

ARTICLE

# Looking at Law School Healthcare Compliance Programs After Loper-Bright: How We Got Here and Where We Should Go Next

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## Abstract

The Supreme Court's decision 2024 in *Loper Bright Enterprises v. Raimondo* to overturn the *Chevron* doctrine, which required Federal Courts to defer to agency interpretations of ambiguous laws, along with other decisions challenging the decisions of regulatory agencies, marks a significant shift in healthcare regulatory oversight and compliance. This article takes this shift as an opportunity to examine the evolution of healthcare compliance education in U.S. law schools and consider how it should evolve to meet new demands. Through analysis of existing J.D. programs, master's degrees, and certificate programs in healthcare compliance, the article explores how law schools are already adapting to meet industry demands while distinguishing between programs designed for licensed attorneys and those for non-lawyer compliance professionals. The article highlights the role of external accreditation by the Compliance Certification Board (CCB) and clarifies the distinction between "certification" awarded through examination and "educational certificates" awarded by institutions. In light of the ironically almost total lack of regulatory attention to these programs from the Council on Legal Education that sets standards for law school J.D. programs, the article advocates for greater transparency in program outcomes and improved data collection regarding graduate career trajectories. It also addresses an often forgotten population, lawyers interested in changing practice areas at different stages of their careers. It concludes with recommendations for law schools to enhance their role in preparing both lawyers and compliance professionals for a post-*Chevron* regulatory environment, emphasizing the need for better tracking of program effectiveness and graduate outcomes to inform curriculum development and career pathways in healthcare compliance.

**Keywords:** Boston University; Career transitions; Certification; Chevron doctrine; Compliance Certification Board (CCB); Educational certificate; Healthcare compliance; Healthcare law; J.D. programs; Legal education; Loper Bright Enterprises v. Raimondo; Non-J.D. programs; Law school programs; Regulatory challenges; Regulatory oversight; Regulatory reform

## Introduction

In 1953, Boston University established the Law-Medicine Research Institute, which remains one of the most influential and important health law programs in the country.<sup>1</sup> Today, the demand for lawyers with knowledge of the legal issues faced by individuals and entities either delivering health care or supporting

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<sup>1</sup>History of Boston University School of Law, Bos. UNIV. SCH. OF L., <https://www.bu.edu/law/about/history-of-the-school/> (last visited July 25, 2024). Note, in researching this essay I was consistently impressed with the range and depth of health law programs in the United States. It is impossible in an overview like this to do any program justice. The inclusion or exclusion of any particular program is no reflection on my views of the quality of that program.

the health care industry continues to boom.<sup>2</sup> In the years since 1953, almost every law school in the United States has added health law courses to its curriculum, and many have developed bona fide health law programs.<sup>3</sup> One of the factors in the growth of health law may be the expanding oversight role played by the federal government in the delivery and funding of health care.<sup>4</sup> It is because helping regulated entities comply with these laws is such an important area of practice that the U.S. Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* is so significant.<sup>5</sup> It, along with the Court's decision in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System* a few days later,<sup>6</sup> is, as one DC law firm explained to its clients, "one of a series of decisions in which the Roberts Court has pared back the flexibility and power of administrative agencies."<sup>7</sup>

Although these cases were not specific to the health care industry, they will have a significant impact on the practice and teaching of healthcare compliance, as they invite stakeholders to "revisi[t] agency positions" the Court had "previously upheld on deference grounds."<sup>8</sup> Whatever the result of these legal challenges, the immediate beneficiaries of this increase in litigation will be lawyers.<sup>9</sup> This is thus an excellent opportunity to look at the current state of what has become of the complex multi-disciplinary industry of healthcare compliance, as well as the programs law schools have been developing to meet the need for knowledge about the federal regulation of health care. In this essay, I will briefly explain how the health care industry is regulated, and why the industry is therefore likely to quickly feel the effects of the new opportunities for parties to bring regulatory challenges. I will then look at the current structure under which the health care industry maintains compliance with federal regulations, with a focus on the role of lawyers.

<sup>2</sup>See Lisa Dimyadi, *The Highest-Growth Legal Practice Areas in 2024 and Beyond*, CLIO: CLIO BLOG (Aug. 29, 2024), <https://www.clio.com/blog/emerging-areas-law/> ("This emerging area of law has seen a surge in demand thanks to the 2020 pandemic and shows no signs of slowing down as the long-term impacts of Long COVID become clearer. With this heightened importance on health and hygiene, more people will be seeking legal advice and guidance on obtaining more affordable and accessible healthcare.").

<sup>3</sup>See Robert Morse & Eric Brooks, *Methodology: 2024 Best Law Schools Rankings*, U.S. NEWS & WORLD REP. (Apr. 8, 2024), <https://www.usnews.com/education/best-graduate-schools/articles/law-schools-methodology> (noting "191 schools ranked for health care law"); Brandon Galarita, *Healthcare Law: What It Is and How to Choose the Right Program*, FORBES: FORBES ADVISOR (Jan. 1, 2024, 2:37 PM), <https://www.forbes.com/advisor/education/law/what-is-health-law/> (discussing considerations for choosing a health law program); *Health Law*, DATA USA, <https://datausa.io/profile/cip/health-law> (last visited July 25, 2024) (listing and discussing certain metrics related to health law programs).

<sup>4</sup>For a historical perspective of the growth of federal healthcare regulation, see Christos A. Makridis & Patrick A. McLaughlin, *Never Letting a Crisis Go to Waste and the Ratcheting Effect of Regulation: Evidence from the Covid-19 Pandemic*, 15 N.Y.U. J.L. & LIBERTY 606 (2022). See, e.g., *Health Law Continues to be Among Hottest Practice Areas*, THE NATIONAL JURIST (Mar. 13, 2017), <https://nationaljurist.com/smartlawyer/health-law-continues-be-among-hottest-practice-areas/> [<https://perma.cc/8QH4-9WQY>].

<sup>5</sup>*Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024) ("Chevron is overruled. Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires.... courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."); see also U.S. Supreme Court Overrules Chevron, *Reshaping the Future of Regulatory Litigation*, SIDLEY AUSTIN LLP (June 28, 2024), <https://www.sidley.com/en/insights/newsupdates/2024/06/us-supreme-court-overrules-chevron-reshaping-the-future-of-regulatory-litigation>.

<sup>6</sup>See *Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 144 S. Ct. 2440 (2024).

<sup>7</sup>After Chevron: *What the Supreme Court's Loper Bright Decision Changed, and What It Didn't*, CLEARY GOTTlieb (July 11, 2024), <https://www.clearygottlieb.com/news-and-insights/publication-listing/after-chevron-what-the-supreme-courts-loper-bright-decision-changed-and-what-it-didnt>.

<sup>8</sup>*The Supreme Court's Double Hammer to Agencies: Loper Bright and Corner Post Set New Precedents for Challenging Federal Agency Action*, CROWELL & MORING (July 11, 2024), <https://www.crowell.com/en/insights/client-alerts/the-supreme-courts-double-hammer-to-agencies-loper-bright-and-corner-post-set-new-precedents-for-challenging-federal-agency-action>.

<sup>9</sup>See, e.g., Claire Heddles, *SCOTUS Is Poised to Make It Easier to Beat the Government. Big Law is Ready to Make a Killing*, NOTUS (June 14, 2024, 1:12 PM), <https://www.notus.org/courts/big-law-lobbying-recruiting-chevron-supreme-court> ("[S]ome of the nation's biggest legal and lobbying firms are telling industry clients: Get ready now to win in court against the government agencies trying to regulate you.").

Having laid that foundation, I will look directly at the development of healthcare compliance programs that support the industry across law schools. In particular, I will look at the development of two kinds of programs: those that create pathways for J.D. students to secure healthcare compliance jobs and those that offer training in healthcare compliance for non-lawyers.

Finally, I will make some observations about the role of law schools in shaping the future of healthcare compliance through subject matter experts and teachers. In so doing, I will suggest that these programs for non-lawyers be more closely aligned with law schools' main J.D. programs in order to provide broader access to the field for people without previous experience in the industry. I also suggest that, although these programs do not fall within the jurisdiction of the ABA or other entities that monitor the delivery of legal education, law schools take voluntary steps to gather and disseminate information about the career trajectories of their graduates.

### How Over-Turning Chevron Will Be of Benefit to Health Lawyers

The U.S. Supreme Court's decision in *Loper Bright* to overturn the Chevron Doctrine is being welcomed by some business interests as a positive development, because it will now be easier to challenge burdensome federal regulations.<sup>10</sup> As one commentator explained in anticipation of the decision, "[m]any businesses would welcome the opportunity to test the boundaries of a newly weakened administrative state."<sup>11</sup> Going forward, "[c]hallengers will no longer be constrained to argue that Congress spoke directly to the issue at hand (a relative rarity) or that the agency's interpretation was outside the bounds of reasonable interpretation."<sup>12</sup> Instead, "litigants can prevail in court by arguing that an agency's interpretation of its authorizing statute is not the best interpretation of the statute."<sup>13</sup>

### Federal Regulation of the Health Care Industry

The extent to which litigants will actually prevail in overturning agencies' interpretations is still a topic of debate, but the litigation process these actions entail "will sow some chaos, and when combined with the numerous other Supreme Court decisions weakening agencies, create a sand-in-the-gears of agency action effect."<sup>14</sup>

<sup>10</sup>See, e.g., David Zimmer, *The Chevron Doctrine Is Dead. What Are the Implications for Business?*, MIT SLOAN MGMT. REV. (July 30, 2024), <https://sloanreview.mit.edu/article/the-chevron-doctrine-is-dead-what-are-the-implications-for-business/> (noting "[t]he decision will almost certainly make it easier for companies to challenge agency regulations and other agency action interpreting federal statutes").

<sup>11</sup>Jonathan Wolf, *Expect Big Business Impacts If Chevron Deference Falls to Conservative Supreme Court*, ABOVE THE L. (May 4, 2023, 11:17 AM), <https://abovethelaw.com/2023/05/expect-big-business-impacts-if-chevron-deference-falls-to-conservative-supreme-court/> ("If *Chevron* does fall, expect a wave of litigation against regulators... .Whose interests that would ultimately serve remains an open, and troublesome, question."); see also Miranda A. Franco & Robert H. Bradner, *What Does the Overturning of Chevron Mean for Healthcare?*, HOLLAND & KNIGHT (July 3, 2024), <https://www.hklaw.com/en/insights/publications/2024/07/what-does-the-overturning-of-chevron-mean-for-healthcare> ("[T]he decision to overturn *Chevron* will likely have significant implications for several agencies, including the U.S. Department of Health and Human Services (HHS), FDA, HHS Office of Civil Rights (OCR) and CMS ... . [T]here will likely be an increase in legal challenges against these agencies' regulations as they are issued.").

<sup>12</sup>Shay Dvoretzky et al., *Supreme Court's Overruling of Chevron Deference to Administrative Agencies' Interpretations of Statutes Will Invite More Challenges to Agency Decisions*, SKADDEN (July 9, 2024), <https://www.skadden.com/insights/publications/2024/07/the-supreme-courts-overruling-of-chevron-deference/>.

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

<sup>14</sup>Leonardo Cuello, *Loper Bright Decision Will Collapse on Itself, Policy Evidence Is More Important than Ever Before in Driving Progress*, GEORGETOWN UNIV. MCCOURT SCH. OF PUB. POL'Y: CTR. FOR CHILD. & FAMS. (July 31, 2024), <https://ccf.georgetown.edu/2024/07/31/loper-bright-decision-will-collapse-on-itself-policy-evidence-is-more-important-than-ever-before-in-driving-progress/> (explaining that some "judges will issue nationwide injunctions, effectively one-man vetoes of entire agencies in real time based on personal opinion. This will sow some chaos, and when combined with the numerous other Supreme Court decisions weakening agencies, create a sand-in-the-gears of agency action effect. Perhaps that is exactly what the Supreme Court intended").

This looming increase in challenges to regulation across all industries raises an opportunity to look at the one most likely to be affected: the health care industry.<sup>15</sup>

In 2018, the American Hospital Association (“AHA”), a national organization that purports to “represent[] and serve[] all types of hospitals, health care networks, and their patients and communities,”<sup>16</sup> issued a report titled *Regulatory Overload*, in which they documented “a growing regulatory morass that fuels higher health care costs.”<sup>17</sup> This burden, which they estimated to be “\$39 billion per year,” results in “doctors, nurses and caregivers...devoting more time to regulatory compliance, taking them away from patient care.”<sup>18</sup> It illustrated the point with a graphic purporting to demonstrate that “[f]our federal agencies account for 629 regulatory requirements [with which] health systems, hospitals and post-acute care providers must comply.”<sup>19</sup> Characterizing these regulations as a whole, the AHA wrote, “[s]ome of these rules do not improve care, and all of them raise costs.”<sup>20</sup> The concern over regulatory burden is bi-partisan.<sup>21</sup> Both the left-leaning Center for American Progress<sup>22</sup> and the right-leaning Heritage Foundation<sup>23</sup> have published reports calling for change.

