such as improvements in blood pressure and reduced risks of complications); *Benefits of Interdisciplinary Teams in Healthcare*, BELLA VISTA HEALTH CTR., <https://www.bellavistahealth.com/blog/interdisciplinary-teams-in-healthcare> (last visited Feb. 8, 2026) (explaining that interdisciplinary care can reduce medical errors, supply faster treatment, and reduce length of hospital stays); Moayed Hussain Alhayder, *Enhancing Interdisciplinary Care Coordination and Communication in Psychiatry, Nursing, Surgical Nursing, Internal Medicine, Physical Therapy, Laboratory Services., Pharmacy, and Health Informatics: A Comprehensive Approach to Improving Patient Outcomes*, 29 J. OF POPULATION THERAPEUTICS & CLINICAL PHARMACOLOGY 3364, 3369 (2022) (stating “[i]nterdisciplinary care coordination also helps to ensure that patients receive holistic care that takes into account their physical, emotional, and social needs.”).

<sup>3</sup> ALEXANDRA HEGJI, CONG. RSCH. SERV., R48768, THE DEPARTMENT OF EDUCATION’S PROPOSED RULE TO DEFINE “PROFESSIONAL STUDENT”: FREQUENTLY ASKED QUESTIONS 5 (2026) (graduate loans are subject to change based on the type of degree being pursued).

professional students to graduate students.<sup>4</sup> This article argues that the Department of Education's ("ED") elimination of the recognition of non-physician professional degree status under federal student loan allocation will hinder health care education, delay advancements of health care practices and limit access to high-quality care.<sup>5</sup>

In this article, Parts I and II will explain the evolution of health care from physician-centered care to interdisciplinary care.<sup>6</sup> Part III will analyze the professionalization of non-physician health care workers and the role that student loans played in facilitating that process.<sup>7</sup> Parts IV and V will examine the ED's proposed change to federal graduate student loan limits and the impacts it may have.<sup>8</sup> Part VI will propose the rescinding of this rule by the ED, and in the alternative, provide strategies to protect non-physician graduate students' access to federal loans, including APA litigation challenging the rule as arbitrary and capricious, congressional legislation defining "professional degree" to include all state-licensed health care programs, state-funded loan repayment assistance for non-physician professionals in underserved areas, employer-sponsored tuition assistance programs, and scholarship development by professional medical associations.

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<sup>4</sup> Jessica Blake, *How the Loan Cap Committee Reached Consensus*, INSIDE HIGHER ED (Nov. 10, 2025), <https://www.insidehighered.com/news/government/student-aid-policy/2025/11/10/how-committee-reached-consensus-loan-caps>.

<sup>5</sup> Letter from Stacey Hughes, Exec. Vice President Gov't Rels. and Pub. Pol'y, Am. Hosp. Ass'n, to Sec'y Nicholas Kent, U.S. Dep't of Educ. (Dec. 22, 2025).

<sup>6</sup> Part II, "Traditional Physician-Centered Health Care Model," at 2; Part III, "The Interdisciplinary Evolution of the Health Care System," at 3.

<sup>7</sup> Part IV, "Professionalization of Non-Physician Health Care Workers," at 5.

<sup>8</sup> Part V, "The Federal Loan Reclassification of Health Care Professionals," at 7; Part VI, "The Dissolving of Diversity by the Actions by the Trump Administration," at 8.

## I. TRADITIONAL PHYSICIAN-CENTERED HEALTH CARE MODEL

In the early 20th century, before health care technology and systems evolved, health models primarily relied on single physicians to provide all aspects of health care to their patients.<sup>9</sup> In these early health care models, specifically in rural areas, one physician would serve an entire community.<sup>10</sup> By contrast, physicians in urban areas took on even more responsibility, often acting as both physicians and public health officers by assuming the duty of regulating their community's health and treating patients.<sup>11</sup> Since health care was primarily delivered by single physicians, there was no need for specialization; rather, physicians acted as generalists, treating a wide range of issues their patients experienced.<sup>12</sup>

The initial focus on physician-centered care was driven by the early practices of medicine.<sup>13</sup> Before the establishment of medical schools, people typically became physicians through apprenticeship.<sup>14</sup> This was evident in the early 19th century, as physicians often provided unregulated care to

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<sup>9</sup> George B. Mosley, *The U.S. Health Care Non-System, 1908-2008*, 10 AMA J. ETHICS 324 (2008) (finding that in the early 20th century, “[m]edical science and technology were primitive, and there was little that physicians could do to treat most illnesses.”); see MCCAULEY ET AL., *supra* note 1, at 71 (stating “[f]or the first two-thirds of the 20th century, the lone general practitioner served as the face of primary care in the United States.”).

<sup>10</sup> *Early Rural Practitioners*, UNIV. NEB. MED. CTR., <https://exhibits.unmc.edu/whc/RuralPractitioners> (last visited Feb. 9, 2026) (describing that in the early 1900s, as new towns were being built, many physicians were the only ones within 100 miles, making them responsible for taking care of hundreds of patients).

<sup>11</sup> See Lauren Hoehn-Velasco & Elizabeth Wrigley-Field, *City Health Departments, Public Health Expenditures, and Urban Mortality over 1910-1940*, 60 ECON. INQUIRY 929, 931-32 (2021) (stating in the early 20th century, full-time physicians consistently headed health departments meaning they played both a managerial and practical role in their communities).

