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## A Flexible Health Care Workforce Requires a Flexible Regulatory Environment: Promoting Health Care Competition Through Regulatory Reform

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# **A FLEXIBLE HEALTH CARE WORKFORCE REQUIRES A FLEXIBLE REGULATORY ENVIRONMENT: PROMOTING HEALTH CARE COMPETITION THROUGH REGULATORY REFORM**

Andrew I. Gavil\* & Tara Isa Koslov\*\*

*Abstract:* Effective competition policy is critical to the success of U.S. health care reform, including efforts to reduce health care costs, increase quality of care, and expand access to health care services. While promoting competition is necessary at every level of the rapidly evolving health care system, it is particularly important with respect to licensed professionals who provide health care services. This Article argues that the current system of health care professional regulation, born of the last century, is in numerous respects an impediment to the kinds of changes needed to fully unleash the benefits of competition among different types of health care service providers. To the contrary, the current system of licensure and related regulations tends to artificially separate professionals in ways that not only insulate them from competition now, but also generate incentives to use regulation to perpetuate and fortify such insulation in the future. Drawing on analytic principles derived from antitrust law enforcement and other regulated industries, the Article argues that, although some regulation is necessary to protect public health and safety, the legacy regulatory system likely impedes the development of innovative, alternate service models that might facilitate enhanced competition by allowing all professionals to practice to the full extent of their education, licensure, and skill. The Article concludes by proposing a range of reforms that would re-conceptualize the core characteristics and methodology of traditional health care professional regulation.

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\* Professor of Law, Howard University School of Law. This Article is adapted from remarks delivered on September 18, 2015 at the Seattle University School of Law Symposium on “Healthcare in the 21st Century: The Role of Competition.” The authors thank Professor John B. Kirkwood for his invitation to participate in the Symposium and for his encouragement of the development of this Article. The authors also thank Daniel J. Gilman and David R. Schmidt for their many helpful suggestions and Professor Gavil thanks Marcus J. Bandy for his research and editing assistance.

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## INTRODUCTION

The American health care system is in the midst of a major transformation. The structure of the industry is in flux as payment methods evolve and innovative care delivery systems emerge, leading not only to new relationships among payers, providers, and patients, but also to novel business models.<sup>1</sup> All of these factors—combined with

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1. The Federal Trade Commission (FTC) conducted workshops in 2014 and in 2015 (the latter jointly with the Antitrust Division of the U.S. Department of Justice) to explore a wide range of issues, including many that relate to this Article. See *Examining Health Care Competition*, FED. TRADE COMMISSION, <https://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition> [<https://perma.cc/PQP6-DQDU>] (last visited Feb. 1, 2016); *Examining Health Care Competition Workshop*, FED. TRADE COMMISSION, <https://www.ftc.gov/news-events/events->

ongoing changes in provider education, certification, and licensure—have complicated the answer to a central question in the health care marketplace: which health care professionals can safely, effectively, and efficiently provide for each component of the broad range of patients’ health care needs?

This Article examines one key component of the U.S. health care system: competition between health care service providers, especially health care professionals. Varied and regulated professionals deliver an ever-widening range of health care services to patients, in many different settings and at every level of care. While each profession is in certain respects discrete, the scope of practice of each category of caregiver is likely to overlap with that of another, especially when professionals are permitted to practice to the full extent of their education, certification, training, and experience. As a result of this overlap, different types of providers may become—or be perceived as—competitors for the safe and effective delivery of some health care services. General practice physicians can encroach on specialists, advanced practice registered nurses can encroach on physicians, or professionals licensed in one state can remotely provide services to patients located elsewhere, intruding upon the practices of local professionals.<sup>2</sup> The ability to flexibly deploy different types of practitioners to perform some of the same services, and the competition this flexibility may engender, can make a valuable

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calendar/2015/02/examining-health-care-competition [https://perma.cc/B64G-9ZQT] (last visited Feb. 1, 2016) (providing workshop agendas, transcripts, and presentations).

2. It is beyond the scope of this Article to discuss the broader potential “mismatch” between existing regulations and modern health care delivery outside of the licensure context. Examples do, however, abound. *See, e.g.*, Karen A. Goldman et al., *Panel Discussion: Innovations in Health Care Delivery*, in MARCH 20, 2014 WORKSHOP TRANSCRIPT: EXAMINING HEALTH CARE COMPETITION 67, 67–122 (2014), [https://www.ftc.gov/system/files/documents/public\\_events/200361/transcriptmar20.pdf](https://www.ftc.gov/system/files/documents/public_events/200361/transcriptmar20.pdf) [https://perma.cc/B64G-9ZQT] (discussing, *inter alia*, the extent to which licensure and reimbursement regulations may affect telehealth innovation and deployment, and whether certain regulatory restrictions may or may not be necessary to promote quality and availability of care); CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., CHRONIC CARE MANAGEMENT SERVICES (2015), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf> [https://perma.cc/P4S9-GA4T] (explaining new Medicare reimbursement mechanism for clinical staff time spent on non-face-to-face care coordination for patients with multiple chronic conditions); Samuel T. Edwards & Bruce E. Landon, *Medicare’s Chronic Care Management Payment – Payment Reform for Primary Care*, 371 NEW ENG. J. MED. 2049 (2014), <http://www.nejm.org/doi/full/10.1056/NEJMp1410790> [https://perma.cc/64T9-7QBM] (describing new Medicare reimbursement policy and praising “investment in primary care that may contribute to the development of a value-oriented health care system,” but also outlining potential implementation challenges, including the risk that reimbursement methodology may not alter financial incentives sufficiently to trigger practice transformations that would constrain costs without sacrificing quality or access).

contribution to the system's ability to achieve lower costs, expanded access, and increased quality of care.<sup>3</sup> It may also be one reason why friction between various types of caregivers has persisted for a long time and appears to be on the rise.<sup>4</sup>

Most health care service providers practice under varied, longstanding, and pervasive regulatory regimes, primarily created at the state level.<sup>5</sup> Some of these regimes have roots in the origins of the modern American medical system. They have developed over decades and tend to reflect the educational systems, training regimens, expectations, and mores of their times.<sup>6</sup> Reflecting those times, these regulations may entrench specific business and care delivery models, creating what might be characterized as “regulatory barriers by design” for some new types of providers.<sup>7</sup> This may be especially true for those who seek to provide the same services as incumbent providers do through innovative practice or business models that do not readily fit within established regulations. Further complicating the competitive landscape, these regulations often are administered by self-interested, nominally state boards constituted either of the very professionals to be

3. See *infra* note 9 and accompanying text.

4. See, e.g., STEPHEN ISAACS & PAUL JELLINEK, PHYSICIANS' FOUND., ACCEPT NO SUBSTITUTE: A REPORT ON SCOPE OF PRACTICE 1 (2012), [http://www.physiciansfoundation.org/uploads/default/A\\_Report\\_on\\_Scope\\_of\\_Practice.pdf](http://www.physiciansfoundation.org/uploads/default/A_Report_on_Scope_of_Practice.pdf) [<https://perma.cc/V4BP-P4X8>]. In their report, Isaacs and Jellinek note that

[o]ne of the most persistent and vexing challenges facing practicing physicians and the organizations that represent them—and an issue with profound implications for health care in this country—has been the growing demand by a broad array of non-physician providers for state legislatures to expand their scope of practice into areas that until now have been restricted to physicians. . . .