The majority of these much complained about regulations originate in the Department of Health and Human Services (“HHS”).<sup>24</sup> While historical accounts differ, HHS traces its origins to the 1839 “appropriation of \$1000 to the Commissioner of Patents for the collection of agricultural statistics, and for other agricultural purposes.”<sup>25</sup> This led to the eventual creation of a separate Department of Agriculture, as well as a division of chemistry within that department formed through the transfer of the Patent Office’s agricultural division.<sup>26</sup> This chemistry division came to be called the “U.S. Food and Drug Administration” (“FDA”) and was later transferred to the Federal Security Agency, which itself was

<sup>15</sup>Brief of Amici Curiae Am. Cancer Soc’y et al. in Support of Respondents at 4, *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (2024) (No. 22-451) (arguing that “[o]verruling *Chevron* would have enormous impact on the administration of federal programs — including Medicare, Medicaid, and CHIP — that are crucial to public health”); see also generally Joshua Weiss et al., *Health Care Impacts Following Chevron Decision*, BROWNSTEIN HYATT FARBER SCHRECK LLP (July 3, 2024), <https://www.bhfs.com/insights/alerts-articles/2024/health-care-impacts-following-chevron-decision>.

<sup>16</sup>About the AHA, AM. HOSP. ASS’N, <https://www.aha.org/about> (last visited Oct. 19, 2024).

<sup>17</sup>AM. HOSP. ASS’N, THE REGULATORY BURDEN ON HOSPITALS AND HEALTH SYSTEMS 1 (2018), <https://trustees.aha.org/sites/default/files/trustees/Regulatory%20Overload%202018.pdf>.

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

<sup>19</sup>*Id.* at 5.

<sup>20</sup>*Id.* at 1; see also *Administrative Burdens*, AM. MED. ASS’N, <https://www.ama-assn.org/health-care-advocacy/administrative-burdens> (last visited July 29, 2024) (“The administrative burdens physicians shoulder each day directly affect the patient-physician relationship and unnecessarily interrupt the delivery of care. The [American Medical Association] is a physician’s chief advocate for minimizing administrative burdens in healthcare associated with health plan interactions and addressing problems that contribute to increased complexity or expense.”).

<sup>21</sup>See, e.g., SHANNA ROSE, FINANCING MEDICAID: FEDERALISM AND THE GROWTH OF AMERICA’S HEALTH CARE SAFETY NET 246–47 (2013) (explaining that “[d]espite their divergent views, liberals and conservatives can agree that Medicaid’s growth is imposing an untenable burden on state budgets”); *Bipartisan Rx for America’s Health Care: A Practical Path to Reform*, BIPARTISAN POL’Y CTR. 17 (Feb. 2020), <https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2020/02/43530-BPC-FHC-Report-Proof.pdf> (“In recent years, a combination of legislative and regulatory changes, including non-payment of cost-sharing reduction (CSR) payments, among other factors, has resulted in an increase in health insurance premiums.”)

<sup>22</sup>See Emily Gee & Topher Spiro, *Excess Administrative Costs Burden the U.S. Health Care System*, CTR. FOR AM. PROGRESS (Apr. 18, 2019), <https://www.americanprogress.org/article/excess-administrative-costs-burden-u-s-health-care-system/>.

<sup>23</sup>See Mary McCloskey & Robert E. Moffit, *Time to Roll Back Excessive Regulation of Medical Practices*, HERITAGE FOUND. (Aug. 7, 2023), <https://www.heritage.org/health-care-reform/commentary/time-roll-back-excessive-regulation-medical-practices>.

<sup>24</sup>HHS Agencies & Offices, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html> (last visited Aug. 2, 2024) (“HHS has 13 operating divisions, including 10 agencies in the U.S. Public Health Service and three human services agencies. These divisions administer a wide variety of health and human services and conduct life-saving research for the nation, protecting and serving all Americans.”).

<sup>25</sup>*Changes in Science, Law and Regulatory Authorities*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-history/changes-science-law-and-regulatory-authorities> (last visited Jun 20, 2024).

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

ultimately “renamed the Department of Health and Human Services in 1979.”<sup>27</sup> Within HHS, the department’s programs are overseen, and its regulations are enforced by, the Office of Inspector General (“HHSOIG”), which is “the largest civilian inspector general’s office in the Federal Government.”<sup>28</sup>

Among the programs administered directly by HHS are Medicare and Medicaid (1965),<sup>29</sup> HIPAA (1996),<sup>30</sup> CHIP (1997),<sup>31</sup> EMTALA (1986),<sup>32</sup> and the Affordable Care Act (2010).<sup>33</sup> Most of these programs have associated anti-fraud provisions, which are also administered by HHS.<sup>34</sup> In 2023, HHSOIG issued a comprehensive compliance guide describing its office as being at the “forefront of the Nation’s efforts to fight fraud, waste, and abuse and improve the efficiency of Medicare, Medicaid, and more than 100 other HHS programs.”<sup>35</sup>

When violations of these laws infringe on individuals’ fundamental rights of nondiscrimination, conscience, religious freedom, and health information privacy, jurisdiction transfers to the HHS’ Office for Civil Rights (OCR). HHS OCR “enforce[s] federal civil rights laws, conscience and religious freedom laws, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule.”<sup>36</sup>

Other programs that relate to employment like ERISA (1974),<sup>37</sup> The ADA (1990),<sup>38</sup> GINA (2008),<sup>39</sup> and the Pregnant Worker’s Fairness Act (2023)<sup>40</sup> are at least partially under the jurisdiction of the Department of Labor, with the exception of the Pregnant Worker’s Fairness Act, which is enforced by the Equal Employment Opportunity Commission.<sup>41</sup> As if that were insufficient responsibility, HHS also

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

<sup>28</sup>OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., GENERAL COMPLIANCE PROGRAM GUIDANCE 6 (2023), <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>.

<sup>29</sup>See *The History of Medicare*, NAT’L ACAD. SOCIAL INS., <https://www.nasi.org/learn/medicare/the-history-of-medicare/> (last visited July 27, 2024); *History: CMS’ Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/about-cms/agency-information/history> (last visited July 27, 2024).

<sup>30</sup>For a history of the development of the HIPAA privacy rule, see Stacey A. Tovino, *A Timely Right to Privacy*, 104 IOWA L. REV. 1361, 1367–1374 (2019).

<sup>31</sup>For a brief overview of the creation of the CHIP program, see Taleed El-Sabawi, *Mhpaea & Marble Cake: Parity & the Forgotten Frame of Federalism*, 124 DICK. L. REV. 591, 607–08 (2020).

<sup>32</sup>For a history of the development of EMTALA, see Wendy S. Heipt, *EMTALA in a Post-Dobbs World: The March Towards Fetal Personhood Continues*, 59 IDAHO L. REV. 369, 373–378 (2023).

<sup>33</sup>For a legislative history of the Affordable Care Act, see generally John Cannan, *A Legislative History of the Affordable Care Act: How Legislative Procedure Shapes Legislative History*, 105 LAW LIBR. J. 131 (2013), and for an account of the constitutional litigation surrounding the Affordable Care Act, see generally Abbe R. Gluck et al., *The Affordable Care Act’s Litigation Decade*, 108 GEO. L.J. 1471 (2020).

<sup>34</sup>See generally Chinelo Diké-Minor, *The Untold Story of the United States’ Anti-Kickback Laws*, 20 RUTGERS J.L. & PUB. POL’Y 103 (2023).

<sup>35</sup>GENERAL COMPLIANCE PROGRAM GUIDANCE, *supra* note 28, at 6

<sup>36</sup>*About Us*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/ocr/about-us/index.html> (last visited Jun. 20, 2024); see also HHS Agencies & Offices, U.S. DEP’T. OF HEALTH & HUM. SERVS., <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html> (last visited Dec. 2, 2024).

<sup>37</sup>*History of EBSA and ERISA*, U.S. DEP’T OF LAB., <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/history-of-ebsa-and-erisa> (last visited July 31, 2024).

<sup>38</sup>For a history of the development of the Americans with Disabilities Act, see Jennifer S. Bard, *Lifting the Barriers Excluding People Living with Disabilities from the Benefits of Inclusion in Research Studies*, 6 U. PA. J.L. & PUB. AFF. 489, 531–535 (2021).

<sup>39</sup>For a history of the development of GINA, see Sonia M. Suter, *GINA at 10 Years: The Battle over “Genetic Information” Continues in Court*, 5 J.L. & BIOSCI. 495, 496–500 (2018) and Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 J.L. MED. & ETHICS 837, 837–38 (2008)

<sup>40</sup>*What You Should Know About the Pregnant Workers Fairness Act*, U.S. EMP. OPPORTUNITY COMM’N, <https://www.eeoc.gov/wysk/what-you-should-know-about-pregnant-workers-fairness-act> (last visited July 31, 2024).

<sup>41</sup>See *Summary of the Major Laws of the Department of Labor*, U.S. DEP’T OF LAB., <https://www.dol.gov/general/aboutdol/majorlaws> (last visited July 31, 2024); *Employee Benefits Security Administration: Laws*, U.S. DEP’T OF LAB., <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws> (last visited Oct. 19, 2024); *Americans with Disabilities Act*, U.S. DEP’T OF LAB., <https://www.dol.gov/general/topic/disability/ada> (last visited Oct. 19, 2024); *What You Should Know About the Pregnant Workers Fairness Act*, *supra* note 40.



incorporates the FDA<sup>42</sup> and oversees the regulations protecting human subject research funded or conducted by the federal government as well those participating in clinical drug trials.<sup>43</sup> In addition to HHS and the Department of Labor, almost every agency from the Department of Agriculture through the rest of the alphabet enforces some portion of a federal regulatory scheme that involves or affects individual or population health.<sup>44</sup>

### Previous Constitutional Challenges to Health Care Legislation

The Supreme Court's watchful oversight of the federal government's administration of health and safety laws precedes the tenure of the current majority.<sup>45</sup> It began with taking on the role of assuring that the new federal government did not exceed the "enumerated powers" it was granted in the 1787 Constitution.<sup>46</sup> Since the Constitution does not specifically give the federal government power over health and safety, the Court has required any law related to these topics be justified by a power granted to the federal government in the Constitution.<sup>47</sup> This allocation of power between the states and the federal government is called "federalism," although that word is not used in the Constitution.<sup>48</sup>

The Court's last comprehensive analysis of the extent of these powers was in 2012, when it reviewed two provisions of the Affordable Care Act in *National Federation of Independent Business v. Sebelius*.<sup>49</sup> Writing for the Court, Chief Justice Roberts explained that "[n]othing [in the Constitution] precludes Congress from offering funds under the Affordable Care Act to expand the availability of health care, and requiring that States accepting such funds comply with the conditions on their use."<sup>50</sup> However, the Court held, "[w]hat Congress is not free to do is to penalize States that choose not to participate in that new program by taking away their existing Medicaid funding."<sup>51</sup> The opinion then turned to the government's argument that the Affordable Care Act's requirement that individuals buy insurance was justified by Congress' power to regulate commerce.<sup>52</sup> The Supreme Court disagreed, writing that

<sup>42</sup>See HHS Agencies & Offices, *supra* note 24.

<sup>43</sup>See *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> (last visited July 31, 2024); *Clinical Trials and Human Subject Protection*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection> (last visited July 31, 2024). For a discussion of the development of these rules and how they work together, see Jennifer S. Bard, *Protecting the Promise to the Families of Tuskegee: Banning the Use of Persuasive AI in Obtaining Informed Consent for Commercial Drug Trials*, 60 SAN DIEGO L. REV. 671, 706–722 (2023).

<sup>44</sup>See, e.g., *Environmental Health & Safety: Regulatory Agencies: Federal, State and City*, ALBERT EINSTEIN COLL. MED., <https://einsteinmed.edu/administration/environmental-health-safety/industrial-hygiene/regulatory-agencies.aspx> (last visited Aug 2, 2024).

<sup>45</sup>See Nathan Richardson, *Antideference: COVID, Climate, and the Rise of the Major Questions Canon*, 108 VA. L. REV. ONLINE 174, 178–81 (2022).

<sup>46</sup>See *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 588 (2012) ("The Framers created a Federal Government of limited powers and assigned to this Court the duty of enforcing those limits. The Court does so today. But the Court does not express any opinion on the wisdom of the Affordable Care Act. Under the Constitution, that judgment is reserved to the people.").

<sup>47</sup>See *United States v. Comstock*, 560 U.S. 126, 146 (2010) ("[W]hen legislating pursuant to the Necessary and Proper Clause, Congress' authority can be no more than one step removed from a specifically enumerated power.").

<sup>48</sup>See THE FEDERALIST NO. 45 (James Madison) ("The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite."); *Bond v. United States*, 564 U.S. 211, 221 (2011) ("Federalism has more than one dynamic. It is true that the federal structure serves to grant and delimit the prerogatives and responsibilities of the States and the National Government vis-a-vis one another."). For a discussion of how recent trends in the application of federalism principles by the Supreme Court may affect public health, see Nicole Huberfeld, *High Stakes, Bad Odds: Health Laws and the Revived Federalism Revolution*, 57 U.C. DAVIS L. REV. 977 (2023).

<sup>49</sup>See generally *Sebelius*, 567 U.S. 519.

<sup>50</sup>*Id.* at 585; see also Henry J. Aaron, *The Supreme Court Ruling on the Affordable Care Act—A Bullet Dodged*, BROOKINGS (June 28, 2012), <https://www.brookings.edu/articles/the-supreme-court-ruling-on-the-affordable-care-act-a-bullet-dodged/>.