<sup>12</sup> NIKITAS J. ZERVANOS, *THE HISTORY OF GENERAL PRACTICE IN AMERICA, HOW THE GENERALIST BECAME A SPECIALIST* 82 (2019).

<sup>13</sup> Monya De, *Towards Defining Paternalism in Medicine*, 6 AMA J. ETHICS 69, 69 (2004).

<sup>14</sup> *Medical Education in the 19th Century*, NAT'L. MUSEUM OF CIV. WAR MED. (Dec. 18, 2023), <https://www.civilwarmed.org/medical-education-in-the-19th-century/>.



patients.<sup>15</sup> The primary reason the physician-centered model was accepted during this time was because there was no technological innovation or significant growth in medical infrastructure, limiting the options consumers had in deciding the care they wanted.<sup>16</sup>

## II. THE INTERDISCIPLINARY EVOLUTION OF THE HEALTH CARE SYSTEM

During World War II, health care delivery slowly shifted from adhering to the traditional physician-centered care to interdisciplinary team care and community health centers aimed to help underprivileged people.<sup>17</sup> Around the same time, specializations became more popular due to the growth of technology and hospital infrastructure.<sup>18</sup> After World War II, rapid advances in medical science and technology led to a growth in medical knowledge and an opening for non-physician specialties such as social psychology, sociology, and anthropology in the health care space.<sup>19</sup>

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<sup>15</sup> David Johnson & Humayun J. Chaudhry, *The History of the Federation of State Medical Boards: Part One – 19th Century Origins of FSMB and Modern Medical Regulation*, 98 J. MED. REGUL. 20, 21 (stating “[a]s the governmental basis behind medical regulation disappeared in most states in the second quarter of the 19th century, many physicians simply pursued their vocation as best they could and were generally free to ply their trade in whatever fashion they chose.”).

<sup>16</sup> See Mosley, *supra* note 9, at 324 (describing the early stages of medicine before innovation).

<sup>17</sup> DeWitt C. Baldwin Jr., *Some Historical Notes on Interdisciplinary and Interprofessional Education and Practice in Health Care in the USA*, 10 J. INTERPROFESSIONAL CARE 24, 24 (1996).

<sup>18</sup> Jeffrey Bendix, *A Century of Primary Care Transformation*, MED. ECONS. (Sep. 28, 2023), <https://www.medicaleconomics.com/view/rise-of-the-specialists> (print pagination unavailable).

<sup>19</sup> ROSE ANN PARRISH & SONYA OPPENHEIMER, DEVELOPMENTAL-BEHAVIORAL PEDIATRICS 203 (Mark L. Wolraich et al. eds., 2008); see also Kelley Piechowicz, *A Brief History of the PA Profession*, GOODRX (Apr. 8, 2022), <https://www.goodrx.com/hcp-articles/students/history-pa-profession> (finding that “[i]n the post-WWII era, the U.S. faced a shortage of primary care physicians, especially in rural areas. The PA role was created to fill that gap in healthcare.”).

Additionally, advances in medicine and the emergence of medical specialties enabled the healthcare system to address more complex health issues, thus necessitating interdisciplinary teams to help manage these conditions.<sup>20</sup> For example, in the late 20th century, the prevalence of serious chronic illnesses in the U.S. shifted the focus of health care from preventing death and the spread of infectious disease to finding treatments and cures for chronic illnesses, such as heart disease, diabetes, and cancer.<sup>21</sup> This shift amplified the need for interdisciplinary teams.<sup>22</sup>

A growing hospital system increased physicians' need for additional support.<sup>23</sup> Unlike the traditional physician-centered model, in which physicians traveled to their patients, health care advances have led hospitals to become the central care sites for patients.<sup>24</sup> Thus, as more patients sought hospital care, there was a need for additional health care workers, such as nurses, lab technicians, and other support staff.<sup>25</sup>

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<sup>20</sup> Helena Temkin-Greener, *Interprofessional Perspectives on Teamwork in Health Care: A Case Study*, 61 MILBANK MEM'L FUND Q. HEALTH SOC'Y 641, 642 (1983) (stating "[i]t has been argued that advances in medical knowledge and technology, the increasing number of subspecialties among health care providers, manpower shortages in some of the highly trained professions, and the broadening concepts of health and illness have all served as an impetus to the development of the interprofessional team approach.").

<sup>21</sup> *Chronic Diseases: A 21st Century Public Health Challenge*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/museum/online/story-of-cdc/chronic/index.html> (last visited Feb. 9, 2026).

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

<sup>23</sup> See, e.g., Pat Fobair, *Historical Threads in the Development of Oncology Social Work*, 27 J. PSYCHOSOCIAL ONCOLOGY 1, 2-4 (2010) (describing the growth of hospitals in the twentieth century to meet the growing need for organized health care, and noting that between 1905 and 1915, social workers were hired in more than 100 hospitals throughout America to assist physicians in patient care.).

<sup>24</sup> Micheal O'Dell & Lynette M. Wheeler, *Home Health Care: Healing Where the Heart Is*, 109 MO. MED. 439, 440 (2012).