. . . .

. . . [T]he pressure is relentless, driven by a range of underlying social, economic and political forces.

*Id.*; cf. AM. ASS'N OF NURSE PRACTITIONERS, ISSUES AT-A-GLANCE: FULL PRACTICE AUTHORITY 1 (2015), <https://www.aanp.org/images/documents/policy-toolbox/fullpracticeauthority.pdf> [<https://perma.cc/2T2E-SSQU>].

There is a disconnect between the higher level of care that nurse practitioners are prepared to provide and the limited level of care that outdated state practice laws will allow them to deliver to patients. Closing this gap between clinical preparation and regulated practice authority will help end some of the obstacles that patients encounter when they seek health care.

*Id.*

5. See *infra* Section I.C.

6. *Id.*

7. See Andrew I. Gavil, *The FTC's Study and Advocacy Authority in Its Second Century: A Look Ahead*, 83 GEO. WASH. L. REV. 1902, 1912 (2015) (“[B]ecause regulations tend to reflect the features of the business models of a specific time period, they can favor incumbent firms over challengers by entrenching a particular business method and insulating the firms that use it from new sources of competition.”).

regulated or their competitors. And those professionals may interpret existing laws and regulations in ways that limit new sources of competition, and may have both the means and incentive to extend these protections through even more restrictive regulations.<sup>8</sup>

Existing regulations and regulatory systems, therefore, may not be consonant with the expectations, capabilities, and needs of the changing health care environment. To the contrary, these laws and regulations, and the traditional way in which they have been administered, together can erect hurdles in the path of competition and innovation. Instead of being conducive to change, they can impede it in whole or in part, are susceptible to manipulation, and invite efforts to impose new restrictions to slow or arrest the development of new, expanded, and non-traditional models of providing health care services. Some health care providers thus have faced significant challenges when they seek to utilize their full knowledge, training, and skills to provide safe and effective care.<sup>9</sup> By contrast, more flexible and forward-facing regulations could allow for greater mobility in the health care work force, enabling caregivers to respond to changes in demand in different regions, states, and locales. By allowing for wider use of the full-range of expertise of all health care service providers, such regulations could more effectively support care delivery teams that are structured and deployed to best meet patient needs.

This Article examines a classic regulatory dilemma that has surfaced in the context of the health care professions: are certain features of the current system of provider regulation a mismatch for the needs of a

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8. In *North Carolina State Board of Dental Examiners v. FTC*, \_\_ U.S. \_\_, 135 S. Ct. 1101 (2015), the United States Supreme Court explained the problem as it relates to the scope of the antitrust state action doctrine:

Limits on state-action immunity are most essential when the State seeks to delegate its regulatory power to active market participants, for established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor. In consequence, active market participants cannot be allowed to regulate their own markets free from antitrust accountability.

*Id.* at 1111.

9. *See, e.g.*, NAT'L COUNCIL OF STATE BDS. OF NURSING, CHANGES IN HEALTHCARE PROFESSIONS' SCOPE OF PRACTICE: LEGISLATIVE CONSIDERATIONS 3 (2009), [https://www.ncsbn.org/ScopeofPractice\\_09.pdf](https://www.ncsbn.org/ScopeofPractice_09.pdf) [perma.cc/BL5R-74PN]. As the report notes,

[p]roposed changes to a healthcare professions' scope of practice often elicit strongly worded comments from several professional interest groups. Typically, these debates are perceived as turf battles between two or more professions, with the common refrain of "this is part of my practice so it can't be part of yours." Often lost among the competing arguments and assertions are the most important issues of whether this proposed change will better protect the public and enhance consumers' access to competent healthcare services.

*Id.*

changing health care marketplace?<sup>10</sup> It concludes that if the goals of lower cost, expanded access, and increased quality of care are to be realized, some important features of these established regulatory schemes will need to change. All providers of health care services should be free to practice to the “top of their license”—that is, to the full extent of their education, certification, and training.<sup>11</sup> Given a broad range of service providers, it is inevitable that there will be overlap in the capabilities of professionals to provide some of the same services. Some of these service providers, however, have been cordoned off into distinct and restricted silos created by law and regulation—sometimes as an unintended consequence, and sometimes deliberately and without justification—thereby unnecessarily restricting competition.<sup>12</sup> Although licensure and related regulation can serve important public purposes, competition considerations should be more fully integrated into the process of deciding who should provide any specific service. The answer to that question should not derive solely from historical regulatory distinctions that cannot be justified today by legitimate safety or quality concerns. Neither should it be influenced by the efforts of self-interested professionals today, who seek to use the regulatory process to erect additional barriers that impede new competitive challenges.<sup>13</sup> The health care work force of the early twenty-first century will need to be more mobile, adaptable, innovative, and flexible, and it will need to be governed by a regulatory philosophy and mechanisms that facilitate those characteristics. In particular, standards for licensure ideally should be more uniform across state lines, tied to functional skills and qualifications rather than arbitrary categories, and determined via a

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10. STEPHEN BREYER, *REGULATION AND ITS REFORM 191–96* (1982) (arguing that regulations should be calibrated to “match” the perceived market defect they are intended to redress).

11. While this principle holds generally for all health care providers, the assertion often is articulated with respect to nursing scope of practice, in particular. *See, e.g.*, INST. OF MED., NAT’L ACAD. OF SCIS., *THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH* (2011) [hereinafter *IOM FUTURE OF NURSING REPORT*], <http://iom.nationalacademies.org/Reports/2010/The-Future-of-Nursing-Leading-Change-Advancing-Health.aspx> [<https://perma.cc/S9QU-K89E>]; *id.* at 4 (stating as one of four “key messages” that “[n]urses should practice to the full extent of their education and training”); *id.* at 72–76 (“Care teams need to make the best use of each member’s education, skill, and expertise, and all health professionals need to practice to the full extent of their license and education.”); *id.* at 144 (“If the current conflicts between what nurses can do based on their education and training and what they may do according to state and federal policies and regulations are not addressed, patients will continue to experience limited access to high-quality care.”).

12. *See infra* notes 28–41, 54–55 and accompanying text (providing examples of such regulations).

13. *See infra* notes 125–29 and accompanying text (discussing accreditation standards for dental therapy education programs).

process that does not vest one type of professional with gatekeeping power over another.

Part I sets out four basic assumptions about the role of health care service providers in today's health care marketplace. First, as the system continues to evolve, many health care professionals' training and experience will overlap with others', leading to increased competition and consequent turf battles over the scope of practice. Second, demands to harmonize the goals of cost containment, increased quality, and enhanced value will continue to intensify. Third, given the tendency to regulate healthcare professionals using "silos" carved out from the practice of medicine and heavily influenced by competing professionals, today's regulatory approach is not well-suited to adaptations that will unleash, rather than constrain, competition. And finally, the specific characteristics of that current regulatory approach also generate incentives, likely to grow, to use regulation to stifle rather than facilitate competition.