<sup>51</sup>*Sebelius*, 567 U.S. at 585.

<sup>52</sup>See *id.* at 552; see also Aaron, *supra* note 50.

while Congress does have the power to regulate “existing commerce,” it did not have power to require people to engage in commerce.<sup>5354</sup>

### From Challenging Congressional Power to Challenging the Decisions of the Federal Agencies

Since *NFIB v. Sebelius*, the Supreme Court has had very little to say about Congress’ power to regulate under either the Spending or Commerce Clause.<sup>55</sup> But it has been highly critical of the agencies created by Congress to effectuate and enforce its laws.<sup>56</sup> As one commentator explains, “[m]uch like the incomplete dinosaur DNA in Jurassic Park, whenever Congress passes legislation, it’s full of holes. Instead of filling these gaps with frog DNA a la everyone’s favorite dinosaur film franchise, the legislative holes get filled by the appropriate government administrative agency.”<sup>57</sup> The Court’s 1984 decision in *Chevron v. Natural Resources Defense Council* recognized the importance of this role when it instructed federal courts to defer to agency interpretations of otherwise ambiguous states.<sup>58</sup> Since *Chevron*, the Supreme Court has “held that when Congress has not expressly spoken, the courts should defer to administrative interpretation “[i]f this choice represents a reasonable accommodation of conflicting policies that were committed to the agency’s care by the statute.”<sup>59</sup>

Several members of the current Supreme Court had long signaled that they thought this deference unwarranted.<sup>60</sup> Indeed, three of the current sitting Supreme Court Justices had “opined that specific regulatory agencies were unconstitutional.”<sup>61</sup>

While the Court has not so far declared any specific agency unconstitutional, they have been very active in overturning agency decisions.<sup>62</sup> In a July 2023 article describing their actions,

Ian Millhiser reported that “[i]n the less than three years since President Joe Biden took office, the Supreme Court has effectively seized control over federal housing policy, decided which workers must be vaccinated against Covid-19, stripped the EPA of much of its power to fight climate change, and rewritten a federal law permitting the secretary of education to modify or forgive student loans.”<sup>63</sup> These

<sup>53</sup> Aaron, *supra* note 50.

<sup>54</sup> Laurie Sobel et al., *Explaining Litigation Challenging the ACA’s Preventive Services Requirements: Braidwood Management Inc. V. Becerra*, KFF (May 15, 2023), <https://www.kff.org/womens-health-policy/issue-brief/explaining-litigation-challenging-the-acas-preventive-services-requirements-braidwood-management-inc-v-becerra/>. (referring to the challenge of Congress’ delegation of its powers to the CDC advisory board).

<sup>55</sup> Although it was not the end of other Constitutional challenges. See Huberfeld, *supra* note 48, at 980 (“The Affordable Care Act (‘ACA’) has been litigated so much throughout its first decade, it is effectively a cottage industry.”).

<sup>56</sup> See generally Joel Seligman, *The Judicial Assault on the Administrative State*, 100 WASH. U. L. REV. 1687 (2023).

<sup>57</sup> Wolf, *supra* note 11.

<sup>58</sup> See *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–843 (1984) (explaining that when a “statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute”), *overruled by* *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244 (2024).

<sup>59</sup> See Seligman, *supra* note 56, at 1706 (quoting *Chevron*, 467 U.S. at 845).

<sup>60</sup> Gillian E. Metzger, *The Roberts Court and Administrative Law*, 2019 SUP. CT. REV. 1, 2–4 (2010); see also Seligman, *supra* note 56, at 1706–14 (discussing the erosion of *Chevron*); John Kruzell, *Explainer: How Is the “War on the Administrative State” Faring at the Supreme Court?*, REUTERS (Jan. 19, 2024, 3:23 PM EST), <https://www.reuters.com/legal/how-is-war-administrative-state-faring-supreme-court-2024-01-19/>; John Kruzell & Andrew Chung, *US Supreme Court Appears Split over US Agency Powers in Fishing Dispute*, REUTERS (Jan. 17, 2024, 2:30 PM EST), <https://www.reuters.com/legal/supreme-court-may-reel-us-agency-powers-fishing-dispute-2024-01-17/>.

<sup>61</sup> See Seligman, *supra* note 56, at 1697.

<sup>62</sup> See Huberfeld, *supra* note 48, at 981 (“The Court also is doubling down on interpretive methods that limit government power, often using formalist tools like clear statement rules that demand specificity and offer little or no deference to lawmakers or regulators.”); see also Seligman, *supra* note 56, at 1723 (“This does not mean that the Supreme Court intends to end all administrative agencies. That would be overreading even the most aggressive text written to date in dissenting or concurring opinions. But the Court does appear prepared to limit agency programs and some new agencies to those expressly created by Congress.”).

<sup>63</sup> Ian Millhiser, *How the Supreme Court Put Itself in Charge of the Executive Branch*, Vox (July 17, 2023), <https://www.vox.com/scotus/23791610/supreme-court-major-questions-doctrine-nebraska-biden-student-loans-gorsuch-barrett>.

cases were decided under the “major questions doctrine,” which Millhiser explained “as it is understood by the Court’s current majority, [has] emerged almost from thin air.”<sup>64</sup> The Court used the “major questions doctrine” not to challenge Congress’ authority to regulate or to determine that an agency’s interpretation of a law was correct, but rather to cast doubt on the likelihood that the Congress would have meant for an agency to make a decision on such an important topic.<sup>65</sup> It has also revitalized another seldom-used doctrine, the “non-delegation doctrine.” Additionally, the Court’s invocation of the Seventh Amendment’s right to a jury trial in *SEC v. Jarkesy* could also invalidate the ability of other agencies to use internal panels to impose civil penalties.<sup>66</sup>

Given their active anti-regulatory docket, the Court’s decision to hear *Loper Bright* was quickly interpreted as a sign they were going to overturn *Chevron*. A regulatory policy associate at the consumer watchdog group Public Citizen explained that “[i]n a post-*Chevron* world, the decisions of agency experts – scientists, engineers, policy professionals – about how to keep the public safe best would be second-guessed by judges who lack subject-matter expertise and are not accountable to the public.”<sup>67</sup> In a post after the oral arguments in *Loper Bright*, Suhasini Ravi of Georgetown’s O’Neill Institute made the case that the “prospect of overruling *Chevron* is especially concerning in health care policy, where agencies must leverage their expertise to address emergencies, adapt to ever-changing technology, and improve health outcomes.”<sup>68</sup>

Shortly before the *Loper Bright* opinion was published, two attorneys from the law firm Foley Hoag predicted that the decision would pose a threat to many different programs administered by the Department of Health and Human Services, noting that the “shift in power from HHS to courts will be felt immediately. If the Supreme Court overturns *Chevron*, it will impact 1) HHS’s consideration of new rules during the notice and comment process, 2) the ability of regulated healthcare entities to challenge new rules, and 3) the permissibility of some long-standing rules, creating short-term uncertainty on the status of numerous regulations.”<sup>69</sup> A month later, the firm issued a detailed follow-up report specific to the likely effect on regulations administered by the FDA.<sup>70</sup>

<sup>64</sup>*Id.* For a discussion of the development of the “major questions doctrine,” see Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine*, 109 VA. L. REV. 1009 (2023).

<sup>65</sup>See *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014)) (explaining that, for certain extraordinary exercises of power, the Court will be “reluctant to read [delegated authority] into ambiguous statutory text” and that instead agencies must point to “clear congressional authorization” for its action); see also Brianne J. Gorod et al., *Major Questions: An Extraordinary Doctrine for “Extraordinary” Cases*, 58 WAKE FOREST L. REV. 599, 621 (2023) (“[T]he Supreme Court has looked to several indicators to determine whether such a transformation has occurred--placing particular emphasis on eyebrow-raising novelty, conflict with the overall regulatory scheme, and reliance on vague, obscure, or ancillary provisions.”).

<sup>66</sup>See *SEC v. Jarkesy*, 144 S. Ct. 2117, 2130 (2024) (quoting *Tull v. United States*, 481 U.S. 412, 422 (1987)) (“[T]he civil penalties in this case are designed to punish and deter, not to compensate. They are therefore ‘a type of remedy at common law that could only be enforced in courts of law.’ That conclusion effectively decides that this suit implicates the Seventh Amendment right, and that a defendant would be entitled to a jury on these claims.”)

<sup>67</sup>*Overturning Chevron Deference Would Harm the Public*, PUB. CITIZEN (Jan. 17, 2024), <https://www.citizen.org/news/overturning-chevron-deference-would-harm-the-public/>.

<sup>68</sup>Suhasini Ravi, *What the Supreme Court’s Rulings on Chevron in Loper Bright Enterprises and Relentless Could Mean for Health Care*, O’NEILL INST. FOR NAT’L & GLOB. HEALTH L. (Oct. 31, 2023), <https://oneill.law.georgetown.edu/what-the-supreme-courts-rulings-on-chevron-in-loper-bright-enterprises-and-relentless-could-mean-for-health-care/>. The concern regarding interference with the notice and comments process

was justified in yet another anti-agency decision issued at the end of the 2024 term, in which the Court stayed an EPA rule for failing to adequately address an industry concern. See *Ohio v. EPA*, 144 S. Ct. 2040, 2056 (2024).

<sup>69</sup>Andrew M. London and Kian Azimpoor, *Practical Guidance: Litigation, Professional Perspective - Loper Bright’s Potential Impact on the U.S. Department of Health and Human Services*, BLOOMBERG L. (June 2024), <https://www.bloomberglaw.com/external/document/X3EH5278000000/litigation-professional-perspective-loper-bright-s-potential-imp>.

<sup>70</sup>See *Loper Bright’s Implications for the Food and Drug Administration and Regulated Industry*, FOLEY HOAG (July 22, 2024), <https://foleyhoag.com/news-and-insights/publications/alerts-and-updates/2024/july/loper-brights-implications-for-the-food-and-drug-administration-and-regulated-industry/>.



Although no one knows for sure which regulations will be challenged or when, observers are already predicting that “agency interpretations” associated with The Inflation Reduction Act, which “authorizes the Centers for Medicare & Medicaid Services (CMS) to directly negotiate prescription drug prices with pharmaceutical companies through the Drug Price Negotiation Program,” could “be subject to increased scrutiny following *Loper Bright*.”<sup>71</sup> Whatever happens, the Court did not overturn or even call into question the programs generating the regulations with which the health care industry has to comply. Therefore, the coming years will most likely bring an increase in need for people with knowledge of these laws. In the rest of this essay, I will look at the infrastructure of existing healthcare compliance programs and the role of lawyers in supporting them.

### The Evolution of “Healthcare Compliance” Programs

Historians trace the practice of designating specific employees as responsible for compliance with federal law to the 1950s, when the federal government entered into settlements of a “series of antitrust cases brought against electronics manufacturers.”<sup>72</sup>

Pursuant to the Inspector General Act of 1978, each federal agency has their own Office of Inspector General (OIG).<sup>73</sup> Their purpose is “to prevent and detect waste, fraud, and abuse relating to their agency’s programs and operations, and to promote economy, efficiency, and effectiveness in the agency’s operations and programs.”<sup>74</sup> Under the terms of the Act, “[a]pproximately half of the 74 federal IGs are appointed by the President subject to Senate confirmation, and approximately half are appointed by the agency head.”<sup>75</sup> Additionally, “IGs are nonpartisan and are selected without regard to political affiliations.”<sup>76</sup>

For health care companies, formal compliance programs are the result of a recommendation by the HHSOIG “that health care providers of all types establish compliance programs to prevent and mitigate violations of federal healthcare program rules and regulations.”<sup>77</sup> The HHSOIG’s “mission is to protect the integrity of HHS programs as well as the health and welfare of program beneficiaries.”<sup>78</sup> In 2010, the HHSOIG’s aforementioned “recommendation” became a mandate for certain providers.<sup>79</sup>

The Patient Protection and Affordable Care Act (“ACA”), “amended the US Social Security Act to give the Secretary of Health and Human Services (“Secretary”) the authority to require Medicare and Medicaid providers, as a condition for enrollment, to establish compliance programs.”<sup>80</sup> The Secretary of HHS was also required by statute to establish criteria for “a compliance and ethics program” for nursing

<sup>71</sup>*Potential Implications of Loper Bright for the Healthcare Industry*, SIDLEY (July 2, 2024), <https://www.sidley.com/en/insights/newsupdates/2024/07/potential-implications-of-loper-bright-for-the-healthcare-industry>.

<sup>72</sup>*Jones Day Talks - The Evolution of Corporate Compliance Programs: Key Issues for Multinational Companies*, JONES DAY (Oct. 3, 2023), <https://www.jonesday.com/en/insights/2023/10/jones-day-talks-the-evolution-of-corporate-compliance-programs--key-issues-for-multinational-companies>.

<sup>73</sup>5 U.S.C. § 402(a).

<sup>74</sup>*About Oversight.gov*, OVERSIGHT.GOV, <https://www.oversight.gov/about> (last visited Sept. 8, 2024); 5 U.S.C. § 404(a).

<sup>75</sup>OVERSIGHT.GOV, *supra* note 74.