<sup>25</sup> See Jean C. Whelan, *American Nursing: An Introduction to the Past*, PENN NURSING, <https://www.nursing.upenn.edu/nhhc/american-nursing-an-introduction-to-the-past> (last visited Feb. 9, 2026) (stating how "[h]ospitals began to proliferate to serve those who were without the resources to provide their own care, and as hospitals increased in numbers so did the demand for caregivers who would be able to deliver thoughtful care to the patients in

### III. PROFESSIONALIZATION OF NON-PHYSICIAN HEALTH CARE WORKERS

The need for interdisciplinary teams created the opportunity for non-physician health care workers to expand their practices.<sup>26</sup> For example, in 1965 Duke University established the first physician assistant program; students who completed the program were eventually recognized as health professionals by the American Medical Association through national certification in 1971.<sup>27</sup> Today, physician assistants play an important role in mitigating the shortage of physicians.<sup>28</sup>

In order to allow individuals to pursue careers as physician assistants, access to professionalization via education became accessible through federal student loans, with many health professions receiving comparable funding.<sup>29</sup> Professionalization is “[t]he action or process of giving an occupation, activity, or group professional qualities, typically by increasing training or raising required qualifications.”<sup>30</sup> Thus it can be understood that the U.S. began supporting professionalization when the first federal student loans were provided under the National Defense Education Act of 1958,

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them.”); Angela Tomei Robinson, *Pathology – The Beginnings of Laboratory Medicine: Second in a Series*, 54 LAB’Y MED. e141, e143 (2023) (finding that by the Roaring 20s, laboratory medicine began becoming highly incorporated in hospitals).

<sup>26</sup> NAT’L ACAD. OF MED. NATIONS, TRANSFORMING HUMAN HEALTH: CELEBRATING 50 YEARS OF DISCOVERY AND PROGRESS 105 (Keith Yamamoto et al., eds., 2022).

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

<sup>28</sup> See James F. Cawley & Roderick S. Hooker, *Physician Assistants in American Medicine: The Half-Century Mark*, 19 AM. J. MANAGED CARE e333, e333 (2013) (estimating that by 2025, physician assistants would play a critical role in addressing care gaps that physicians could not fill).

<sup>29</sup> Jason Cohn, *How New Federal Student Loan Limits Could Affect Borrowers*, URBAN WIRE (July 24, 2025), <https://www.urban.org/urban-wire/how-new-federal-student-loan-limits-could-affect-borrowers> (describing that “[c]urrently, the Grad PLUS loan program allows graduate students to borrow up to their full cost of attendance.”).

<sup>30</sup> *Professionalisation*, PEOPLE THAT DELIVER, <https://www.peopletthatdeliver.org/professionalisation> (last visited Mar. 8, 2026).

allowing individuals to increase their skills via education and training.<sup>31</sup> The loan program was restructured in 1965 through the Federal Family Education Loan program.<sup>32</sup> At the time, the U.S. government stated that the goal of giving these loans was to develop a strong workforce, especially in the fields that needed training for national security purposes such as science and medicine.<sup>33</sup>

Similar to other careers, professional status for the non-physician health professions were developed by degree structure and licensure requirements.<sup>34</sup> For example, nursing established professionalization through formal degree programs that standardized education within bachelor's and graduate degrees.<sup>35</sup> These formal degree requirements are often seen as an indicator of a professional's competence.<sup>36</sup> By requiring professionalization through accredited programs, licensed professionals are distinguishable from those

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<sup>31</sup> *Why Did the Federal Government Get Involved in Student Loans?*, PETER G. PETERSON FOUND., <https://www.pgpf.org/article/why-did-the-federal-government-get-involved-in-student-loans> (last visited Feb. 9, 2026).

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

<sup>33</sup> *National Defense Education Act*, U.S. HOUSE: HISTORY, ART & ARCHIVES, <https://history.house.gov/HouseRecord/Detail/15032436195> (last visited Feb. 9, 2026).

<sup>34</sup> COMM. ON THE HEALTH PROS. EDUC. SUMMIT, *HEALTH PROFESSIONS EDUCATION: A BRIDGE TO QUALITY* 98 (Ann C. Greiner & Elisa Knebel, eds., 2003).

<sup>35</sup> Laura Gonzalez, *Healthcare Innovation: The Evolution of Nursing Education*, SENTINEL U, <https://www.sentinelu.com/knowledge-center/published-works/healthcare-innovation-evolution-nursing-education> (last visited Feb. 9, 2026) (finding that the Nurse Training Act in 1964 pushed for nursing education to be attained from a university program, instead of a hospital program).

<sup>36</sup> See Folorunso Obayemi Temitope Obasuyi, *Signalling Theory, Education Policy and Labour Market Efficiency: A Review of Prof. Garry Becker*, 9 INT'L J. RSCH. & INNOVATION SOC. SCI. 8134, 8135 (2025) (stating that “[s]ignalling theory posits that education serves as a signal to employers about an individual’s productivity and potential (Becker, 1964). This signal can take the form of a degree, certification, or other credential (García-Aracil & Albert, 2018). Employers use this signal to make inferences about an individual’s ability and potential for job performance.”).

without formal training and show the public who should be deemed a reliable physician.<sup>37</sup>

Stated simply, federal loans allow students to complete higher education and pursue careers that they may not have been able to,<sup>38</sup> as higher education can be financially taxing for young professionals.<sup>39</sup> By increasing accessibility to graduate education through federal loans, students have been empowered to pursue careers in non-physician health care professions such as nursing, physical therapy and other necessary health roles.

#### IV. THE FEDERAL LOAN RECLASSIFICATION OF HEALTH CARE PROFESSIONALS

On July 1, 2026, the ED will implement its final rule determining which degrees qualify as “professional” for federal graduate loan purposes pursuant to the One Big Beautiful Bill Act signed into law by President Trump on July 4, 2025.<sup>40</sup> While the ED has yet to finalize the regulation for the new federal loan definitions of a “professional degree,” language has been released indicating a decrease in students’ access to federal loans for some medical

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<sup>37</sup> *Advocacy of Qualified Exercise Professionals – Why Precise Credentialing Language Matters*, U.S. REGISTRY OF EXERCISE PROS. (Aug. 29, 2025), <https://usreps.org/resources/blog/why-credentialing-language-matters/>.