Part II begins with an overview of three areas of antitrust law enforcement that together provide a useful framework for evaluating anticompetitive regulations in the health care sector: the law and economics of exclusion, suppression of innovation, and the coordinated conduct of professionals and their trade groups. This framework helps to illuminate the economic mechanisms of regulatory exclusion that characterize the most objectionable types of regulations. As is true of exclusionary conduct that violates the antitrust laws, exclusion can occur when laws or regulations impose additional and unjustified burdens and costs on service providers thereby impeding new entry or expansion of services without any related benefits for consumers. The result is harm to competition, which can take the form of higher prices and lower output of services, reduced quality, reduced service, or less innovation in business and care delivery models.

In important ways, anticompetitive regulations in the health care sector share common characteristics with private conduct that has been challenged under the federal antitrust laws in these three areas. They can also frustrate the goals of health care reform. To illustrate the connection, Part II then surveys a sampling of specific regulations affecting a range of regulated health care professions, some established and others still emerging. Although regulations that protect legitimate concerns for public health and safety are necessary, this sampling demonstrates why decision-makers should more fully integrate a competitive effects analysis into their deliberations to ensure that any restrictions on competition are both warranted and, if so, no greater than necessary to mitigate genuine health and safety risks.

Part III begins by providing a guide for regulators, which builds on the law, economics, and regulatory examples examined in Part II. It explains how exclusionary regulations impose impediments to competition that can range in their impact: from absolute barriers to entry, to significant entry-detering strategies, to mere annoyances that can be overcome but still impose costs. We categorize the range of exclusionary mechanisms to facilitate future recognition and consideration of their likely competitive effects by lawmakers and regulators. Part III also provides regulators with a set of useful questions to answer that will assist them to identify and evaluate potentially exclusionary regulations in the health care sector.

Part III concludes by challenging legislators, regulators, and health care industry stakeholders alike to envision a different regulatory future, in which competition principles better inform regulatory choices. It outlines select principles that could help to identify reasonable, but more conceptual and therefore more flexible, regulations for the modern health care workforce. For example, as the health care system continues to transition, legislators and regulators might consider moving beyond static, profession- and credential-specific models for specifying how each profession, as if in a silo, can safely go about providing services. They could consider more generally expressed performance, quality, and ethical benchmarks, which might work in lieu of or in tandem with more traditional specifications of the range of services that each provider can deliver safely and effectively. They might increasingly consider using regional or national compacts that would generalize standards beyond state boundaries. They might also consider how best to administer their regulatory systems to make them less prone to local capture by self-interested professionals who participate in the markets to be regulated.

## I. ASSUMPTIONS ABOUT THE ROLE OF HEALTH CARE SERVICE PROVIDERS IN TODAY'S HEALTH CARE MARKETPLACE

In this Part, the Article distills a few underlying assumptions about the current state of the health care industry and its likely near-term direction, particularly with respect to the role of health care service providers. These baseline assumptions provide context for the subsequent analysis of the regulation of health occupations.

Nearly all health policy discussions today flow from the so-called "triple aim" of health care reform, the original formulation of which includes three dimensions: "[i]mproving the [individual] patient experience of care (including quality and satisfaction); [i]mproving the health of populations; and [r]educing the per capita cost of health

care.”<sup>14</sup> To achieve the triple aim, all of the institutional players in the health care industry must pursue strategies that will harness the benefits of competition. These strategies will necessarily include an examination of the role of health care professionals and a concerted effort to adapt long-standing regulatory approaches to the changing needs of the industry.

A. *Increased Overlap of Service Capabilities Will Lead to Greater Competition Between Health Care Professionals*

To maximize the efficiency of the health care system and ensure adequate access to quality care, all providers of health care services must be allowed and encouraged to practice to the top of their license, utilizing the full extent of their training, skills, and experience to provide safe and effective care. As the health care workforce evolves to fulfill that promise, however, it is inevitable that the services performed by different types of health care providers will increasingly overlap. In market terms, providers will compete to provide services that fall within the competency of more than one profession. For example, the skills of physicians and nurses can overlap somewhat, especially in primary care settings.<sup>15</sup> Although these two types of professionals are not broad substitutes for each other and their skill sets are largely complementary, as is depicted in Figure 1, the two sets of services do intersect, which

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14. *The IHI Triple Aim*, INST. FOR HEALTHCARE IMPROVEMENT, <http://www.ihl.org/engage/initiatives/tripleaim/Pages/default.aspx> [<https://perma.cc/EN5X-M39G>] (last visited Feb. 3, 2016); Donald M. Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759 (2008). While the Institute for Healthcare Improvement developed the initial framework, the triple aim terminology and concept have been widely adopted in health policy circles, in no small part because implementation of the triple aim goals was Dr. Berwick’s self-professed “main focus” during his tenure as Administrator of the Centers for Medicare and Medicaid Services (CMS) from July 2010 through December 2011. See, e.g., Chris Fleming, *Berwick Brings the “Triple Aim” to CMS*, HEALTH AFF. BLOG (Sept. 14, 2010), <http://healthaffairs.org/blog/2010/09/14/berwick-brings-the-triple-aim-to-cms/> [<https://perma.cc/QNF4-2FSA>]. The triple aim is closely aligned with, but not identical to, the earlier concept of the health care “iron triangle” of access, quality, and cost containment. See WILLIAM L. KISSICK, *MEDICINE’S DILEMMAS: INFINITE NEEDS VERSUS FINITE RESOURCES* 2 (1994) (“[A]ccess, quality, and cost containment have equal angles, representing identical priorities, and an expansion of any one angle compromises one or both of the other two.”).

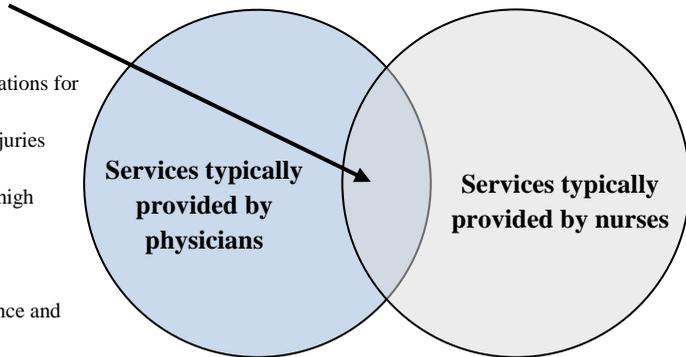
15. See, e.g., *Health Policy Briefs, Nurse Practitioners and Primary Care (Updated)*, HEALTH AFF. (May 15, 2013), [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=92](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=92) [<https://perma.cc/8Q8W-QBY5>] (“Primary care comprises a broad range of services, including the initial evaluation of new symptoms, ongoing care for chronic diseases, and preventive services such as immunizations or screenings. . . . Primary care services can be provided by physicians and by a range of nonphysician practitioners, such as physician assistants [“PAs”] and nurse practitioners [“NPs”], both of whom have graduate degrees and are authorized to examine, diagnose, and treat patients.”).

means there are a substantial number of services for which physicians and nurses could be practical and economic substitutes.<sup>16</sup>