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

<sup>77</sup>Lauren Carboni, *Healthcare Compliance Programs in the United States 101*, ASS’N OF CORP. COUNS. (Apr. 6, 2022), <https://www.acc.com/resource-library/healthcare-compliance-programs-united-states-101>.

<sup>78</sup>*Department of Health & Human Services OIG*, OVERSIGHT.GOV, <https://www.oversight.gov/Inspectors-General/Department-Health-Human-Services-OIG> (last visited Sept. 8, 2024). In support of this mission, HHSOIG “oversees activities in more than 100 HHS programs, conducts thousands of audits, evaluations, and inspections each year, and provides compliance guidance to tens of thousands of individuals and organizations to encourage compliance with regulations published by HHS agencies such as CMS, CDC, SAMHSA, and OCR.” Steve Alder, *What is OIG in Healthcare?*, HIPAA J. (Jan. 11, 2024), <https://www.hipaajournal.com/what-is-oig-in-healthcare/>.

<sup>79</sup>See Carboni, *supra* note 77 (discussing the ACA’s establishment of mandatory effective compliance programs for nursing facilities and skilled nursing facilities, as well as for “enrolled providers and suppliers, Medicare Advantage Organizations, and Medicare Prescription Drug Plans”).

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

facilities and skilled nursing facilities to assist them in establishing a compliance program “effective in preventing and detecting criminal, civil, and administrative violations.”<sup>81</sup> There are “seven core elements” which every healthcare compliance program should typically include, which elements were originally “derived, in part, from the seven elements of an effective compliance and ethics program” in “Chapter 8 of the US Federal Sentencing Guidelines.”<sup>82</sup> In its most recent recommendation, HHSOIG describes these seven “core elements” as:

1. Implement written policies, procedures, and standards of conduct.
2. Designate a compliance officer and a compliance committee.
3. Conduct effective training and education.
4. Develop effective lines of communication.
5. Conduct internal monitoring and auditing.
6. Enforce standards through well-publicized disciplinary guidelines.
7. Respond promptly to detected offenses and undertake corrective action.<sup>83</sup>

In addition to compliance programs mandated by HHS, some health care entities also have compliance obligations stemming from other federal regulations, such as those associated with publicly traded companies.<sup>84</sup>

### The Price of Non-Compliance

A 2018 article in the *Harvard Business Review* titled *Why Compliance Programs Fail—and How to Fix Them* reported that “[m]any executives are rightly frustrated about paying immense and growing compliance costs without seeing clear benefits.”<sup>85</sup> It concluded, however, that companies “continue to invest—not because they think it’s necessarily productive but because they fear exposing their organizations to greater liability should they fail to spend enough.”<sup>86</sup>

The extent of this potential liability, civil and criminal, is enormous. On June 27, 2024, the Department of Justice reported that it had brought “criminal charges against 193 defendants, including 76 doctors, nurse practitioners, and other licensed medical .... for their alleged participation in various health care fraud schemes involving approximately \$2.75 billion in intended losses and \$1.6 billion in actual losses.”<sup>87</sup> A few days later it followed up with the warning that “[c]ombating health care fraud is a critical priority for the Justice Department.”<sup>88</sup> Earlier the same year, on February 22, 2024, the Department announced that in the past fiscal year it had “collected over \$2.68 billion” from civil “settlements and judgments under the False Claims Act.”<sup>89</sup> The “leading source” of these settlements and

<sup>81</sup>42 U.S.C. § 1320a-7j(b)(1), (3).

<sup>82</sup>Carboni, *supra* note 77 (citing U.S. SENT’G GUIDELINES MANUAL § 8B2.1 (U.S. SENT’G COMM’N 2018)).

<sup>83</sup>See GENERAL COMPLIANCE PROGRAM GUIDANCE, *supra* note 28, at 32.

<sup>84</sup>See Jaclyn Jaeger, *Healthcare Compliance Enforcement Trends to Watch in 2024*, NAVEX (Feb. 29, 2024) <https://www.navex.com/en-us/blog/article/healthcare-compliance-enforcement-trends-to-watch-in-2024/>; see also Nina Kelleher & Jerry Ravi, *The Critical Role of Risk Assessments for Public Companies*, EISNERAMPER, (Feb. 15, 2024).

<sup>85</sup>Hui Chen & Eugene Soltes, *Why Compliance Programs Fail—and How to Fix Them*, HARV. BUS. REV. (Mar.- Apr. 2018), <https://hbr.org/2018/03/why-compliance-programs-fail>.

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

<sup>87</sup>*National Health Care Fraud Enforcement Action Results in 193 Defendants Charged and Over \$2.75 Billion in False Claims*, U.S. DEP’T OF JUST. (June 27, 2024), <https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-193-defendants-charged-and-over-275-0>.

<sup>88</sup>*Combating Health Care Fraud: 2024 National Enforcement Action*, U.S. DEP’T OF JUST. (July 1, 2024), <https://www.justice.gov/opa/blog/combating-health-care-fraud-2024-national-enforcement-action>.

<sup>89</sup>*False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023*, U.S. DEP’T OF JUST. (Feb. 22, 2024), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023>; see also Karl Buch et al., *New DOJ Whistleblower Pilot Program Places Corporate Compliance Programs Under More Scrutiny*, DLA PIPER

recoveries involved “health care fraud.”<sup>90</sup> The volume of HIPAA enforcement actions is lower, but, in what an industry website described as a “a banner year for healthcare fines and breaches,” the HHS’ Office of Civil Rights collected “\$4,176,500” from “eight covered entities and four business associates” in 2023.<sup>91</sup>

To provide covered entities further incentive to maintain robust compliance programs, the programs are structured to reward self-disclosure.<sup>92</sup> As one law firm advises its potential clients, “[w]hen a healthcare provider realizes the entity may have violated federal healthcare laws or requirements, it is often the best course of action to report the violation instead of waiting for the Government to potentially investigate the violation and bring criminal and/or civil action.”<sup>93</sup>

## Lawyers’ Role in Regulatory Compliance

### Law Firms

The market for lawyers with knowledge of how the federal government regulates the health care industry is strong.<sup>94</sup> As discussed earlier, this is because the federal government’s mandate that certain health care entities have compliance programs, the penalties associated with violating the law, and the benefits associated with self-reporting all create a need for health care entities to hire lawyers.<sup>95</sup> The 12,000-member-strong American Health Law Association (AHLA) describes these lawyers as practicing “health law” which they define as “the body of federal, state, and local laws, rules, regulations and cases that governs the health care industry, including the delivery of all health-related services to patients by all of its individual and institutional participants.”<sup>96</sup> These lawyers are distinctive in that they have an “in-depth knowledge and experience working in this regulatory framework, and provide advice to hospitals, physician organizations, long term care facilities, home health agencies, health insurance companies, pharmaceutical companies, as well as to physicians and other individual health care providers on how to comply with these rules.”<sup>97</sup>

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(Aug. 7, 2024), <https://www.dlapiper.com/en/insights/publications/2024/08/doj-announces-corporate-whistleblower-awards-pilot-program> (announcing program to “incentivize reporting of corporate misconduct to the government”).

<sup>90</sup>See DLA PIPER, *supra* note 89.

<sup>91</sup>Monica McCormack, 2023 HIPAA Year-End Wrap-Up: HHS Issued \$4 Million in Fines, Breaches Affected 109M Patients, COMPLIANCY GRP., <https://compliance-group.com/2023-hipaa-breaches-and-fines/> (last visited Aug. 2, 2024).

<sup>92</sup>See OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., OIG’S HEALTH CARE FRAUD SELF-DISCLOSURE PROTOCOL 2 (2021), <https://oig.hhs.gov/documents/self-disclosure-info/1006/Self-Disclosure-Protocol-2021.pdf>; see also, e.g., Palo Alto Medical Foundation and Palo Alto Foundation Medical Group Agreed to Pay \$291,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Services Not Provided as Claimed, U.S. DEP’T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN. (June 25, 2024); *Self-Referral Disclosure Protocol Settlements*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/self-referral-disclosure-protocol-settlements> (last visited Aug. 2, 2024).

<sup>93</sup>*The OIG Self-Disclosure Protocol: A Valuable Tool in Effective Compliance*, POWERS PYLES SUTTER & VERVILLE PC (Nov. 23, 2022), <https://www.powerslaw.com/the-oig-self-disclosure-protocol-a-valuable-tool-in-effective-compliance/>.

<sup>94</sup>See Dimyadi, *supra* note 2 (“This emerging area of law has seen a surge in demand thanks to the 2020 pandemic and shows no signs of slowing down as the long-term impacts of Long COVID become clearer. With this heightened importance on health and hygiene, more people will be seeking legal advice and guidance on obtaining more affordable and accessible healthcare.”).

<sup>95</sup>See CATHERINE PATTANAYAK ET AL., HEALTH LAW: A CAREER GUIDE 1–9 (2012), <https://hls.harvard.edu/wp-content/uploads/2022/08/2012HealthLaw-1.pdf>.

<sup>96</sup>About AHLA, AM. HEALTH L. ASS’N, <https://www.americanhealthlaw.org/about-ahla?Token=441ebd59-1686-489b-b945-b205c63735f1> (last visited July 1, 2024).

<sup>97</sup>*Id.* (listing practice areas included in health law, such as: “Antitrust, Behavioral Health, Dispute Resolution, Fraud and Abuse, Governance, Government Reimbursement, Health Care Delivery Models, Health Care Finance and Transactions, Health Information, Health Insurance, Health Policy and Administration, Labor and Employment, Life Sciences, Long Term Care, Medical Staff, Credentialing, and Peer Review, Patient Care Liability and Litigation, Tax and Nonprofit”).

Many of these lawyers with specific knowledge of health care regulation work directly in departments of large U.S. law firms.<sup>98</sup> One example is Latham and Watkins, which reports on its website that its:

[H]ealthcare and life sciences regulatory team draws on market-leading experience and deep industry knowledge to advise healthcare and life sciences companies, digital health and technology providers, private equity, investment banks, venture capital firms, and other industry stakeholders. We advise on regulatory counseling, fraud and abuse compliance, reimbursement and related matters, data, privacy, and security, licensure, accreditation, quality management, controlled substances regulation, as well as on the regulatory aspects of mergers and acquisitions and other corporate transactions in the sector.”<sup>99</sup>

This description is followed by links and biographies for 17 Partners, 15 Associates, and 4 Counsel.<sup>100</sup>

### *In-House Counsel*

In addition to retaining outside law firms, most companies subject to health regulations have their own internal legal departments.<sup>101</sup> These departments are often staffed by lawyers who started their careers at law firms.<sup>102</sup> In 2023, a large legal recruiting firm reported that there were currently “around 130,000 in-house lawyers in the U.S. . . . In fact, the number of lawyers who are in-house is almost equal to the number of lawyers across the nation’s top 500 law firms.”<sup>103</sup> Looking more specifically at health care companies, another recruiter described a “fiercely competitive landscape” with a “median total compensation at private healthcare companies [of] \$325,000, compared to \$400,000 at public companies. Total compensation at private life sciences companies is \$431,000 versus \$478,000 at public companies.”<sup>104</sup>

Because these in-house jobs involve providing legal advice to clients, the states where the lawyers work require that they have an active license to practice law.<sup>105</sup> Violations of these rules can lead to a criminal charge for the “unauthorized practice of law.”<sup>106</sup> They can also result in a disciplinary referral to the state where they are licensed or serve as a barrier to future licensure.<sup>107</sup> Advertisements for in-house lawyers,

<sup>98</sup>Note, there are so many excellent law firms in the United States that work in the area of healthcare compliance that to mention any one of them is to leave out others of equal quality. See e.g., *HealthEdge Blog*, HEALTHEDGE, <https://healthedge.com/resources/blog> (last visited Jun 24, 2024); *Best Law Firms for Health Care Law*, VAULT, <https://legacy.vault.com/best-companies-to-work-for/law/best-law-firms-in-each-practice-area/health-care> (last visited July 21, 2024); *Healthcare Law Firms*, <https://law.usnews.com/law-firms/practice-area/healthcare> (last visited Aug. 5, 2024).

<sup>99</sup>*Healthcare Regulatory*, LATHAM & WATKINS LLP, <https://www.lw.com/en/practices/healthcare-regulatory> (last visited July 21, 2024).

<sup>100</sup>*People*, LATHAM & WATKINS LLP, <https://www.lw.com/people> (last visited Oct. 22, 2024).

<sup>101</sup>See BARKERGILMORE, 2023 HEALTHCARE AND LIFE SCIENCES IN-HOUSE AND COMPLIANCE COMPENSATION REPORT 3–5 (2023), <https://bg.barkergilmore.com/hubfs/2023/research/BarkerGilmore-2023-Healthcare-and-Life-Sciences-In-House-and-Compliance-Compensation-Report.pdf> (discussing compensation trends for General Counsel, Managing Counsel, and Senior Counsel positions and noting that “[a]fter extensive statistical analysis of the survey data, JD School, law firm experience, and practice area appear to impact compensation significantly for all three positions”).

<sup>102</sup>ASS’N OF CORP. COUNS., BECOMING IN-HOUSE COUNSEL: A GUIDE FOR LAW STUDENTS AND RECENT GRADUATES 19 (2013), [https://www.acc.com/sites/default/files/resources/vl/membersonly/InfoPAK/19654\\_2.pdf](https://www.acc.com/sites/default/files/resources/vl/membersonly/InfoPAK/19654_2.pdf).