<sup>38</sup> SANDY BAUM & KELIA WASHINGTON, RETURNING TO SCHOOL: HELPING STUDENTS NAVIGATE DECISIONS ABOUT BORROWING FOR COLLEGE 3 (2020) (explaining how the federal government provides loans regardless of “financial circumstances, credit history, or academic preparation.”).

<sup>39</sup> Ben Unglesbee, *Rising Costs, Student Debt Turn Graduate Degrees into a ‘Risky’ Proposition, Research Finds*, DIVE BRIEF (Sept. 26, 2024), <https://www.highereddive.com/news/rising-costs-student-debt-turn-graduate-degrees-into-a-risky-proposition>.

<sup>40</sup> Reimagining and Improving Student Education, 91 Fed. Reg. 4254, 4254 (Jan. 30, 2026) (to be codified at 34 C.F.R. pts. 674, 682, 685) (summarizing the federal loan cap included in the One Big Beautiful Bill Act).

professions.<sup>41</sup> These professions include nursing, occupational therapists, physician assistants, and physical therapists.<sup>42</sup> This action by the Trump Administration will create a structural disconnect in the health care field.<sup>43</sup> As borrowing limits change for aspiring professionals, it is likely that the length of schooling will remain unchanged and the cost of schooling will increase.<sup>44</sup>

Further, licensure requirements are governed by state-specific laws for different professions across the U.S.<sup>45</sup> Therefore, the reclassification of professional degrees without taking into consideration state licensure requirements may result in the ED failing to comply with the Administrative Procedure Act (“APA”).<sup>46</sup> Under the APA, courts can decide that an agency’s actions are unlawful if they are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”<sup>47</sup> Courts may also act if the

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<sup>41</sup> *Fact Sheet: Federal Student Loan Limits for Graduate and Professional Programs*, AM. HOSP. ASS’N, <https://www.aha.org/2026-02-11-fact-sheet-federal-student-loan-limits-graduate-and-professional-programs> (last visited Feb. 9, 2026).

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

<sup>43</sup> *See, e.g.*, Press Release, SEIU Healthcare Communications Staff, We Will Not Let This Administration Undermine Our Healthcare Professions (Nov. 25, 2025), <https://www.seiu1199nw.org/we-will-not-let-this-administration-undermine-our-healthcare-professions> (expressing that “[b]y stripping graduate nursing and advanced healthcare degrees from the “professional” category, they are limiting loan access, devaluing our education, and undermining the future of our workforce. At a time when our state and our country are still grappling with building the pipeline to meet growing needs, and the lasting trauma of the pandemic, this move shows just how little these leaders think of the skill, dedication, and expertise it takes to provide safe, high-quality care.”).

<sup>44</sup> Letter from Jason M. Goldman, President, Am. College of Physicians, to Tim Walberg & Robert C. Scott, U.S. House, Committee on Education and Workforce. (May 13, 2025) (stating “[t]he average total cost of medical school is \$238,420 or \$59,605 annually, with the average cost increasing by over \$1,200 every year” and how students would have to take out private loans to cover the costs no longer covered by federal loans).

<sup>45</sup> *Professional Licensure*, U.S. DEP’T OF EDUC., <https://www.ed.gov/about/initiatives/international-affairs/professional-licensure> (last visited Feb. 9, 2026).

<sup>46</sup> CONG. RSCH. SERV., R44699, AN INTRODUCTION TO JUDICIAL REVIEW OF FEDERAL AGENCY ACTION 16 (2025).

<sup>47</sup> *Id.*

agency's decisions are "unsupported by substantial evidence."<sup>48</sup> In this case, the actions of the ED seem to disregard that certain states require health professionals to become licensed and accredited through graduate school programs, and yet, the agency is minimizing access to these programs. In ignoring the relevance of state laws, the ED has failed to consider that professional status for health-based graduate students is not solely the ED's decision to make.<sup>49</sup> It is therefore possible that a court could find the ED's decrease of graduate student loan funding unlawful under the APA, striking down the professionalization reclassification as arbitrary and capricious. The agency's failure to account for state licensure requirements, could give way to a court remanding the policy back to the ED for reconsideration, requiring the agency to account for the factors it ignored.

#### V. THE DISSOLVING OF DIVERSITY BY THE ACTIONS OF THE TRUMP ADMINISTRATION

The Trump Administration's lowering of the cap for graduate federal student loans for supportive health professionals increases structural inequities within the health field.<sup>50</sup> Many of the professionals in fields

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

<sup>49</sup> *Scope of Practice*, AM. NURSES ASS'N, <https://www.nursingworld.org/practice-policy/scope-of-practice/> (last visited Mar. 8, 2026) (explaining that Specialty Nursing Scope and Standards of Practice "describe the responsibilities, professional boundaries, and expected competencies of nurses practicing within a recognized specialty," and that all healthcare licensure is state-based, requiring state legislatures to pass nurse practice acts and regulatory bodies to implement corresponding rules and regulations.).