Figure 1: Opportunities for Competition

**Services that may be provided safely and effectively by physicians or nurses:**

- Take and interpret health histories
- Conduct physical exams
- Diagnose, treat, and prescribe medications for common acute illnesses
- Diagnose and treat common acute injuries and wounds
- Manage chronic conditions, such as high blood pressure and diabetes
- Order and interpret X-rays and other laboratory tests
- Counsel patients on health maintenance and disease prevention
- Provide referrals to other health care providers, as needed



16. The lists of services offered by so-called “retail clinics” run by major pharmacy chains, such as CVS and Walgreens, provide a useful real-world example of the breadth of overlap as determined by firms that sell primary care services. These clinics typically are staffed by NPs or, occasionally, PAs. *See, e.g., Services, CVS MINUTE CLINIC*, <http://www.cvs.com/minuteclinic/services> [<https://perma.cc/QA97-VVK9>] (last visited Feb. 29, 2016); *Our Services, WALGREENS HEALTH CLINIC*, <http://www.walgreens.com/topic/pharmacy/healthcare-clinic/our-services.jsp> [<https://perma.cc/56MH-LYTK>] (last visited Feb. 29, 2016); *see also* AM. NURSES ASS’N, *ADVANCED PRACTICE NURSING: A NEW AGE IN HEALTH CARE 2* (2011), <http://www.nursingworld.org/FunctionalMenuCategories/MediaResources/MediaBackgrounders/A-PRN-A-New-Age-in-Health-Care.pdf> [<https://perma.cc/MYC3-DCLA>] (“NPs take health histories; conduct physical exams; diagnose and treat common acute illnesses and injuries; give immunizations; manage high blood pressure, diabetes, and other chronic conditions; order and interpret X-rays and other laboratory tests; counsel patients on disease prevention and healthy lifestyles; and refer patients to other health providers as needed.”). *See generally* NAT’L GOVERNORS ASS’N, *NGA PAPER: THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE* (2012) [hereinafter *NGA NP PAPER*], <http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf> [<https://perma.cc/7UKA-KRTS>] (drawing conclusions based on literature review of empirical work and meta-analyses regarding NP performance). As the *NGA NP Paper* concludes,

[r]esearch suggests that NPs can perform many primary care services as well as physicians do and achieve equal or higher patient satisfaction rates among their patients . . . None of the studies in *NGA’s* literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures. Moreover, the studies suggest that NPs may provide improved access to care.

*Id.* at 7–8. Although this Article focuses primarily on overlaps between physicians and nurses, it is useful to recognize that overlaps occur in other contexts as well, such as between primary care physicians and specialists, or between hospital-based and office-based practitioners.

Similar diagrams could be drawn to depict other examples of likely service overlap, where the overlap represents opportunities for competition.

Moreover, as hospitals increasingly serve as focal points for comprehensive health care systems—whether through some degree of vertical integration, contractual affiliations, or other alliances—they are paying closer attention to the relative efficiency and quality of care delivered in outpatient care delivery settings beyond the hospital itself.<sup>17</sup> This trend may create an additional dimension of competition between health systems as they seek to maximize profits across the entire continuum of inpatient and outpatient care by, for example: acquiring or partnering with local physicians in outpatient primary care and specialty practices; competing to build loyalty among patients, who may perceive benefits from centralizing their outpatient care within a particular system; and incentivizing physicians to drive inpatient referrals to the system’s hospital facilities.<sup>18</sup> This type of integration is also likely to exacerbate existing tensions between different types of health care

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17. In a vertically-integrated hospital system, the quality and efficiency of care outside the hospital obviously contribute to the system’s financial bottom line. This is even more true if health care services are reimbursed under a bundled payment methodology. *See, e.g., Comprehensive Care for Joint Replacement Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/cjr> [<https://perma.cc/2H7N-7HN6>] (last updated Jan. 29, 2016). Under the new Medicare program, certain hospitals will be held accountable for an entire “episode of care” for a hip or knee replacement, including almost all related items and outpatient services that normally would be covered by Medicare, beginning at hospital admission and ending ninety days after discharge. *Id.* In addition, under changes to Medicare that were first implemented in 2012 and have been refined annually, most hospitals now face an explicit financial penalty for “excess” readmissions (defined according to specific criteria), which may be affected by the level of communication with outpatient providers upon discharge, as well as the amount and quality of post-discharge care. *See Hospital Readmissions Reduction Program*, 42 C.F.R. §§ 412.150–.154 (2016) (implementing the readmissions penalty program created by the Affordable Care Act); *Readmissions Reduction Program (HRRP)*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html> [<https://perma.cc/8ER2-4RBR>] (last updated Feb. 4, 2016).

18. *See, e.g., BERKELEY FORUM FOR IMPROVING CALIFORNIA’S HEALTHCARE DELIVERY SYS., A NEW VISION FOR CALIFORNIA’S HEALTHCARE SYSTEM: INTEGRATED CARE WITH ALIGNED FINANCIAL INCENTIVES* 38 (2013), <http://berkeleyhealthcareforum.berkeley.edu/wp-content/uploads/A-New-Vision-for-California%E2%80%99s-Healthcare-System.pdf> [<https://perma.cc/3TSH-K7EG>] (suggesting that, while greater employment of physicians by hospitals may improve clinical integration and care coordination, it may also raise costs, because care provided at hospitals may be reimbursed at higher rates, and also because “physicians may be influenced by hospitals to order more expensive care or increase referrals and admissions”); *Saint Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke’s Health Sys., Ltd.*, Nos. 12-CV-00560-BLW, 13-CV-00116-BLW, 2014 WL 407446, at \*13 (D. Idaho Jan. 24, 2014), *aff’d*, 778 F.3d 775 (9th Cir. 2015) (discussing typical referral practice patterns that result from integration in the context of an analysis of the potential anticompetitive effects of a hospital system’s acquisition of a large multispecialty physician group).

providers as traditional office-based, physician-led practices face new financial pressures from affiliated systems looking to contain overall costs.<sup>19</sup>

*B. Demands to Harmonize Cost, Quality, and Value Will Continue to Intensify*

Another common triple aim theme is greater emphasis on value, which explicitly recognizes the relationship between quality and cost, and also prioritizes outcomes over procedures.<sup>20</sup> Several major health care reform efforts seek to promote value over volume by fine-tuning reimbursement methodologies to disincentivize unnecessary, duplicative, or otherwise low-value services that do not appear to promote better health outcomes. Some of these new payment models also seek to harness the power of competition by explicitly rewarding value-based care and better outcomes.<sup>21</sup> In response, existing care

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19. The services provided by hospitals and hospital-based health care professionals, for example, are increasingly overlapping with the services provided by freestanding physician practice groups. This was a phenomenon explored by the FTC and the Ninth Circuit in *Saint Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System, Ltd.*, 778 F.3d 775 (9th Cir. 2015), in which the FTC and the State of Idaho successfully challenged the acquisition by a hospital of a physician practice group because it would substantially reduce competition.

20. See generally Michael E. Porter, *What Is Value in Health Care?*, 363 *NEW ENG. J. MED.* 2477 (2010).

Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent.

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... Since value depends on results, not inputs, value in health care is measured by the outcomes achieved, not the volume of services delivered, and shifting focus from volume to value is a central challenge. Nor is value measured by the process of care used; process measurement and improvement are important tactics but are no substitutes for measuring outcomes and costs.

*Id.* at 2477.