<sup>103</sup>Jonathan Wylie, *The Swell of the In-House Legal Department*, MAJOR LINDSEY & AFRICA (Feb. 27, 2024), <https://www.mlaglobal.com/en/insights/articles/the-swell-of-the-in-house-legal-department>.

<sup>104</sup>*Study Reveals Healthcare General Counsel at Public Companies Make Double the Total Compensation of Private Company Counterparts*, BARKERGILMORE (Aug. 22, 2023), <https://www.barkergilmore.com/newsroom/study-reveals-healthcare-general-counsel-at-public-companies-make-double-the-total-compensation-of-private-company-counterparts/>.

<sup>105</sup>See, e.g., John E. Iole, *State Bar Compliance: In-House Counsel Beware*, CORP. COUNS. BUS. J., (Dec. 1, 2006) <https://ccbjournal.com/articles/state-bar-compliance-house-counsel-beware>.

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

<sup>107</sup>See *Navigating Multistate Practice for In-House Counsel*, ASS’N OF CORP. COUNS. (Sept. 22, 2023), <https://www.acc.com/resource-library/navigating-multistate-practice-house-counsel>; Peter Horvath, *How to Salvage Your Legal Career After Disciplinary Actions*, VAULT (Mar. 8, 2023), <https://vault.com/blogs/vaults-law-blog-legal-careers-and-industry-news/how-to-salvage-your-legal-career-after-disciplinary-actions>.

like this one from Vault Health, indicate this requirement directly: “[m]ust have a J.D. degree from an ABA-approved law school and be an active member of the Bar in good standing”<sup>108</sup>

### *J.D. Preferred, Licensure not Required*

While “in-house counsel” as a term refers to lawyers who are, according to the rules of the state where they work, actively practicing law, there is a much larger and less defined category of jobs for people knowledgeable about regulation, but not requiring active law degrees or licensure. The National Association for Law Placement calls these “JD Advantage Jobs.”<sup>109</sup> These are jobs that for “which the employer is seeking an individual who has a J.D., but the position itself does not require admission to the bar or a law license. These are law related positions in which knowledge of the law is part of the job, but the job itself does not require bar admission.”<sup>110</sup> These jobs are also called “JD preferred” because neither a law degree nor admission to the bar is among the “require[d]” criteria for hiring.<sup>111</sup> For example, a job posted in July 2024 by UF Health’s Shands Hospital (Jacksonville, FL) advertised for a compliance specialist “[t]o ensure compliance with applicable legal and regulatory requirements, and to promote ethics within the hospital” identifies the “educational qualifications” as “Bachelor’s Degree Required; Preferred Education: Master’s or J.D., MD, PhD, HIM, RN.”<sup>112</sup>

There is no single source of information to track J.D. Advantage jobs, whether in general or specific to health care. There are anecdotal reports that the market for recent law school graduates in compliance jobs that do not require law degrees is not as strong as had been hoped. A 2022 report by the NALP using 2020 data showed that while “the percentage of jobs taken by law school graduates which are JD Advantage” went “from 8.8% of all jobs in 2006 to 16.9% of jobs in 2016,” that trend is now going in the other direction.<sup>113</sup> Only 11.8% of the Class of 2020 enrolled in J.D. Advantage jobs, a drop of “more than 5 percentage points.”<sup>114</sup> There is no explanation offered for why this dropped happened or whether some industries were more affected than others.<sup>115</sup>

### *No J.D. Needed or Preferred*

The final category of jobs related to compliance neither require nor necessarily prefer a person with a law degree.<sup>116</sup> As one consulting firm explains, the difference in roles between “Compliance Officers” and “lawyers” is that “Compliance officers are more involved in the day-to-day operations and

<sup>108</sup>Google search “jobs in healthcare compliance with jd degree”, <https://g.co/kgs/3ss7w83> (last visited June 14, 2024). See *About Vault Workforce Screening*, <https://geebo.com/jobs-online/view/id/1003830329-health-care-regulatory-attorney-/> (last visited July 24, 2024) (“Vault Health, a company that provides drug screening services for employers, seeking “a seasoned Associate General Counsel to help us through the next phase of our company’s growth and expansion. The ideal candidate will have 3-5 years of experience in healthcare and life sciences (HCLS) law and a focus on regulatory and compliance, regulatory submissions; healthcare licensing regulations, SaMD, telemedicine.” “Certification in Healthcare Compliance or Compliance is preferred”) [<https://perma.cc/X4R9-HXAQ>].

<sup>109</sup>See *What We Know About JD Advantage Jobs - An Update for the Class of 2020*, NAT’L ASS’N FOR L. PLACEMENT (Jan. 2022), <https://www.nalp.org/0122research>.

<sup>110</sup>Hillary Mantis, *What Is a J.D. Advantage Career?*, NAT’L JURIST (Dec. 3, 2015, 12:50 PM), <https://nationaljurist.com/national-jurist-magazine/what-jd-advantage-career/>.

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

<sup>112</sup>*Compliance Spec*; FT M-F 8am-5pm, INDEED, <https://www.indeed.com/viewjob?jk=8964a8753ad5a7c7&tk=1i0trg8g2k6qt8cu&from=serp&vjs=3> (last visited July 21, 2024) (also “preferred” were “Any of the following healthcare related certifications: CHC, CPC / CPC-H, CCS, CIPP, CPMA, CPA, RHIA or RHIT, LLM, LHRM. Additional preferred education/degrees: JD, CPA, MBA, MHA, MSM”).

<sup>113</sup>See *What We Know About JD Advantage Jobs - An Update for the Class of 2020*, *supra* note 109.

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

<sup>115</sup>One of my recommendations in this essay is that law schools themselves take a more direct role in tracking the careers of their students holding JD preferred positions.

<sup>116</sup>There is no externally recognized distinction between “JD preferred” positions and those that state no preference for a J.D.



implementation of compliance programs, focusing on prevention and education,” while “compliance lawyers are typically consulted for legal advice, and representation, and to address compliance issues after they have arisen.”<sup>117</sup> These “no JD degree required” jobs may be positions in compliance, or they could be executive positions that require knowledge of regulatory issues.<sup>118</sup> Even clinicians need knowledge of the regulations governing their work.<sup>119</sup> Given the variety in job responsibilities, what these jobs are called and what the people holding them do varies considerably. One category, as outlined by guidance from the U.S. Sentencing Commission Guidelines, consists of people who are designated to have “day-to-day operational responsibility for the compliance and ethics program.”<sup>120</sup> Such a role is “not merely a recommendation but a requirement,” practically speaking.<sup>121</sup> But the need for knowledge of healthcare compliance requirements can extend beyond those administrators with direct responsibility for operating compliance programs.<sup>122</sup>

### Health Law Instruction in American Law Schools

Having reported on the likelihood that the Supreme Court’s recent anti-regulatory decisions will increase demand for those with legal training and described the development of the healthcare compliance industry, I now turn to the role of U.S. law schools in meeting this demand.

“Health Law” as a field of instruction or study is relatively new.<sup>123</sup> Professor Mark Hall noted, in 2006, that law schools had been offering classes in “health law” or “law and medicine...for decades,” and that health law “as a legal academic field” began with “William Curran’s 1960 publication of the first casebook.”<sup>124</sup> Three years later, in 2009, Professor Wendy Mariner took on the “challenge” of describing

<sup>117</sup>See *Understanding the Role of Compliance in Healthcare: Officers vs. Lawyers*, CHAPMAN CONSULTING GRP., <https://www.ccghealthcare.com/compliance-officer-vs-compliance-lawyer> (last visited Oct. 22, 2024).

<sup>118</sup>See *id.*; Becca van Sambeck, *What Are the Top Legal Jobs You Can Land Without Obtaining a JD Degree?*, UNIV. OF S. CAL. ONLINE (Oct. 31, 2023), <https://online.usc.edu/news/top-legal-jobs-without-jd-non-lawyer-careers/>.

<sup>119</sup>See *Physician Leadership Matters: The Importance of Understanding the Regulatory and Legal Aspects of Healthcare*, AMERICAN ASSOCIATION FOR PHYSICIAN LEADERSHIP - Inspiring Change. Together, AM. ASS’N FOR PHYSICIAN LEADERSHIP (Sept. 29, 2023), <https://www.physicianleaders.org/about/press-room/physician-leadership-matters-the-importance-of-understanding-the-regulatory> (“Yet they need a working understanding of healthcare regulations and employment laws, which can significantly impact their medical practice life, potentially leading to the loss of their medical license, harm to their reputation, and civil or criminal penalties.”).

<sup>120</sup>U.S. SENT’G GUIDELINES MANUAL § 8B2.1 (U.S. SENT’G COMM’N 2023).

<sup>121</sup>See *Understanding the Role of Compliance in Healthcare: Officers vs. Lawyers*, *supra* note 117. Strictly speaking, for those entities not legally required to have compliance and ethics programs, the HHS OIG guidance regarding compliance programs only makes a strong recommendation that entities have a dedicated Compliance Officer. See GENERAL COMPLIANCE PROGRAM GUIDANCE, *supra* note 28, at 37.

<sup>122</sup>See, e.g., Andrei M. Constantino, *Why an Alliance Between Compliance and Leadership in Health Care Is Crucial*, HEALTH PROGRESS, Spring 2024, AT 33, 33 (2024), [https://www.chausa.org/docs/default-source/health-progress/why-an-alliance-between-compliance-and-leadership-in-health-care-is-crucial.pdf?sfvrsn=f46adb2\\_1](https://www.chausa.org/docs/default-source/health-progress/why-an-alliance-between-compliance-and-leadership-in-health-care-is-crucial.pdf?sfvrsn=f46adb2_1) (“To navigate the complex landscape of health care regulations and to ensure high-quality care, health care organizations must foster a strong partnership between their compliance teams and other leadership”).

<sup>123</sup>See, e.g., Einer R. Elhauge, *Can Health Law Become a Coherent Field of Law?*, 41 WAKE FOREST L. REV. 365, 365 (2006) (“I want to concede at the outset that health law, today, is not yet a coherent field of law. It is, rather, a disjointed set of statutes and doctrines, designed mainly with nonmedical cases in mind, based on different principles and paradigms, which are applied to health care issues in a way that not only lacks coordination but results in each undermining the other.”); see also Theodore W. Ruger, *Health Law’s Coherence Anxiety*, 96 GEO. L.J. 625, 627 (2008) (“Health law flunks most of the classical attributes of field coherence. It is a mishmash of various legal forms, applied by divergent and often colliding institutions, and has developed much more often through external pressures and even historical accidents than from any determinate internal evolution or refinement.”).

<sup>124</sup>See Mark A. Hall, *The History and Future of Health Care Law: An Essentialist View*, 41 WAKE FOREST L. REV. 347, 354 (2006) (citing Elmer D. Brothers, MEDICAL JURISPRUDENCE: A STATEMENT OF THE LAW OF FORENSIC MEDICINE (1914)) (“I have found only one earlier published teaching text written primarily for law students rather than practitioners the author of this earlier text was a practicing lawyer in Chicago who lectured at John Marshall Law School. The 276-page book consisted of the following topics in these proportions: evidence and procedure, 20%; forensics, 17%; fiduciary relationship, 25%; malpractice, 26%; and regulation, 12%.”)

“the health law field as a whole” and “as separate from other fields of law.”<sup>125</sup> In so doing, she identified “two major challenges: (1) the range of legal issues the field covers; and (2) the fact that many doctrines formerly unique to medicine have given way to more general principles from other legal domains.”<sup>126</sup> After careful review of these issues and doctrines, she concluded that “[h]ealth law is an eclectic and integrated translegal field, drawing on multiple domains of law to create an identifiable applied field of law. It applies and adapts existing law to protect health within the constraints of justice and human rights.”<sup>127</sup>

### From Health Law to Healthcare Compliance

In 2017, Professor Peter L. Lindseth, director of UConn’s Professional Certificate Program in Corporate and Regulatory Compliance, then described “[t]he proliferation of compliance programs in US law schools over the last several years” as a “[r]espon[se] to a fundamental shift in the market for law graduates.”<sup>128</sup> Looking backwards, he explained that “[t]he last two decades have seen a dramatic increase in the number of jobs for in-house lawyers, far outpacing the growth in government or law firm positions over the same period.”<sup>129</sup> Attributing this to “[t]he expanding compliance demands on businesses,” he concluded that “[a]lthough today some argue that the growth may have peaked, there is no denying that law schools have needed to respond to the new reality.”<sup>130</sup> It is evident that many law schools have done so by developing health law programs and offering certificates in healthcare compliance.<sup>131</sup>

For the rest of this article, I will describe and discuss what law schools in the United States offer students interested in the field of healthcare compliance. Primarily, these offerings are in the form of programs for law students enrolled in their J.D. programs and for healthcare compliance professionals who are seeking master’s degrees or certificates in healthcare compliance law, but not a law degree.