<sup>50</sup> See, e.g., *Trump Administration Plan to Reduce Some Student Loans Angers Nurses, Healthcare Groups*, CNN (Nov. 25, 2025), <https://www.cnn.com/2025/11/25/health/nurse-education-loans-trump> ("[t]he organizations contend that capping federal student loans will make the ongoing nursing shortage even worse, force students to seek more expensive private loans and threaten patient care.").

affected by the new federal loan cap are dominated by women.<sup>51</sup> For example, in 2023, about 88% of registered nurses were female.<sup>52</sup> Additionally, occupational therapy is female-dominant, with 86% of practitioners being female.<sup>53</sup>

Federal loans also often enable low-income and minority students to pursue graduate degrees in health professions.<sup>54</sup> While reductions in loan access would affect graduate students broadly, these cuts would fall disproportionately on those from low-income and Black and Hispanic backgrounds, who often lack the financial safety nets that their well-off peers can rely on.<sup>55</sup> The racial disparity is reflected in borrowing data: approximately 19% of African Americans who received a master's degree finished graduate school without borrowing money, and 16% borrowed \$75,000 or more; 43% of white master's degree students did not borrow student loans, and 7% borrowed \$75,000 or more; and 27% of Hispanic master's students avoided borrowing student loans, while 13% borrowed

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<sup>51</sup> Sean Smith & Andrew Blank, *Healthcare Occupations: Characteristics of the Employed*, U.S. DEP'T. OF LAB. (June 2023), <https://www.bls.gov/spotlight/2023/healthcare-occupations-in-2022> (finding that “[a]bout 8 in 10 of all healthcare workers are women.”).

<sup>52</sup> HRSA HEALTH WORKFORCE, STATE OF THE U.S. HEALTH CARE WORKFORCE 9 (2024).

<sup>53</sup> Phil McHugh, *Occupational Therapy Statistics 2025: Workforce, Salaries, and Outcomes*, BEAMING HEALTH (May 29, 2025), <https://beaminghealth.com/article/occupational-therapy-statistics>.

<sup>54</sup> TOMAS MONARREZ ET AL., STUDENT LOANS FOR GRADUATE SCHOOL: WHO WILL BE AFFECTED BY THE NEW FEDERAL LENDING LIMITS? 9 (2025).

<sup>55</sup> See Melanie Hanson, *Student Loan Debt Statistics*, EDUC. INITIATIVE, <https://educationdata.org/student-loan-debt-statistics> (last updated Feb. 2, 2026) (stating that “61% of graduate students borrow federal loans.”); see SANDY BAUM, STUDENT DEBT: THE UNIQUE CIRCUMSTANCES OF AFRICAN AMERICAN STUDENTS 203-04 (Am. Council Educ. ed., 2024) (containing data showing that Black and Hispanic graduate students borrow more than their white peers); see also Matthew Chingos, *What Do Racial and Ethnic Wealth Gaps Mean for Student Loan Policy?*, URBAN WIRE (Feb. 25, 2019), <https://www.urban.org/urban-wire/what-do-racial-and-ethnic-wealth-gaps-mean-student-loan-policy> (explaining that due to racial and ethnic wealth disparities, students of color have fewer family assets to draw on when financing their graduate education).



\$75,000 or more.<sup>56</sup> Regarding low-income graduate students, “[s]ome observers worry that many borrowers, especially those from more disadvantaged backgrounds, those with a poor or thin prior credit history and those with no available cosigner,” may not be able to obtain a private loan when federal loans are capped.<sup>57</sup> Restricting federal student loans from covering most, if not all, of the costs associated with obtaining health profession graduate degrees will likely decrease diversity throughout the health care profession, as students from these backgrounds already rely on borrowing to finish graduate school, and if there is less money available, some may be deterred from pursuing graduate school altogether.<sup>58</sup>

Furthermore, diversity breeds innovation because people are likely to produce new ideas when they are surrounded by those who do not think similarly to them, and generally, increasing diversity in the medical profession leads to better patient outcomes.<sup>59</sup> Thus, decreasing the amount of federal student loans of graduate health professionals can lead to an

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<sup>56</sup> BAUM, *supra* note 38, at 203-04 (providing data on graduate school loan amounts borrowed by racial group).

<sup>57</sup> Jon Marcus, *Funding Cuts, Shifts in Aid Make College Harder to Afford for Low-Income Families*, U.S. NEWS (Feb. 9, 2026), <https://www.usnews.com/news/national-news/articles/2026-02-09/funding-cuts-shifts-in-aid-make-college-harder-to-afford-for-low-income-families> (finding that 38% of graduate and professional students lack the credit score needed to qualify for a private loan to cover the difference once the new federal borrowing caps take effect).

<sup>58</sup> *Federal Student Loan Changes: Impact on Medical and Dental Education Access for Underrepresented Students*, HEALTHFORCE CTR. AT UCSF (Dec. 2025), <https://healthforce.ucsf.edu/document/federal-loans-fact-sheetpdf>.