21. For example, the CMS Innovation Center has launched a number of Accountable Care Organization (ACO) and related demonstration models designed to reimburse services provided to Medicare beneficiaries differently than the traditional fee-for-service approach. The Medicare Shared Savings Program (MSSP) ACO model encourages providers to form groups that will coordinate care for a defined group of patients in a variety of settings, incentivized in part by the promise of bonus payments (on top of traditional fee-for-service payments) if the ACO's provider members meet or exceed certain quality standards and cost savings for those patients. See generally *Shared Savings Program*, *CTRS. FOR MEDICARE & MEDICAID SERVS.*, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html> [https://perma.cc/7GD3-5TFJ] (last visited Feb. 4, 2016). Taking this approach one step further, the Pioneer ACO model offers participating providers not only the carrot of shared savings, but also the stick of having to pay back CMS for shared losses if the ACO fails to meet certain quality and cost targets. See generally *Pioneer ACO Model*, *CTRS. FOR MEDICARE & MEDICAID SERVS.*, <https://innovation.cms.gov/initiatives/Pioneer-ACO-Model/> [https://perma.cc/HJ2P-2YXK] (last visited Feb 4, 2016). The CMS Innovation Center continues to develop additional models that will

delivery models are evolving and new models are emerging, relying on greater collaboration, coordination, and financial interdependence among various types of health care providers according to a flexible, team-based approach.<sup>22</sup> Ideally, responsibilities would be allocated functionally—based on which type of professional is available, qualified, and able to deliver the best value. From the perspective of some health care professionals, however, this challenges the traditional hierarchical structure of medicine, whereby supervising physicians typically make decisions and issue orders to authorize the actions of other members of the care delivery team whose autonomy is limited.<sup>23</sup>

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shift provider reimbursement methodologies from volume to value. *See, e.g., Next Generation ACO Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/> [<https://perma.cc/X4LS-2HMW>] (last visited Feb. 4, 2016); *Comprehensive ESRD Care Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/comprehensive-ESRD-care/> [<https://perma.cc/K7JW-APM8>] (last visited Feb. 4, 2016) (providing information regarding an accountable care model to cover Medicare patients undergoing treatment for End-Stage Renal Disease (ESRD)). *See generally Innovation Models*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/index.html#views=models> [<https://perma.cc/Q4YM-DUQE>] (last visited Jan. 30, 2016).

22. *See generally* Atul Gawande, *Cowboys and Pit Crews*, *NEW YORKER* (May 26, 2011), <http://www.newyorker.com/news/news-desk/cowboys-and-pit-crews> [<https://perma.cc/W7JJ-SYNN>] (Harvard Medical School commencement address arguing, inter alia, that medicine has become so complex that the lone “cowboy” model of practice no longer works; rather, a coordinated, team-based, “pit crew” approach is required, including realignment of financial incentives; “[w]e have every indication . . . that where people in medicine combine their talents and efforts to design organized service to patients and local communities, extraordinary change can result”).

The Next Generation ACO Model, while limited to the Medicare context, is a good example of how this vision might be realized more broadly throughout the U.S. health care system. Next Generation Medicare ACOs—comprising hospitals, physicians, nurses, and various other health care providers and suppliers—will receive financial incentives to enhance coordination among team members and achieve high-quality care, while reducing costs and improving the overall patient experience. *Next Generation ACO Model*, *supra* note 21. Target participating providers are experienced in coordinating care and willing to assume greater financial risk, in return for the promise of greater rewards if they meet financial and clinical outcome goals. The program will supply ACO participating providers with additional tools to support coordinated care management and patient engagement by the entire provider team. *Id.*; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., *NEXT GENERATION ACO MODEL: FREQUENTLY ASKED QUESTIONS 1* (2015), <https://innovation.cms.gov/Files/x/nextgenacofaq.pdf> [<https://perma.cc/KJX4-6F3E>] (“[B]enefit enhancement’ tools to help ACOs improve engagement with beneficiaries” will include “greater access to home visits, telehealth services, and skilled nursing facility services.”).

23. *See, e.g.,* INST. OF MED., NAT’L ACAD. OF SCIS., *ASSESSING PROGRESS ON THE INSTITUTE OF MEDICINE REPORT THE FUTURE OF NURSING 2–9* (2015), [http://download.nap.edu/cart/download.cgi?&record\\_id=21838](http://download.nap.edu/cart/download.cgi?&record_id=21838) [<https://perma.cc/Y5VN-PZCC>] (prepublication copy, uncorrected proofs) (discussing transformation to value-based care, triple aim goals, and greater emphasis on collaboration among different types of providers, within context of report section advocating generally for expanded scope of practice for nurses).

C. *The Current Regulatory Framework Will Prove Increasingly Incapable of Adapting to Changes in the Industry*

These developments and trends highlight the deficiencies of the U.S. system of regulation for health care professionals, which is not well suited to attain the triple aim goals. It neither encourages appropriate competition among different types of qualified health care providers, nor supports an increasingly collaborative environment based on cross-functional provider teams whose members practice to the full extent of their training and competence. Rather, the traditional approach to health care professional licensure tends to create “silos” that promote and sustain counterproductive turf battles between different types of health care providers, especially physicians and nurses.<sup>24</sup> In competition policy terms, these kinds of regulations establish a division of service markets that, if achieved through private conduct, would be likely condemned as unlawful.<sup>25</sup>

Physicians in the United States are licensed by individual states, pursuant to very broad and general definitions of the practice of medicine.<sup>26</sup> Although specialists and subspecialists receive additional training and certification compared to general practitioners, state practice laws typically confer a broad license to practice medicine and surgery on all physicians in a given state.<sup>27</sup>

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24. See *infra* notes 28–41.

25. See, e.g., *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (holding that an agreement by rivals to divide markets and customers was a per se violation of the antitrust laws).

26. For a representative example, see section 18.71.011 of the Revised Code of Washington:

A person is practicing medicine if he does one or more of the following:

- (1) Offers or undertakes to diagnose, cure, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;
- (2) Administers or prescribes drugs or medicinal preparations to be used by any other person;
- (3) Severs or penetrates the tissues of human beings;
- (4) Uses on cards, books, papers, signs or other written or printed means of giving information to the public, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human disease or conditions the designation “doctor of medicine”, “physician”, “surgeon”, “m.d.” or any combination thereof unless such designation additionally contains the description of another branch of the healing arts for which a person has a license . . . .

WASH. REV. CODE § 18.71.011 (2016).

27. “By the early 20th century, each state had adopted a so-called ‘medical practice act’ that essentially claimed the entire human condition as the exclusive province of medicine. The statutory definitions of physicians’ scope of practice were—and remain—extremely broad.” Barbara J. Safriet, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing*

In stark contrast, almost every other health profession, including nursing, is regulated pursuant to a licensure scheme based on “carve-outs” from the practice of medicine.<sup>28</sup> The licensure laws and regulations typically define a rigid “scope of practice” based on permission to perform an enumerated set of procedures and services.<sup>29</sup> For example, if a service is not specifically listed as within the scope of practice for an Advanced Practice Registered Nurse (APRN) in a given state, an APRN in that state is not authorized to perform the service, even if her training and experience would enable her to do so safely and effectively.<sup>30</sup> This

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*Quality, Cost-Effective Health Care*, in IOM FUTURE OF NURSING REPORT, *supra* note 11, at 443, 451 app. H. In theory—and setting aside important ethical and liability issues—a general practitioner could perform neurosurgery without violating the scope of a state-granted license to practice medicine.