### The Role of External, CCB Accreditation in Law School Healthcare Compliance Programs

It is common for both J.D.-required and J.D.-preferred jobs in healthcare compliance to list “Certification in Healthcare Compliance” as an additional credential.<sup>132</sup> This credential usually refers to certificates offered through a collaboration between the Society of Corporate Compliance and Ethics® (“SCCE”)<sup>133</sup> and the Healthcare Compliance Association® (“HCCA”).<sup>134</sup>

In recognition of the value of this credential to healthcare compliance professionals, fourteen U.S. law schools have become “accredited”<sup>135</sup> by the Compliance Certification Board (“CCB”) to offer their

<sup>125</sup>Wendy K. Mariner, *Toward an Architecture of Health Law*, 35 AM. J.L. & MED. 67, 68 (2009).

<sup>126</sup>*Id.*

<sup>127</sup>*Id.* at 86.

<sup>128</sup>Peter L. Lindseth, *Compliance and Legal Education: Reflections on the Transformative Potential*, N.Y. UNIV. SCH. OF L. (Aug. 10, 2017), [https://wp.nyu.edu/compliance\\_enforcement/2017/08/10/compliance-and-legal-education-reflections-on-the-transformative-potential/](https://wp.nyu.edu/compliance_enforcement/2017/08/10/compliance-and-legal-education-reflections-on-the-transformative-potential/). Professor Lindseth is the Olimpiad S. Ioffe Professor of International and Comparative Law and Director, Graduate, International, and Non-JD Programs at UCONN Law School. See Peter L. Lindseth, UNIV. OF CONN. SCH. OF L., <https://law.uconn.edu/person/peter-l-lindseth/> (last visited Oct. 23, 2024).

<sup>129</sup>See Lindseth, *supra* note 128.

<sup>130</sup>*Id.*

<sup>131</sup>See *supra* note 3 and accompanying text.

<sup>132</sup>See Emily Anderson, *Land a Job in Healthcare*, INDEED (July 30, 2024), <https://www.indeed.com/career-advice/career-development/how-to-get-health-care-compliance-certification>; *Compliance Spec*; FT M-F 8am-5pm, *supra* note 112.

<sup>133</sup>See *Become Certified*, SOC’Y OF CORP. COMPLIANCE & ETHICS, <https://www.corporatecompliance.org/certifications/become-certified> (last visited Oct. 23, 2024).

<sup>134</sup>See *About HCCA*, HEALTH CARE COMPLIANCE ASS’N, <https://www.hcca-info.org/about-hcca> (last visited Aug. 4, 2024).

<sup>135</sup>CCB Accredited University Compliance and Ethics Programs, SOC’Y OF CORP. COMPLIANCE & ETHICS, <https://www.corporatecompliance.org/university-program> (last visited Aug. 2, 2024).

students a “Certificate in Healthcare Compliance,” which creates an expedited pathway for their students to take the exam which leads to them being certified in “Healthcare Compliance.”<sup>136</sup> The terminology is unintentionally confusing, because while both of these credentials are called “certificates,” one is awarded by a specific law school and the other by an external credential entity.

The U.S. Department of Education distinguishes between “Certification” and an “Educational Certificate.”<sup>137</sup> The first is “[a] credential awarded by a certification body based on an individual demonstrating through an examination process that he or she has acquired the designated knowledge, skills, and abilities to perform a specific job.”<sup>138</sup> The second, an “Educational Certificate,” is “[a] credential awarded by an educational institution based on completion of all requirements for a program of study, including coursework and test or other performance evaluations. Certificates are typically awarded for life (like a degree).”<sup>139</sup> CCB certification, then, would fall under the first definition while a certificate offered by a law school itself is the second.<sup>140</sup>

The SCEE and HCCA work with the CCB “to develop criteria for the determination of competence in the practice of compliance at a variety of levels, and to recognize individuals meeting these criteria.”<sup>141</sup> As CCB explains, it offers “[c]ompliance certification by the profession, for the profession and of the profession.”<sup>142</sup> One of the certifications CCB offers is in “Healthcare Compliance.”<sup>143</sup> It is, therefore, more like the specialty certificates offered by state bar associations than a measure of minimal competence.<sup>144</sup>

This Certificate is designed to demonstrate competence among people who are already healthcare compliance professionals. CCB defines a “Compliance Professional” as someone with:

- “[A]t least one year in a full-time compliance position or 1,500 hours of direct compliance job duties earned in the two years preceding your application date; and
- “[J]ob duties directly relate to the tasks reflected in the ‘Detailed Content Outline’ on pages 22-24 of the Candidate Handbook.”<sup>145</sup>

<sup>136</sup>About CCB, Soc’y OF CORP. COMPLIANCE & ETHICS, <https://www.corporatecompliance.org/certification> (last visited Aug 4, 2024).

<sup>137</sup>See *Working Definitions of Non-Degree Credentials*, NAT’L CTR. FOR EDUC. STATS., <https://nces.ed.gov/surveys/gemena/definitions.asp> (last visited Aug 6, 2024).

<sup>138</sup>*Id.*

<sup>139</sup>*Id.*

<sup>140</sup>*Program Eligibility, Written Arrangements, and Distance Education*, FED. STUD. AID., <https://fsapartners.ed.gov/knowledge-center/fsa-handbook/2022-2023/vol2/ch2-program-eligibility-written-arrangements-and-distance-education> (last visited July 29, 2024); See SHARON A. BOIVIN & ISAAH L. O’REAR, NAT’L CTR. FOR EDUC. STAT., MEASUREMENT STRATEGIES FOR IDENTIFYING HOLDERS OF CERTIFICATES AND CERTIFICATIONS 2-3 (2012), <https://nces.ed.gov/surveys/gemena/pdf/FCSMpaper.pdf>.

<sup>141</sup>*Healthcare Certification SCCE Official Site*, SCCE, <https://www.corporatecompliance.org/certifications/become-certified/healthcare-certification> (last visited July 21, 2024). For example, American University’s Law School explains that they offer a Health Care Compliance Certificate to students in all three of the degrees they offer. This Certificate is awarded to “students who have completed a concentration of courses in health care law and compliance.” *Health Care Compliance Certificate Program*, AM. UNIV., <https://www.wcl.american.edu/impact/initiatives-programs/health/curriculum/compliance-certificate/> (last visited July 21, 2024).

<sup>142</sup>*Certified Compliance & Ethics Professional (CCEP)*, Soc’y OF CORP. COMPLIANCE & ETHICS, <https://www.corporatecompliance.org/certification/become-certified/ccep> (last visited Oct. 23, 2024).

<sup>143</sup>Note, CCB describes their credential by referring to the individual as “Certified in Healthcare Compliance (CHC)” rather than calling the credential a Health Law Certificate. *Certified in Healthcare Compliance (CHC)*, HEALTH CARE COMPLIANCE ASS’N, <https://www.hcca-info.org/certification/become-certified/chc> (last visited Oct. 24, 2024); see also *Become Certified*, Soc’y OF CORP. COMPLIANCE & ETHICS, <https://www.corporatecompliance.org/certifications/become-certified> (last visited Oct. 24, 2024) (explaining “a certificate program from a CCB-accredited university within the last two years” is the only way to be “exempt from the work experience requirement, and can apply to sit for a CCB certification examination, provided the examination is taken within 12 months of successfully completing the CCB-accredited university program”).

<sup>144</sup>See, e.g., *Certification: Attorney and Paralegal Certification Programs*, OHIO BAR, <https://www.ohiobar.org/cle-certification/certification/> (last visited Aug. 4, 2024).

<sup>145</sup>*Become Certified*, *supra* note 143.

But this work criteria is waived for students who complete a Certificate of Healthcare Compliance in a CCB-accredited school.<sup>146</sup> Seton Hall University's Law School advertises that it "cooperates with the CCB as well as offering its own extensive array of programs in healthcare compliance."<sup>147</sup> MitchellHamline Law School encourages "all qualified program graduates ... to take the Compliance Certification Board's (CCB) Certified in Healthcare Compliance Exam."<sup>148</sup> It also offers its students "access to [its own] proprietary *CHC Exam Toolkit* featuring tips from ... alumni."<sup>149</sup>

The value, then, of getting a Certificate from a CCB-accredited Law School program is twofold. First, for students who are not yet working in healthcare compliance, it is the only path to taking the exam without relevant work experience.<sup>150</sup> Second, it provides a structured program of study that satisfies at least part of the 20-hour continuing education requirement.<sup>151</sup>

Since 13 of the 21 academic programs accredited by the CCB are law schools,<sup>152</sup> it seems likely that it is only law students, not former law students working in other disciplines and seeking new areas of practice, who have the greatest interest in taking the exam without the otherwise required work experience. It is therefore reasonable to ask whether being certified without previous work experience enhances the employment opportunities for these law students. One reason to think it does is that while these students may not have had prior careers in Healthcare Compliance, they are able to obtain relevant experience while in law school.

### J.D. Programs

The 2024 UNWR law school specialty rankings list 191 of the "nearly 200 [ABA recognized law schools]" self-reporting that they offered a "health care law" program.<sup>153</sup> While UNWR provides no definition of the word "program," the large number suggests that almost all U.S. law schools are now offering at least one class falling under the banner of "health law" as part of their J.D. curriculum.<sup>154</sup> A closer look at this list shows that many schools are doing much more than offering one course and, following BU's lead, have made a substantial investment in health law.<sup>155</sup> In looking at the history of the development of health law programs, there is evidence that not many "focus[ed] heavily in the areas of regulatory and

<sup>146</sup>See *id.*

<sup>147</sup>See *How To Get Certified In Health Care Compliance*, UNIV. OF PITTSBURGH SCH. OF L. (Mar. 20, 2023), <https://online.law.pitt.edu/blog/how-to-get-certified-in-health-care-compliance> (last visited July 31, 2024) ("If you successfully complete a graduate certificate program offered by a CCB-accredited university, you will be qualified to take several certification exams...").

<sup>148</sup>*Health Care Compliance Certificate*, MITCHELL HAMLINE SCH. OF L., <https://mitchellhamline.edu/health-law-institute/certificates/health-care-compliance-certificate/> (last visited Aug. 6, 2024).

<sup>149</sup>*Id.*

<sup>150</sup>See *Become Certified*, *supra* note 143.

<sup>151</sup>See, e.g., *Graduate Certificate in Health Care Compliance*, DREXEL UNIV., <https://www.online.drexel.edu/online-degrees/law-degrees/cert-hc-comp/index.aspx> ("Completion of the Kline School of Law's Master of Legal Studies or Graduate Certificate in Health Care Compliance programs with a GPA of 3.0 or higher fulfills the professional work experience and continuing education units (CEU) requirements within applicable eligibility time frames per candidate handbook, allowing you to be eligible to sit for a CCB exam.")

<sup>152</sup>See *CCB Accredited University Compliance and Ethics Programs*, *supra* note 135.

<sup>153</sup>Morse & Brooks, *supra* note 3; see also Galarita, *supra* note 3; *Health Law*, *supra* note 3.

<sup>154</sup>See *Best Health Care Law Programs*, U.S. NEWS & WORLD REP., [https://www.usnews.com/best-graduate-schools/top-law-schools/clinical-healthcare-law-rankings?\\_sort=my\\_rankings-asc](https://www.usnews.com/best-graduate-schools/top-law-schools/clinical-healthcare-law-rankings?_sort=my_rankings-asc) (last visited July 21, 2024). It is important to note that this specialty ranking list is based on programs offered to J.D. students and is based exclusively on the votes of other law school professors and makes no claim to any independent investigation into the content of the program or success in job placement. See Morse & Brooks, *supra* note 3. Schools seeking a spot on the list produce elaborate marketing materials designed to inform and influence the voters. So, while to a large extent this list may reflect only what a school's voters have "heard of," in fact today most schools earning a spot have made an investment in faculty and programming beyond grouping together classes already taught into a pathway to a career in health law.

<sup>155</sup>See *Best 10 Law Schools for Health Care Law*, KAPLAN, <https://www.kaptest.com/study/lSAT/best-10-law-schools-for-health-care-law/> (last visited Aug. 6, 2024).

transactional health care.”<sup>156</sup> It is difficult to tell when and to what extent these programs began using the term “healthcare compliance” to describe parts of their curriculum. In 2014, a report by the American Health Law Association which both surveyed practitioners and law schools and provided a model health law curriculum used the word frequently.<sup>157</sup> The portion of the report reflecting employers’ perspectives noted “that 89.2% of respondents reported that their practice includes Compliance” and commented that “[g]iven the complexity and pervasiveness of regulatory issues, it is not surprising” that this percentage was as high as it was.<sup>158</sup> A review of the UNWR top health law programs shows that Healthcare Compliance’s place in the curriculum is secure.<sup>159</sup> At least 13 law schools offer Certificates in Healthcare Compliance.<sup>160</sup>

### Law School Programs That Do Not Lead to Law Degrees

In addition to programs leading to legal degrees, many U.S. law schools offer master’s degrees and certificates designed for people who do not have and are not seeking a J.D.<sup>161</sup> Several law schools offer advanced law degrees specific to health law.<sup>162</sup> But the focus of this essay is on master’s degree programs in healthcare compliance designed for people who are not seeking a law degree.<sup>163</sup>

### Master’s degrees in Healthcare Compliance

The “Standards” set by the Council on Legal Education (the “Council”), a division of the American Bar Association (the “ABA”), only apply to J.D. degrees.<sup>164</sup> While law schools seeking to offer degrees other than the J.D. are required to inform the Council of their intent to offer additional degrees, the Council’s only role is to “determine[e] whether the proposed degree program will interfere with the ability of the

<sup>156</sup>Lawrence E. Singer & Megan Bess, Column, *Teaching Health Law: Combining Pedagogy and Practice: Creating a 21st Century Health Law Curriculum*, 37 J.L. MED. & ETHICS 852, 853 (2009) (noting that the Beazley Institute for Health Law and Policy, Loyola University Chicago’s Law School’s choice, in 1984, to focus on business and regulatory law constituted a focus on a “unique niche in health law”).