<sup>59</sup> See Sylvia Ann Hewlett et al., *How Diversity Can Drive Innovation*, HARV. BUS. IMPACT (Dec. 2013), <https://hbr.org/2013/12/how-diversity-can-drive-innovation> (finding that employees who work in diverse environments are more likely to report that their teams developed innovative ideas and solutions.); Quinn Capers, IV et al., *The Urgent and Ongoing Need for Diversity, Inclusion, and Equity in the Cardiology Workforce in the United States*, 10 J AM. HEART ASS'N 1, 1-2 (2021) (noting that a diverse physician workforce is associated with improved patient outcomes, particularly for minority patients who receive better care when treated by physicians of similar backgrounds.).

increase in adverse medical experiences for patients.<sup>60</sup> Therefore, without diversity, innovation in the medical field may suffer, sending the evolution of healthcare backwards.<sup>61</sup>

## VI. ADDRESSING THE ISSUE OF DE-PROFESSIONALIZATION

To ensure that professionalization continues, federal policy must align with the modern practice of health care. The ED should rescind its plan to reduce federal graduate student loans based on their proposed definition of “professional” degrees. This would create an opening for the ED to create uniformity throughout the health care education system by ensuring that all graduate students pursuing licensure as health care professionals are eligible as “professionals” under federal graduate loan regulations. Thus, establishing that all graduate health care students would be eligible for a maximum of \$200,000 in federal student loans.<sup>62</sup>

The federal government’s reasoning on limiting graduate loans for specific health care professionals is to reduce tuition costs under the belief “that capping student loans will push universities charging higher-than average tuition to look at lowering rates”, however, there was no specification on

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<sup>60</sup> See, e.g., Kayla Henderson, *Proposed Federal Loan Changes Could Impact Colorado Healthcare Workforce*, KKTV 11 (Jan. 14, 2026), <https://www.kktv.com/2026/01/14/proposed-federal-loan-changes-could-impact-colorado-healthcare-workforce> (finding that limiting access to graduate education may lower patients’ access to the amount of providers available to treat them, and how “[e]ducators warn that fewer advanced providers could lead to longer wait times for appointments and more patients turning to emergency rooms for care that could be treated earlier in clinics.”).

<sup>61</sup> Trenell J. Mosley, *Intersectionality and Diversity, Equity, and Inclusion in the Healthcare and Scientific Workforces*, 41 LANCET REG’L HEALTH – AMS. 1, 1-2 (2025).

<sup>62</sup> Press Release, U.S. Dep’t. of Educ., *Myth vs. Fact: The Definition of Pro. Degrees*, (Nov. 24, 2025) <https://www.ed.gov/about/news/press-release/myth-vs-fact-definition-of-professional-degrees> (stating the maximum amount of loan students pursuing “professional” graduate degrees can receive).

what “higher-than average” means.<sup>63</sup> While the Trump Administration may believe that students’ inability to access graduate school due to lack of loans will force universities to lower tuition, this reasoning is faulty.<sup>64</sup> Graduate schools set tuition based on their own institutional characteristics, such as whether they are public or private institutions, the fields of study they offer, and the financial support available to students, not based on how much students can borrow from the government.<sup>65</sup> Experts believe that due to already existing pressures on university budgets, from research funding challenges to the federal government’s goal to limit international enrollment at U.S. institutions, it is “just incredibly optimistic thinking, bordering on fantasy” to believe that schools can gain enough funding to cut their graduate tuition prices in response to the loan caps.<sup>66</sup> Instead, it is likely that schools will have to eliminate programming or keep their prices at a flat rate, while inflation continues to rise.<sup>67</sup>

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<sup>63</sup> Collin Binkley & John Seewer, *Trump Administration Excludes Nursing, Teaching from ‘Professional’ Degree List. Here’s Why*, NBC WASH. (Nov. 25, 2025), <https://www.nbcwashington.com/news/national-international/trump-administration-professional-degree-list-student-loan-limits>.

<sup>64</sup> See Jessica Blake, *New Federal Caps Could Lead Students to Take Out Private Loans, Studies Show*, INSIDE HIGHER ED. (Sep. 11, 2025), <https://www.insidehighered.com/news/government/student-aid-policy/2025/09/11/loan-caps-could-force-students-private-market> (describing how the caps on federal student loans will likely lead push graduate students to take out private loans to afford their education).

<sup>65</sup> See Kevin Brouillard, *Average Tuition Costs for Master’s Degree (2026 Guide)*, SOFI (Feb. 20, 2026), <https://www.sofi.com/learn/content/masters-degree-cost/> (explaining the costs of graduate degree programs); see also Monica Konaté, *From Aspiration to Limitation – The Impact of Graduate Loan Caps*, ACCESSLEX INST. (Sep. 4, 2025), <https://www.accesslex.org/news-tools-and-resources/aspiration-limitation-impact-graduate-loan-caps> (explaining how “[r]estricting federal loans is unlikely to reduce tuition but is certain to reduce access.”).

<sup>66</sup> Josh Moody, *Grad Programs Brace for Loan Caps*, INSIDE HIGHER ED (Dec. 15, 2025), <https://www.insidehighered.com/news/business/academic-programs/2025/12/15/grad-programs-brace-loan-caps>.

<sup>67</sup> Ben Unglesbee, *What Does the End of Grad PLUS Loans Mean for Higher Ed?*, HIGHER ED DIVE (Sept. 22, 2025), <https://www.highereddive.com/news/end-of-grad-plus-loans-impact-higher-ed>.

The problem of ensuring access to loans, however, should not only fall on the ED rescinding their actions. Regardless of whether the ED's final rule takes effect, there are less threatening strategies that may reduce financial barriers to education and protect the non-physician workforce. These strategies include prioritizing litigation, congressional legislation, state action, employer educational assistance programs, and professional association scholarships. Each of these options could allow a pathway to maintain interdisciplinary health care.