28. *See, e.g.*, Safriet, *supra* note 27, at 452 (“[T]he real mischief was accomplished through corresponding provisions making it illegal for anyone not licensed as a physician to undertake any of the acts included in the definition.”); *id.* at 450 (“[T]he scopes of practice for [advanced practice nurses] (and other health professionals) are exercises in legislative exception making a ‘carving out’ of small, politically achievable spheres of practice authority from the universal domain of medicine.”); *see also* NGA NP PAPER, *supra* note 16, at 3 (“State medical laws originated by defining the practice of medicine expansively and restricting such activities to licensed physicians. Subsequent efforts to alter scope of practice laws to account for other developing health professions have taken the form of ‘carving out’ services that non-physician providers could perform.”).

29. *See*, for example, Washington Administrative Code sections 246-840-300 to -455, for a comprehensive set of regulations (beyond the state’s nursing licensure statute) that spell out precisely what an advanced registered nurse practitioner (ARNP) in the State of Washington is allowed to do. Conversely, an ARNP would run the risk of being accused of the unlawful practice of medicine if he or she performed any service not specifically enumerated in these regulations. Even in Washington—a state with broad practice authority for advanced practice nurses—the initial regulatory section defining an ARNP’s basic scope of practice is detailed.

Under subsection 246-840-300(6) of the Washington Administrative Code:

Performing within the scope of the ARNP’s knowledge, experience and practice, the licensed ARNP may perform the following:

- (a) Examine patients and establish diagnoses by patient history, physical examination and other methods of assessment;
- (b) Admit, manage and discharge patients to and from health care facilities;
- (c) Order, collect, perform and interpret diagnostic tests;
- (d) Manage health care by identifying, developing, implementing and evaluating a plan of care and treatment for patients;
- (e) Prescribe therapies and medical equipment;
- (f) Prescribe medications when granted authority under this chapter;
- (g) Refer patients to other health care practitioners, services or facilities; and
- (h) Perform procedures or provide care services that are within the scope of practice according to the commission approved certification program.

WASH. ADMIN. CODE § 246-840-300(6) (2016).

30. A common example is prescriptive authority. For example, consider the case of an APRN who has practiced for many years in a state like Wyoming, where licensed APRNs are authorized to independently write a wide range of prescriptions, including antibiotics to treat basic infections.

regulatory approach likely does not provide sufficient flexibility to enable the APRN to practice to the top of her license. The siloed licensure classifications based on discrete occupation names and regulatory code sections, rather than actual education, training, and skills, also tend to mask the fact that the APRN could compete directly with physicians to perform certain services safely and effectively.<sup>31</sup>

In addition, the siloed system stifles adaptation when—as often happens in medicine—specialized aspects of treatment gradually become routine. When an innovative procedure or therapy is first introduced, it may be performed or prescribed only by highly specialized physicians. As the treatment becomes more common and routine, it may be incorporated into basic medical training and experience, such that general practitioners may become competent to provide it. An example might be the reading of x-rays, which all physicians are trained to do. When presented with a suspected broken arm, a general practitioner in an urgent care clinic or emergency room could and would review an x-ray in the first instance and make an initial diagnosis, even if a specialized radiologist might later review the image to confirm. Because physicians practice under a broad license, with full discretion to determine the appropriate standard of care as it relates to their own capabilities, if a general practitioner determined she possessed adequate skills to read such an x-ray, she already would be automatically licensed

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WYO. STAT. ANN. § 33-21-120 (West, Westlaw through 2015 Gen. Sess.) (defining APRN to include a nurse who “[m]ay prescribe, administer, dispense or provide nonprescriptive and prescriptive medications”); *see also* 024-054-003 WYO. CODE R. § 2 (LexisNexis 2016) (governing “Scope and Standards of Nursing Practice for the APRN”); *id.* § 2(b) (governing “Prescriptive Authority”). Suppose that, over the years, the APRN has appropriately written thousands of prescriptions for antibiotics for routine ear infections, sinus infections, urinary tract infections, and the like. If the same APRN moved to Texas and obtained licensure there, he would no longer have any prescribing authority, unless he demonstrated advanced pharmacotherapeutics education, applied separately for prescriptive authority (beyond his licensure application), applied separately for prescribing authority for each population focus (e.g., children, women, etc.), and obtained and filed with the Texas Medical Board a written delegation of prescriptive authority from a specific supervising physician. *See* 22 TEX. ADMIN. CODE §§ 222.1–.10 (2016) (governing “Advanced Practice Registered Nurses with Prescriptive Authority”); *id.* § 222.4 (governing “Minimum Standards for Prescribing or Ordering Drugs and Devices”).

31. *See* Roger D. Blair & Christine Piette Durrance, *Economic Effects of Licensing Health Care Professions*, 28 ANTITRUST HEALTH CARE CHRON., Apr. 2015, at 29, 30 (describing that the medical profession controls licensure by defining the practice of medicine broadly, which denies consumers the ability to substitute the services of lower-cost providers); Jennifer Perloff et al., *Comparing the Cost of Care Provided to Medicare Beneficiaries Assigned to Primary Care Nurse Practitioners and Physicians*, 70 HEALTH SERVS. RES. (2015), <http://onlinelibrary.wiley.com/doi/10.1111/1475-6773.12425/epdf> [<https://perma.cc/4MLH-Y929>] (concluding that cost of care for Medicare beneficiaries managed by nurse practitioners was lower compared to those managed by primary care physicians).

to provide that service. In contrast, even when a service or treatment becomes routine and is incorporated into APRN training and experience, such that APRNs are competent to provide it independently, static scope-of-practice carve-outs for nurses may prevent APRNs from providing the service. APRNs—unlike physicians—likely would need to seek specific legislative or regulatory changes, to expand their legal scope of practice to match their capabilities.<sup>32</sup>

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32. The evolution of Georgia's APRN supervision requirements provides a stark example. Under the state's 1989 nurse protocol statute, Georgia APRNs were able to order radiographic imaging tests when such authority had been delegated by a supervising physician. Professions and Business—Physician's Assistants; Nurses; Authority to Order or Dispense Drugs, Medical Treatments, or Diagnostic Studies, § 3, 1989 GA. LAWS 261, 261. Georgia APRNs lost most of their authority to order these tests—even if a physician is willing to delegate such authority—when, in 2006, a revised statute provided that APRNs cannot order radiographic imaging except in a “life threatening” situation. GA. CODE ANN. § 43-34-25 (West, Westlaw through 2015 Reg. Sess.). For an account of these changes, see James F. Lawrence, *Key Legislative Points Impacting APRNs in Georgia: A History of Important Legislation of APRNs in Georgia*, UNITED ADVANCED PRACTICE REGISTERED NURSES GA., <https://uaprn.enpnetwork.com/page/17851-key-legislative-points-impacting-aprns-in-georgia> [<https://perma.cc/X6QY-VYHY>] (last visited Feb. 20, 2016). Restoration of the authority routinely delegated to APRNs between 1989 and 2006 would require amendments to the statute, but proposed legislative fixes have failed. *See, e.g.*, S. 386, 151st Gen. Assemb., Reg. Sess. (Ga. 2012). This limitation is particularly troublesome in Georgia, a state with a significant population of low income and rural patients who may be disproportionately affected by a lack of access to care, and who may suffer from unnecessary delays in diagnosis and treatment if APRNs cannot independently order such tests. For additional background on Georgia's physician shortage and the evolution of APRN regulation in Georgia, including its regulation of APRN prescriptive authority, see BETH STEPHENS, GA. WATCH, PERSPECTIVES ON ADVANCED PRACTICE REGISTERED NURSING IN GEORGIA (2015), <http://www.georgiawatch.org/wp-content/uploads/2015/01/APRN01072015WEB.pdf> [<https://perma.cc/7RCQ-R9XB>]. The report describes Georgia's APRN practice laws as “some of [the] most restrictive in the nation.” *Id.* at 1.