<sup>157</sup>See generally AM. HEALTH LAWS. ASS’N, THE AHLA HEALTH LAW CURRICULUM MANUAL (2014), [https://thaddeuspope.com/images/AHLA\\_HEALTH\\_LAW\\_CURRICULUM.pdf](https://thaddeuspope.com/images/AHLA_HEALTH_LAW_CURRICULUM.pdf). Note, even though this document is now ten years old and is no longer available on AHLA’s website, it remains helpful both for historic purposes and as a reference.

<sup>158</sup>*Id.* at 6.

<sup>159</sup>See *Best Health Care Law Programs*, *supra* note 154; see also, e.g., *Compliance Studies*, LOYOLA UNIV. CHI. SCH. OF L., <https://www.luc.edu/law/academics/areasofstudy/specializations/compliancestudies/> (last visited Oct. 24, 2024); *Health Care Corporate Compliance*, BOS. UNIV. SCH. OF L., <https://www.bu.edu/law/courses/lawjd745/> (last visited Oct. 24, 2024); *Healthcare Compliance*, NE. UNIV. GRADUATE PROGRAMS, <https://graduate.northeastern.edu/program/graduate-certificate-in-healthcare-compliance-17756/> (last visited Oct. 24, 2024).

<sup>160</sup>See CCB Accredited University Compliance and Ethics Programs, *supra* note 135.

<sup>161</sup>See, e.g., *Graduate Programs*, YALE L. SCH., <https://law.yale.edu/study-law-yale/degree-programs/graduate-programs> (“Yale Law School offers a Master of Studies in Law (M.S.L.) degree program for a small number of non-lawyers who seek to obtain a basic familiarity with legal thought and to explore the relation of law to their disciplines. It is a one-year terminal program designed for those who do not desire a professional law degree, but who are interested in a rigorous curriculum and grounding in legal studies.”) (last visited Aug. 5, 2024).

<sup>162</sup>See *LLM Programs in Health Law / Medical Law - United States*, LLM GUIDE, <https://llm-guide.com/schools/usa/concentration/health-law-medical-law> (last visited July 29, 2024); see also, e.g., *University of Houston Law Center LL.M. Program - Health Law LL.M.*, UNIV. OF HOUS. L. CTR., <https://www.law.uh.edu/llm/health.asp> (last visited July 29, 2024).

<sup>163</sup>See, e.g., *Healthcare Law: Program Overview*, UNIV. OF OKLA. COLL. OF L., <https://lawonline.ou.edu/healthcare-law> (last visited July 29, 2024) (“OU College of Law has designed programs for both nonlawyers and lawyers to master the complexity of Healthcare Law.”).

<sup>164</sup>See AM. BAR ASS’N, STANDARDS AND RULES OF PROCEDURE FOR APPROVAL OF LAW SCHOOLS 2024–2025 ix–x (2024), [https://www.americanbar.org/content/dam/aba/administrative/legal\\_education\\_and\\_admissions\\_to\\_the\\_bar/standards/2024-2025/2024-2025-standards-and-rules-for-approval-of-law-schools.pdf](https://www.americanbar.org/content/dam/aba/administrative/legal_education_and_admissions_to_the_bar/standards/2024-2025/2024-2025-standards-and-rules-for-approval-of-law-schools.pdf) (“‘J.D. degree’ means the professional degree in law granted upon completion of a program of legal education that is governed by the Standards.”).



law school to ... carry out its program of legal education” in “compliance with the standards” for J.D. programs.<sup>165</sup> Among these programs, several are specific to healthcare compliance.<sup>166</sup> These are, as the schools offering them explain, “directed at educating working professionals seeking to enhance their knowledge in Compliance and Risk Management while gaining a comprehensive understanding of how the law intersects with and applies to this field.”<sup>167</sup> Without the oversight of the Council, law schools’ “non-J.D. degree programs” are “subject to the oversight of the law school’s or its university’s national accreditor.”<sup>168</sup>

If the Council determines that the additional degree program will not interfere with the J.D. program, it “acquiesces” to its being offered.<sup>169</sup> This is not, however, “approval of the degree itself and, therefore, the law school may not announce that the degree is approved by the Council.”<sup>170</sup> Therefore, “the content and requirements of those degrees, such as an LL.M., are created by the law school itself and do not reflect any judgment by the ABA accrediting bodies regarding the quality of the program.”<sup>171</sup>

That lack of direct oversight by the ABA allows law schools considerable flexibility in offering programs other than the J.D. It also, however, puts these programs outside of the jurisdiction of organizations that while not regulatory, track and set voluntary standards for ABA-recognized law schools.

This extends not just to the curriculum, but to all the standards for operation that apply to law schools. For example, MLS and Certificate programs can be offered entirely online, even though J.D. degrees (so far) cannot.<sup>172</sup> Each school can also set its own criteria for admissions without concern about the ABA’s requirements which require law schools to “only admit applicants who appear capable of satisfactorily completing its program of legal education and being admitted to the bar.”<sup>173</sup> If the law school is granting a master’s degree, it must comply with the general rules of the university with which it is associated.<sup>174</sup>

Although both master’s Degrees and Certificates are largely untethered from ABA regulation, law schools are usually bound by the rules that apply to degree granting programs at their university or in their state. For example, Cleveland State University’s School of Law MSL’s home page states that “MLS students pay graduate tuition rate. Graduate tuition is \$616.50 per credit hour for Ohio residents (\$1,058.20 for non-residents).<sup>175</sup> Finally, law schools can, again depending on the rules of their university, choose not to disclose tuition at all.

At least one law school offering MSL degrees specific to healthcare compliance is careful to advise students that while the MSL “does not qualify graduates to take a bar exam or to practice law as an

<sup>165</sup>Overview of Post J.D. and Non-J.D. Programs, AM. BAR ASS’N, [https://www.americanbar.org/groups/legal\\_education/resources/llm-degrees\\_post\\_j\\_d\\_non\\_j\\_d/](https://www.americanbar.org/groups/legal_education/resources/llm-degrees_post_j_d_non_j_d/) (last visited Oct. 24, 2024).

<sup>166</sup>See, e.g., *The Best Healthcare Compliance Jobs You Can Land after Earning Your MLS Degree*, SEATTLE UNIV. SCH. OF LAW, <https://onlinelaw.seattleu.edu/blog/best-healthcare-compliance-jobs/> (last visited July 24, 2024).

<sup>167</sup>FAQ: Seattle University School of Law Online MLS in Compliance and Risk Management, SEATTLE UNIV. SCH. OF L., <https://onlinelaw.seattleu.edu/faq/> (last visited Oct. 24, 2024).

<sup>168</sup>See Overview of Post J.D. and Non-J.D. Programs, *supra* note 165.

<sup>169</sup>*Id.*

<sup>170</sup>*Id.*

<sup>171</sup>*Id.*

<sup>172</sup>Julianne Hill, *Journey Toward Fully Online Law Schools Inches Forward After ABA Legal Ed Council Vote*, AM. BAR ASS’N J. (May 20, 2024, 2:34 PM CDT), <https://www.abajournal.com/web/article/journey-toward-fully-online-law-schools-inches-forward-after-aba-council-vote> (“Currently, ABA standards state that only law schools with brick-and-mortar campuses can become accredited, and only fully accredited schools can apply to offer a fully online JD programs [sic]. That excludes online law schools starting from scratch.”).

<sup>173</sup>STANDARDS AND RULES OF PROCEDURE FOR APPROVAL OF LAW SCHOOLS 2024–2025, *supra* note 164, at 35.

<sup>174</sup>See, e.g., *Admission Requirements: Master of Legal Studies*, UNIV. OF CINCINNATI ONLINE, <https://online.uc.edu/masters-programs/master-legal-studies/admissions/> (last visited July 21, 2024) (setting out University of Cincinnati’s admission “prerequisites” and noting that standardized test scores, including the LSAT, are optional).

<sup>175</sup>*Admissions: Master of Legal Studies*, CLEVELAND STATE UNIV. SCH. OF L., <https://www.law.csuohio.edu/admissions/mls> (last visited July 21, 2024).

attorney in any jurisdiction,” it is “designed for professionals who desire a comprehensive knowledge of law, policy, and principles in compliance and risk management, but do not require a JD degree to accomplish their goals.”<sup>176</sup>

But even though these statements are clear in making the distinction between a degree that qualifies a student to take the bar exam and become a licensed attorney and one that does not, the fact that Master of Studies in law degrees are offered by ABA-recognized law schools may be confusing to students. For example, edX, a “global online learning platform that exists to help learners everywhere unlock their potential,”<sup>177</sup> hosts a website that offers a list of “**Accredited Master of Legal Studies (MLS) Programs.**”<sup>178</sup> edX explains, correctly, that “[m]any MLS programs and related law degrees are recognized by the American Bar Association (ABA) by way of ‘acquiescence.’”<sup>179</sup> But it then goes on to incorrectly advise that “ABA-recognition for MLS programs may help prospective students understand that a program is affirmed by rigorous academic and career standards.”<sup>180</sup> It then correctly notes that “[i]t is important to note that the ABA does not grant accreditation to any non-Juris Doctor (J.D.) or post-J.D. programs.”<sup>181</sup> The distinction edX seems to be drawing is between MLS programs offered by ABA-recognized law schools and those that are offered by schools not affiliated with a law school.

But the implication that the ABA’s recognition of a law school or even “acquiescence” toward that law school having additional degree or certificate programs is an indication of those programs’ quality is absolutely false. As the ABA explains, although a law school operating an MSL or Certificate Program may be recognized by the ABA for adhering to these Standards,<sup>182</sup> the Council “does not...accredit or approve non-J.D. degrees or certificates.”<sup>183</sup> Moreover, a statement of “acquiescence” means only that the ABA has determined that the additional program will not be a drain on the resources of the J.D. program.<sup>184</sup>

Another source of possible confusion is that law schools offering master’s Degrees or Certificates may advertise that they are “accredited” by CBB.<sup>185</sup> Prospective students may not know that this “accreditation” is limited to that specific program. Moreover, while CBB accreditation is the only way to for a prospective examinee to get a waiver of the work experience requirement, CBB does not require the continuing education credits come from an accredited program.<sup>186</sup>

<sup>176</sup>FAQ: Seattle University School of Law Online MLS in Compliance and Risk Management, *supra* note 167; see also Overview of Post J.D. and Non-J.D. Programs, *supra* note 165 (“The Council of the Section of Legal Education and Admissions to the Bar has adopted a statement that no post-J.D. or other degree program is a substitute for the J.D. and should not be considered the equivalent of the J.D. for bar admission purposes.”)

<sup>177</sup>About edX, A 2U Company, PUB. HEALTH DEGREES, <https://www.publichealthdegrees.org/about> (last visited Oct. 25, 2024).

<sup>178</sup>See Accredited Master of Legal Studies Programs, ONLINE MASTER OF LEGAL STUD. PROGRAMS WITH EDX, <https://onlinemasteroflegalstudies.com/mls-degrees/accredited/> (last visited July 21, 2024).

<sup>179</sup>*Id.*

<sup>180</sup>*Id.*

<sup>181</sup>*Id.*

<sup>182</sup>See ABA-Approved Law Schools, AM. BAR ASS’N, [https://www.americanbar.org/groups/legal\\_education/resources/aba\\_approved\\_law\\_schools/](https://www.americanbar.org/groups/legal_education/resources/aba_approved_law_schools/) (last visited July 21, 2024).

<sup>183</sup>Overview of Post J.D. and Non-J.D. Programs, *supra* note 165.

<sup>184</sup>See *id.* (“Standard 313 of the ABA Standards for Approval of Law Schools states that an ABA-approved law school may not establish a degree program other than its J.D. degree program unless the school is fully approved, and the additional degree program will not detract from a law school’s ability to maintain a sound J.D. degree program. The school must obtain acquiescence prior to commencing such a program. The ABA does not formally approve any program other than the first degree in law (J.D.).”)

<sup>185</sup>See, e.g., Compliance Certification (CCB) Accreditation, UNIV. OF S. CAL. GOULD SCH. OF L., <https://gould.usc.edu/academics/certificates/ccb/> (last visited Nov. 6, 2024).

<sup>186</sup>See How to Earn CEUs, HEALTH CARE COMPLIANCE ASS’N, <https://www.hcca-info.org/certification/continuing-education-units-ceus/how-earn-ceus> (last visited Aug. 6, 2024) (“CCB accepts relevant CEUs from any organization or event sponsor.”).

### Educational Certificate Programs for Non-Lawyers

In addition to offering master's degrees to non-lawyers, many law schools have now developed certificate programs for professionals already working in regulated fields like healthcare.