First, advocacy organizations representing non-physician professionals should bring cases under the APA to challenge the reclassification of federal graduate loans. As discussed in Part IV, the reclassification rule neglects to consider state licensure requirements, providing a basis for a claim under the APA, in which a court can find the ED's actions to be arbitrary and capricious.<sup>68</sup> A court can choose to vacate the ED's rule if it finds that the creation of the rule was not based on "reasoned decision-making."<sup>69</sup> This argument is promising as it appears that the ED's proposal ignored the existing state professional licensing structures. If an advocacy organization is successful in this challenge, it could stop the implementation of the rule and allow these professionals to access higher loan amounts.

Second, Congress can address this problem through direct legislation that defines the status of a "professional degree" for the purposes of federal graduate loans. Congressional legislation supersedes federal agency

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<sup>68</sup> See *supra* pp. 7-8 (discussing the APA in the context of the Department of Education's reclassification of federal graduate student loans).

<sup>69</sup> See *IV. Review of Agency Decisions*, U.S. CT. APP. NINTH CIR. (2022), [https://cdn.ca9.uscourts.gov/datastore/uploads/guides/stand\\_of\\_review/IV.%20Review%20of%20Agency%20Decisions%202022.htm](https://cdn.ca9.uscourts.gov/datastore/uploads/guides/stand_of_review/IV.%20Review%20of%20Agency%20Decisions%202022.htm) (finding the APA "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts" and "requires agencies to engage in 'reasoned decisionmaking[.]'").

regulations, meaning that a clear statutory definition would override any rule issued by the ED, including the upcoming federal loan cap rule.<sup>70</sup> In the absence of legislation by Congress, administrative agencies are left to their own rulemaking, which allowed the ED to exclude non-physician health care professionals to be excluded from the definition of a “professional degree.”<sup>71</sup> A definition by Congress should state that any graduate program required for state licensure is to be included in the definition of a “professional degree.” This definition would establish that professional status in health care is determined by state licensing boards, not by the ED. This action may require bipartisan support, but there are bipartisan concerns over student loan burdens, suggesting that common ground is likely.<sup>72</sup> Regardless, all legislators should have a significant interest in ensuring that their constituencies will not be negatively affected by the inability of some non-physician graduate students to access federal student loans.<sup>73</sup>

Next, states can and should act to combat the federal policy. More specifically, state legislatures and governors should implement state-funded repayment assistance programs for licensed non-physician health

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<sup>70</sup> KATE R. BOWERS & DANIEL J. SHEFFNER, CONG. RSCH. SERV., R46673, AGENCY RECISSIONS OF LEGISLATIVE RULES 23-25 (2021).

<sup>71</sup> See *U.S. v. Mead Corp.*, 533 U.S. 218, 229 (2001) (holding that agencies may fill statutory gaps with binding authority where Congress would expect them to resolve ambiguity, so long as the agency’s interpretation is reasonable and not arbitrary and capricious).

<sup>72</sup> Even without accounting for the barriers non-physician medical students may soon experience in accessing graduate school financing, people across political parties find repaying their student loans to be difficult. See Sarah Sattelmeyer & Rich Williams, *Americans Support Federal Action to Make Student Loan Repayment Easier*, PEW (Oct. 14, 2019), <https://www.pew.org/en/research-and-analysis/articles/2019/10/14/americans-support-federal-action-to-make-student-loan-repayment-easier> (finding that 91% of Democrats and 69% of Republicans want the government to make it easier for borrowers to repay student loans).

<sup>73</sup> See CNN, *supra* note 50 (stating how there is a concern that the proposed student loan caps will increase the already present nursing shortage).

professionals. To make this implementation broadly appealing, even to those hesitant to allocate taxpayer money, repayment assistance should only be provided to non-physician health workers who practice in underserved areas for at least three years. Many states already offer similar loan repayment programs for physicians, so extending this type of program to nurses, physician assistants, occupational therapists, and physical therapists should help offset some of the expenses attributed to the federal loan cap.<sup>74</sup>

Fourth, health systems have an incentive to subsidize the educational costs of the professionals in their workforce because professional shortages pose a direct threat to hospital operations.<sup>75</sup> Creating employer-sponsored tuition assistance for professions affected by the federal graduate loan cap may allow health systems to recruit and retain talent while these students are still in school. Additionally, tuition assistance packages could allow students who lack the financial means to cover their first year of professional school to secure the support necessary to continue their education. Health systems that rely on the interdisciplinary model of care have an obligation to their patients and employees, as well as a business interest, to ensure that the next generation of non-physician professionals can afford to enter the field of medicine.

Finally, accredited professional associations such as the American Association of Nurse Practitioners and the American Occupational Therapy

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<sup>74</sup> See, e.g., *State Loan Repayment Program (SLRP) and Maryland Loan Assistance Repayment Program for Physicians (MLARP)*, MD. HIGHER EDUC. COMM'N, [https://mhec.maryland.gov/preparing/Pages/FinancialAid/ProgramDescriptions/prog\\_mlarp.aspx](https://mhec.maryland.gov/preparing/Pages/FinancialAid/ProgramDescriptions/prog_mlarp.aspx) (last visited Mar. 8, 2026) (describing two loan repayment programs that help Maryland licensed physicians and physicians' assistants repay educational loans).

<sup>75</sup> See, e.g., Lisa M. Haddad et al., *Nursing Shortage*, STATPEARLS PUBL'G (last updated Feb. 13, 2023) (finding that "[n]ursing shortages lead to errors, increased morbidity, and mortality.").