Anesthesia care provides another good example of how APRN skills and expertise may expand over time, creating a challenge when laws and regulations do not keep pace. Certified Registered Nurse Anesthetists (CRNAs) are a specialized type of APRN trained to provide various types of anesthesia services. While their scope of practice differs from state to state, over time the independent practice authority of CRNAs has expanded in many states, such that they can provide services ranging from in-hospital anesthesia for surgery, to epidurals for labor and delivery, to outpatient interventional pain management services for chronic pain. *See, e.g.*, IOM FUTURE OF NURSING REPORT, *supra* note 11, at 111 (“[E]vidence shows that CRNAs provide high-quality care [and] there is no evidence of patient harm from their practice . . . . A study by Dulisse and Cromwell (2010) found no increase in inpatient mortality or complications in states that [do not require] that an anesthesiologist or surgeon oversee the administration of anesthesia by a CRNA.” (citing Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians*, 29 HEALTH AFF. 1469 (2010))); INST. OF MED., COMM. ON ADVANCING PAIN RES., CARE, & EDUC., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 11 (2011), <http://www.nap.edu/read/13172/chapter/1> [<https://perma.cc/TNY5-F9DC>] (recommending an increase in the number of health professionals with advanced expertise in pain care). *See generally id.*; About CRNAs, AM. ASS'N NURSE ANESTHETISTS, <http://www.aana.com/aboutus/value-of-crnas/Pages/Facts-About-CRNAs.aspx> [<https://perma.cc/YRD3-6ME9>] (last visited Feb. 5, 2016).

These problems are exacerbated by the state-by-state nature of occupational licensure, which affects health care providers as it does virtually all licensed professionals.<sup>33</sup> An experienced APRN may have worked for many years in a state with relatively broad scope of practice rules; she then moves to another state where she is not be authorized to provide comparable services without meeting additional requirements.<sup>34</sup> In particular, an APRN who may have been licensed, and practiced safely and effectively for years in a state that permits “independent” practice (subject to the APRN’s own judgment regarding consultations and referrals), who then moves to a state where every APRN is required to have a written physician supervision agreement, may find her ability to practice independently severely curtailed.<sup>35</sup> As Federal Trade Commission (FTC) staff explained in a 2014 policy paper, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses*,<sup>36</sup> discussed in greater detail below,<sup>37</sup> such physician supervision requirements are likely to deny consumers the benefits of competition, reduce access to care, and inhibit innovation in the development of new models of health care delivery.<sup>38</sup>

In addition, regulatory silos may suppress innovation to develop new types of providers, including the kinds of innovation that may foster experimentation and comparisons across states. First, if a new approach to care delivery does not fit neatly into an existing silo, it may be barred

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33. For a recent, broad survey of the expansion and competitive consequences of state licensure of professions and trades, see Aaron Edlin & Rebecca Haw, *Cartels by Another Name: Should Licensed Occupations Face Antitrust Scrutiny?*, 162 U. PA. L. REV. 1093 (2014). See also MORRIS M. KLEINER, THE HAMILTON PROJECT, REFORMING OCCUPATIONAL LICENSING POLICIES (2015), [http://www.hamiltonproject.org/files/downloads\\_and\\_links/reform\\_occupational\\_licensing\\_policies\\_kleiner\\_v4.pdf](http://www.hamiltonproject.org/files/downloads_and_links/reform_occupational_licensing_policies_kleiner_v4.pdf) [<https://perma.cc/CV6G-5LB7>] (asserting that state-based occupational licensing systems unduly restrict competition and therefore should be reformed).

34. See, e.g., *supra* note 30 (discussing state-by-state differences in prescriptive authority).

35. The American Association of Nurse Practitioners (AANP) maintains a database that categorizes each state’s nursing regulations as allowing “full,” “reduced,” or “restricted” practice, along with links to each state’s nursing practice act and related laws and regulations. *State Practice Environment*, AM. ASS’N NURSE PRAC., <https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment> [<https://perma.cc/F6HA-RR2D>] (last visited Feb. 5, 2016) [hereinafter *AANP State Practice Environment Data*]. Requirements for so-called “collaborative practice agreements,” which impose mandatory physician supervision, are the main determinative factor for the state-by-state categorizations.

36. FED. TRADE COMM’N STAFF, *POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES* (2014), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/policy-perspectives-competition-regulation-advanced-practice-nurses/140307\\_apmpolicypaper.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/policy-perspectives-competition-regulation-advanced-practice-nurses/140307_apmpolicypaper.pdf) [<https://perma.cc/W36H-H2RN>] [hereinafter *FTC APRN POLICY PAPER*].

37. See *infra* notes 109–13 and accompanying text.

38. See generally *infra* Section II.B (discussing regulations that may impede competition among health care professionals).

entirely until it secures some kind of statutory or regulatory approval, which can take years. Second, if regulators are receptive to permitting it, a typical approach will be to create a whole new silo rather than to adapt current regulations, thus exacerbating the sense of “separateness” among professionals and adding potentially needless regulatory complexity. Both approaches de-emphasize the potential for, and the perception, of competition. The recent and ongoing development of the dental therapy profession, discussed in greater detail below,<sup>39</sup> is an excellent example. Dental therapists fall somewhere between dentists and dental hygienists: they typically have more training than licensed hygienists, and are specifically trained to provide some dental services traditionally provided only by licensed dentists.<sup>40</sup> The profession is so new that only a few states have established or proposed licensure pathways and scope of practice definitions for dental therapists. All have created entirely new regulatory silos that would contain dental therapists and separate them from other dental professions.<sup>41</sup>

Finally, two other important trends will stress the regulatory model for health care professionals: increasing demand and stagnant or slowly increasing supply, which together produce a shortage. Demand for health care services continues to climb, not only due to an aging population, but also because of the growing number of people and families who now have health care insurance.<sup>42</sup> Many geographic areas

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39. See *infra* notes 124–28 and accompanying text.