These programs are designed specifically for “non-lawyers who work in fields where legal knowledge would enhance their occupational success and satisfaction.”<sup>187</sup> Some schools offer students an opportunity to obtain a certificate in healthcare compliance by taking the same classes as the master's degree program.<sup>188</sup>

While the majority of programs seem to be entirely online, some offer in-person instruction.<sup>189</sup> For example, Seton Hall Law School offers a four-day, in-person Healthcare Compliance Certificate program not just at its home campus but also in other locations around the world.<sup>190</sup> Attesting to the value of Program, George Peters, Vice President of Quality Systems and Chief Compliance Officer at Flowonix, said that “[a]s someone new to the world of compliance, this certification program featured a comprehensive syllabus and offered a wealth of knowledge across a broad spectrum of topics.”<sup>191</sup>

### Observations and Recommendations

With respect to the *Loper Bright* ruling, I am optimistic that it is not the end of federal regulation of health law. Limits on deference to ambiguous interpretations of federal law should not mean that any agency decision is ripe for second guessing by any federal judge.<sup>192</sup> Nor does *Loper Bright*, or the Court's other anti-regulatory decisions, mean that Congress can no longer use its enumerated powers to fund programs that provide healthcare services or regulate activity related to healthcare that affects interstate commerce.<sup>193</sup> That being said, while I doubt I could find support for the statement that these decisions alone interfering with Congress' efforts to manage the health programs on which so many people rely have played a central role in serious efforts to curb judicial overreach, I predict that their disruptive consequences over the next few years will only add fuel to the fire.<sup>194</sup>

Law schools, and law professors, have a big role to play in shaping what is likely to be a period of considerable post-*Loper Bright* litigation.<sup>195</sup> As scholars and advocates for sound public policy, health

<sup>187</sup>See, e.g., *Graduate Certificate Programs*, UNIV. OF CINCINNATI COLL. OF L., <https://law.uc.edu/education/academic-programs/graduate-certificates.html> (last visited Oct. 25, 2024); see also generally CCB Accredited University Compliance and Ethics Programs, *supra* note 135 (providing a list of universities which have received accreditation, though there is no further information on the programs they offer that lead to Healthcare Compliance Certificates).

<sup>188</sup>See, e.g., *Compliance Law Certificate – Online*, UNIV. OF S. CAL. GOULD SCH. OF L., <https://gould.usc.edu/academics/certificates/compliance/standalone/> (last visited Oct. 25, 2024) (“The online Health Care Compliance Certificate — taken independently or concurrently with our online Master of Studies in Law (MSL) or online Master of Laws (LLM) — will provide you with a competitive edge in the area of compliance, whether you are a recent university graduate or an established professional.”).

<sup>189</sup>*Healthcare Compliance Certificates*, SETON HALL L., <https://law.shu.edu/compliance/health/index.html> (last visited Oct. 25, 2024) (listing both online and in-person program dates).

<sup>190</sup>See *id.*

<sup>191</sup>*Healthcare Compliance Training – United States Program*, SETON HALL L., <https://law.shu.edu/compliance/health-union-states/index.html> (last visited Oct. 25, 2024).

<sup>192</sup>See SIDLEY AUSTIN LLP, *supra* note 5.

<sup>193</sup>See Seligman, *supra* note 56, at 1723.

<sup>194</sup>See *Report Finds ‘Withering Public Confidence in the Courts’*, PENN TODAY (Aug. 2, 2024), <https://penntoday.upenn.edu/news/appc-report-finds-withering-public-confidence-courts>.

<sup>195</sup>See, e.g., Rebecca B. Kimmelfield & Nathan A. Beaver, *FDA: The Effects of Loper on the Regulatory Agenda*, FOLEY & LARDNER LLP (Aug. 1, 2024), <https://www.foley.com/insights/publications/2024/08/fda-effects-loper-regulatory-agenda/> (speculating on whether FDA is likely to rely more heavily on non-binding guidance rather than implementing new rules); Richard J. Pierce, Jr., *Two Neglected Effects of Loper Bright*, REGUL. REV. (July 1, 2024), <https://www.theregreview.org/2024/07/01/pierce-two-neglected-effects-of-loper-bright/> (speculating that by over-ruling Chevron the Court would have less reason to deploy the “radical new” Major Questions Doctrine).

law professors have consistently advised and guided Congress and agencies by testifying as experts or becoming directly involved in drafting complex legislation.<sup>196</sup>

Since the Supreme Court's concern over the past several years seems to be on how Congress is using its powers, rather than questioning that power,<sup>197</sup> it should be within Congress' own ability clarify its intent. Law professors can help to develop and disseminate proposals for ways Congress can address the Supreme Court's objections, such as incorporating the agencies into the structure of Congress.

As experts in the field, health law professors have a considerable advantage in helping those tasked with healthcare compliance navigate these uncertain times. We can do so, in part, by addressing the coming change on all fronts, working directly with regulators and industry, contributing ideas through scholarship, and developing a curriculum that prepares our students to lead and advise in the face of ongoing and unpredictable change. We will also be supporting lawyers across the spectrum of affected regulated industries, from financial services to transportation to telecommunications.

Law schools have already made substantial investments in developing healthcare compliance programs for lawyers and lay people. Because there is no central source of information about these programs, a helpful first step is to learn more about these programs and what they are offering. Based on my review of information available to the public, these programs are of considerable benefit to students who know of them and can be part of a larger effort to open career pathways to lawyers, both those newly graduated and well into their careers. These programs could be of considerable benefit because they could create pathways into careers in health compliance even for students who had not previously been healthcare compliance professionals. For these students in particular, such a program could introduce them to an industry with which they either might not be familiar or which they might think requires a background in healthcare.

Of course, any change in the law made by the Supreme Court requires changes in the content of individual law school classes. Law schools tend to be siloed, with each professor teaching their own course in sixteen-week blocks. But the coming changes to regulatory practice create an opportunity for planning a curriculum to prepare students for working in regulated industries, whether it be healthcare, airlines, or banking. It also appears, anecdotally, that students who come into law school with a background in the healthcare industry but do not meet the narrow hiring criteria of big law may have job opportunities that would not be available for students without that background.

## Recommendations

It would be helpful to have more data about healthcare compliance programs. The lack of mandated consumer information about MSL and Certificate Programs for people who are already healthcare professionals is unfortunate. While these programs are, by definition, offered to sophisticated consumers who are already healthcare compliance professionals and therefore familiar with what they need to do to advance their careers, it would still be helpful to allow them to compare one program to another. Because these programs are largely offered online, potential consumers have little basis for comparison other than the reputation of the school itself.

Information would also be helpful for prospective J.D. students. There is no ABA mandate to track the career paths of alumni. While this might have been an expensive task thirty years ago, it is now very easy

<sup>196</sup>See, e.g., Michelle M. Mello, *Stanford Law's Michelle Mello Testifies Before the United States Senate Committee on Finance*, STAN. L. SCH. BLOGS: LEGAL AGGREGATE (Feb. 8, 2024), <https://law.stanford.edu/2024/02/08/stanford-laws-michelle-mello-testifies-before-the-united-states-senate-committee-on-finance/>; *Georgetown Law Professor David Hyman Publishes New Book, Testifies Before Congress on the Costs of Health Care*, GEORGETOWN L. (July 5, 2018), <https://www.law.georgetown.edu/news/georgetown-law-professor-david-hyman-publishes-new-book-testifies-before-congress-on-the-costs-of-health-care/>; *Senate Judiciary Committee Hearing on COVID-19 Liability*, SEC. INDUS. & FIN. MKTS. ASS'N, <https://www.sifma.org/resources/general/senate-judiciary-committee-hearing-on-covid-19-liability/> (last visited Oct. 25, 2024) (summarizing testimony of David Vladeck, a Professor at Georgetown Law).

<sup>197</sup>See *supra* note 67 and accompanying text.

to stay in touch. There are several organizations who might partner with us to get this information. For example, in 2018 the “AccessLex Institute commissioned Gallup to conduct a study of law school graduates at various stages of their careers, as well as graduates in other disciplines.”<sup>198</sup> Additionally, LSAC,<sup>199</sup> NALP,<sup>200</sup> and the American Bar Foundation<sup>201</sup> have all been involved in projects studying law school graduates. Perhaps they could be persuaded to look at graduates of other programs as well.

Without information from reliable sources, we are left with commercial data aggregators and anonymous information from on-line forums where people seek career advice.<sup>202</sup> For example, the subreddit r/Lawyertalk recently contained a thread responding to a request for advice by “entitledfanman,” who described themselves as three years out of law school doing bankruptcy work in a law firm and wanting to transition to a career in health law compliance.<sup>203</sup> Specifically, they stated that “the law school near me offers an online Master of Law in Healthcare Compliance, and a shorter certification program as well. They’re not terribly expensive, but not chump change to throw away either” and asked “Would those be helpful at all in jumping over?”<sup>204</sup>

“Snowed\_up6152,” who reported that they took “healthcare compliance classes for [their] JD,” advised “entitledfanman” that, “if you can swing it financially, I would recommend pursuing education because healthcare compliance is super niche. Frankly, understanding the business of healthcare is a huge piece of the puzzle that plays into understanding the regulatory piece, so getting a 30,000 ft perspective from the classroom may help. The field also is growing competitive with candidates who have educational credentials.”<sup>205</sup> User “Unreasonably-Clutch” stated, “I don’t think you need to get a full blown masters of law [sic] if you can get a cheaper alternative certification. Getting the Certified in Health Care Compliance (CHC) credential from the Health Care Compliance Association is a good choice.”<sup>206</sup> User “mrtoren” also joined the thread to advise that “[i]f you truly want to pursue this, my recommendation would be to shell out for a healthcare compliance certification program. The school or organization may be able to connect you with experiential learning opportunities that will lead to a job.”<sup>207</sup>

While nothing a law school does can, of course, ever be at the detriment of their own students, many law schools have enough connections and resources to facilitate external placements for the benefit of lawyers either transitioning from one field to another or reentering the legal workplace after raising a family or pursuing other interests. Gathering more information about the programs and the experiences of students from different backgrounds would be valuable to lawyers like “entitledfanman” seeking to change careers.

<sup>198</sup>GALLUP & ACCESSLEX INST., EXAMINING VALUE, MEASURING ENGAGEMENT: A NATIONAL STUDY OF THE LONG-TERM OUTCOMES OF A LAW DEGREE (2018), <https://www.accesslex.org/research-and-data-tools-and-resources/examining-value-measuring-engagement-national-study-long-term>. This report builds on work they did in 2016 tracking the lives of law school graduates. See ACCESSLEX INST. & GALLUP, LIFE AFTER LAW SCHOOL: A PILOT STUDY EXAMINING LONG-TERM OUTCOMES ASSOCIATED WITH GRADUATING LAW SCHOOL AND THE VALUE OF LEGAL EDUCATION (2016), <https://arc.accesslex.org/cgi/viewcontent.cgi?article=1010&context=commissioned>.

<sup>199</sup>See Susannah Pollvogt & James Leipold, *Student Academic and Career Advising Reimagined*, LAW SCH. ADMISSION COUNCIL (Apr. 9, 2024), <https://www.lsac.org/blog/student-academic-and-career-advising-reimagined>.

<sup>200</sup>See *What We Know About JD Advantage Jobs - An Update for the Class of 2020*, *supra* note 109.

<sup>201</sup>See Robert L. Nelson et al., *After the JD: A National Study of Lawyer Careers*, AM. BAR FOUND., <https://www.americanbarfoundation.org/projects/after-the-jd-a-national-study-of-lawyer-careers/> (last visited July 29, 2024); see also D. Benjamin Barros, *After the JD III, A Law Professor’s Take*, ASS’N OF AM. L. SCHS., *AJD-III-summary.pdf*, <https://www.aals.org/wp-content/uploads/2014/09/AJD-III-summary.pdf> (last visited Oct. 25, 2024).

<sup>202</sup>See *supra* notes 177–81 and accompanying text for a discussion of the misinformation of edX and the unreliability of US News specialty rankings because they are entirely based on the impressions of other law professors.

<sup>203</sup>See entitledfanman, *How Do I Get into Healthcare Compliance?*, REDDIT (Sept. 6, 2023, 12:01 PM EDT), [https://www.reddit.com/r/Lawyertalk/comments/16bo28i/how\\_do\\_i\\_get\\_into\\_healthcare\\_compliance/](https://www.reddit.com/r/Lawyertalk/comments/16bo28i/how_do_i_get_into_healthcare_compliance/)

<sup>204</sup>*Id.*

<sup>205</sup>*Id.*

<sup>206</sup>*Id.*

<sup>207</sup>*Id.*



## Conclusion

I want to close by thanking the Boston University Health Law Program for its role in creating the academic field of health law and, by extension, creating a career for many health law professors. My research for this essay shows that health law is thriving across the spectrum of law schools, public and private, large and small. I have also been impressed by the success in sharing knowledge about the law with the larger community of professionals who must grapple with it every day without any training.

The early investment law schools like Boston University have been making in health law make our entire community of health law teachers and health lawyers ready to not just navigate these changes, but to use them as an opportunity to support our students. I wish the law school, their faculty who have been so influential to me professionally and personally, and their students past, present, and future much continued success and happiness!

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