Association, should develop more scholarship and fellowship opportunities for students from marginalized backgrounds. These organizations can use scholarships to support students before they begin their educational studies and take on considerable debt, or before students decide not to apply to graduate school altogether. Professional associations are easily accessible via the internet, and through organization, event coordination, and scheduling they can provide resources to help students fill the gap between the reduced federal loan amount and the full cost of their programs.

These solutions still present challenges. The APA litigation may be time-consuming and expensive, and legislation based on bipartisan cooperation may be difficult in today's political climate.<sup>76</sup> Additionally, employer-based programs may favor well-connected and financially stable institutions, as smaller organizations with limited budgets are less likely to offer tuition assistance.<sup>77</sup> Furthermore, professional association scholarships cannot fully replace federal loan access and the cost of graduate school for many students.<sup>78</sup> Despite these limitations, combining these solutions will increase

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<sup>76</sup> See Susan Smith et al., *2024 Litigation Look Ahead Series: Challenges to Administrative Law Judges, Judicial Review Process Could Limit Executive Power*, BEVERIDGE & DIAMOND (Feb. 27, 2024), <https://www.bdlaw.com/publications/2024-litigation-look-ahead-series-challenges-to-administrative-law-judges-judicial-review-process-could-limit-executive-power/> (finding that enforcement actions are “a more time-consuming, resource-intensive, and costly process.”); see Cynthia R. Farina, *Congressional Polarization: Terminal Constitutional Dysfunction?*, 115 Colum. L. Rev. 1689, 1701 (2015) (finding steadily increasing distance between Republican and Democratic caucuses).

<sup>77</sup> See *Guide to Tuition Reimbursement and Education Benefits*, STAN., <https://online.stanford.edu/guide-tuition-reimbursement-and-education-benefits> (last visited Apr. 24, 2026) (explaining how smaller organizations may lack the financial capacity to offer tuition reimbursement, and some have yet to establish this opportunity at all).

<sup>78</sup> See Sravani Atluri, *How to Find Free Money for Graduate School as Federal Loans Tighten in 2026*, KIPLINGER (Feb. 23, 2026), <https://www.kiplinger.com/personal-finance/college/how-to-find-free-money-for-graduate-school-as-federal-loans-tighten> (stating “competition for scholarships will intensify as borrowing caps push more students toward non-loan funding.”).

the number of students who can gain access to the financial support they need.

These solutions also support low-income and minority students in pursuing professional degrees in various health professions. Under the current Trump Administration, ensuring this access may face political hurdles, as recent initiatives perceived as advancing diversity, equity, and inclusion (“DEI”) have faced opposition.<sup>79</sup> To ensure continued access to health professional graduate schools for students and quality treatment for patients, legislators, accredited organizations, health systems, and states must rally voters against the cap on loans, which can, in turn, promote diversity in the medical field by providing financial access to pursue professional education. This will be especially true if these individuals and entities create diversity-specific financial support, such as diversity scholarships, for those pursuing affected health specialties.

While it would be ideal for the ED to rescind its final rule<sup>80</sup> on the federal graduate loan cap, other entities and individuals must provide support to affected healthcare students to solidify the message that access to education is imperative to our healthcare system. The success of our healthcare system is based on our ability to provide interdisciplinary care, and without the ability for those to become non-physician professionals through federal graduate loans, the healthcare system regresses, toward a time where

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<sup>79</sup> *Trump’s Executive Orders on Diversity, Equity, and Inclusion, Explained*, THE LEADERSHIP CONF. ON CIV. AND HUM. RTS. (Feb. 12, 2025), <https://civilrights.org/resource/anti-deia-eos/> (showing how the Trump Administration has made it clear that they are against promoting DEI initiatives).

<sup>80</sup> BOWERS, *supra* note 70, at 10 (stating that an agency cannot simply undo a final rule; rather, rescission requires a rulemaking process under the APA through which the agency may retain, amend, or eliminate provisions of the previous rule).



physicians were prioritized, rather than where all healthcare workers are seen as professional.<sup>81</sup>

#### CONCLUSION

The health care field has moved from a physician-centered system to an interdisciplinary system.<sup>82</sup> Actions by the Trump Administration's ED, however, look to alter federal graduate loans, an action that could possibly revert the U.S. health care system to the time before the professionalization of non-physician health professionals. The federal graduate loan cap that is to take effect on July 1, 2026, will likely have dire effects on the health care system, including reducing the workforce, blocking individuals from going to school, and diminishing medical innovation.<sup>83</sup>

To benefit all patients, physician-centered care is not enough, and access to interdisciplinary teams must continue to be available. The ED should stop its action to reduce the amount of graduate federal loans available for certain medical professions, because federal loan policy is not something that merely pays for graduate education, but it also affects the way that health care is delivered. If the ED does not make this move, states, health systems, Congress, professional associations, and the courts have a duty to ensure that the next generation of nurses, physician assistants, occupational therapists, and physical therapists can still pursue their career aspirations. The

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<sup>81</sup> AM. HOSP. ASS'N, *supra* note 41 (stating that “[h]ealth care — and hospital care in particular — requires a full team of highly trained health care professionals working together to provide high quality, comprehensive, person-centered care” and that “[t]his interdisciplinary model is more important than ever to address increasingly complex health needs.”).

<sup>82</sup> Baldwin, *supra* note 17, at 23 (describing the World War II shift from physician-based care to interdisciplinary-based care).

<sup>83</sup> AM. HOSP. ASS'N, *supra* note 41 (providing information on the federal graduate loan redetermination).

interdisciplinary model did not build itself overnight, and in turn, it should not be ruined overnight by the ED's proposed rule.