40. “A dental therapist is a licensed oral health professional who practices as part of the dental team to provide educational, clinical and therapeutic patient services. Dental therapists provide basic preventive and restorative treatment to children and adults, and extractions of primary (baby) teeth under the supervision of a dentist.” *Dental Therapy – A New Profession*, U. MINN. SCH. DENTISTRY, <http://dentistry.umn.edu/programs-admissions/dental-therapy/index.htm> [https://perma.cc/7SWQ-DAZQ] (last updated Dec. 16, 2015). The University of Minnesota was one of the first schools to offer a dental therapy curriculum, and Minnesota was the first state to establish licensure of dental therapists. *Id.*

41. For an overview of states where dental therapist licensure has been established or contemplated, see Letter from Fed. Trade Comm’n Staff to Sherin Took, Dir., Comm’n on Dental Accreditation 3–4 (Dec. 2, 2013) [hereinafter FTC 2013 CODA Comment], [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-commission-dental-accreditation-concerning-proposed-accreditation-standards-dental/131204codacomment.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-commission-dental-accreditation-concerning-proposed-accreditation-standards-dental/131204codacomment.pdf) [https://perma.cc/9USU-ETHV] (providing an overview of the Minnesota program); *id.* at 5 nn.34–37 and accompanying text (surveying other states where legislation has been introduced); see also *id.* at 4 n.21 (describing Alaska’s federally mandated Dental Health Aide Therapist program for Alaska Native Americans).

42. See, e.g., HEALTH RES. & SERVS. ADMIN., U.S. DEP’T HEALTH & HUMAN SERVS., PROJECTING THE SUPPLY AND DEMAND FOR PRIMARY CARE PRACTITIONERS THROUGH 2020, at 1 (2013), <http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/projectingprimarycare.pdf> [https://perma.cc/AK2L-9C5R] (“Demand for primary care services is projected to increase through 2020, due largely to aging and population growth and, to a much lesser extent, the expanded insurance coverage implemented under the Affordable Care Act . . .”);

in the United States already are plagued by poor or inconsistent access to care,<sup>43</sup> and provider shortages are predicted to worsen in the coming years.<sup>44</sup> Current regulatory silos and inflexible scope-of-practice restrictions exacerbate provider shortages by making it more difficult to match the supply of skilled health care providers with patients in need of care.

#### D. *Incentives to Use Regulation to Stifle Competition Will Increase*

Whether in health care or in other areas of the economy, anticompetitive regulation is more likely to arise in markets that share certain common characteristics. These characteristics tend to make such markets more conducive to anticompetitive regulation, and thus increase the probability that incumbent suppliers will have the incentive to advocate for new or continued restrictive regulation.<sup>45</sup> They include: (1) extensive regulation, often at the state or local level; (2) regulations that tend to reflect a dominant, “legacy” business model; (3) changing market conditions; (4) the emergence of new products, services, or business models that are incompatible with the existing regulatory

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IHS INC., THE COMPLEXITIES OF PHYSICIAN SUPPLY AND DEMAND: PROJECTIONS FROM 2013 TO 2025 (2015), <https://www.aamc.org/download/426242/data/ihsreportdownload.pdf> [<https://perma.cc/BK4A-P4SV>] (“Study results suggest the demand for physician services is growing faster than supply. While growth in the supply of APRNs and other health occupations may help to alleviate projected shortfalls to an extent, even taking into consideration potential changes in staffing, the nation will likely face a growing shortage in many physician specialties . . .”).

43. The Health Resources and Services Administration (HRSA) designates Health Professional Shortage Areas (HPSAs) for certain geographies or populations, using a variety of criteria. According to HRSA’s most recent data, the United States has over 6000 designated primary care HPSAs, over 5000 dental health HPSAs, and over 4000 mental health HPSAs (located in every state). *Shortage Areas*, U.S. DEP’T HEALTH & HUMAN SERVS., HRSA, <http://datawarehouse.hrsa.gov/topics/shortageAreas.aspx#chart> [<https://perma.cc/6PA9-B5J5>] (last visited Feb. 5, 2015) (interactive charts based on real-time data). HRSA also designates Medically Underserved Areas/Populations (MUA/Ps), of which there are currently over 4000 (again, in every state). HEALTH RES. & SERVS. ADMIN., U.S. DEP’T HEALTH & HUMAN SERVS., MEDICALLY UNDERSERVED AREAS/POPULATIONS (MUA/P) STATE SUMMARY OF DESIGNATED MUA/P, <http://datawarehouse.hrsa.gov/tools/hdwreports/Reports.aspx#> [<https://perma.cc/3BWG-SJSG>] (click on “Shortage Areas, Medically Underserved Areas/Populations (MUA/P),” then “State Summary” to generate report based on real-time data).

44. Shortages of dental providers are, and will continue to be, particularly acute. *See, e.g.*, Jane Koppelman, *Access to Care Could Worsen as Dentist Shortages Intensify*, PEW CHARITABLE TR. (Sept. 22, 2015), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/09/21/access-to-care-could-worsen-as-dentist-shortages-intensify> [<https://perma.cc/B9EQ-ER96>]; BUREAU OF HEALTH WORKFORCE, U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL AND STATE-LEVEL PROJECTIONS OF DENTISTS AND DENTAL HYGIENISTS IN THE U.S., 2012–2025 (2015), <http://bhpr.hrsa.gov/healthworkforce/supplydemand/dentistry/nationalstatelevelprojectionsdentists.pdf> [<https://perma.cc/6G5C-K3R7>].

45. For a discussion of examples from various industries, see Gavil, *supra* note 7, at 1911–17.

framework; and (5) a consequent increase in the incentives for incumbents to use the regulatory process to impede new market entrants. These characteristics are evident today in markets as varied as electrical power distribution<sup>46</sup> and automobile sales.<sup>47</sup> They have also given rise to near warfare in sectors of the sharing economy,<sup>48</sup> taxi and related transportation services,<sup>49</sup> and municipal broadband,<sup>50</sup> where incumbents

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46. FTC staff have long been vocal in promoting regulatory reforms to promote competition in the provision of electrical power. For a recent example, see Reply Comment of the Staff of the Fed. Trade Comm'n, Proceeding on the Motion of the Commission in Regard to Reforming the Energy Vision (Nov. 23, 2015), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-reply-comment-state-new-york-public-service-commission-reforming-energy-vision-proceeding/112315nypsc.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-reply-comment-state-new-york-public-service-commission-reforming-energy-vision-proceeding/112315nypsc.pdf) [<https://perma.cc/8FXK-JMV5>]. Regulatory barriers may also be inhibiting the adoption of renewable energy sources. See, e.g., *Renewable Energy*, U.S. ENVTL. PROTECTION AGENCY, <http://www3.epa.gov/statelocalclimate/state/topics/renewable.html> [<https://perma.cc/U87Y-JFHM>] (last updated July 8, 2015) (discussing "Barriers to Renewable Energy").

47. The sale and service of automobiles is extensively regulated by the states, many of which prohibit the direct sale of automobiles to consumers by manufacturers. The effect is to mandate that all consumer purchases be made through independent dealers, which stifles innovation in automobile distribution, such as direct-to-consumer internet-based sales. FTC staff has encouraged state legislators to eliminate such limitations on competition, which have been vigorously defended by automobile dealers and their trade associations. See, e.g., Letter from Fed. Trade Comm'n Staff to Darwin L. Boorher, Senator, Mich. State Senate (May 7, 2015) [hereinafter FTC Letter to Darwin L. Boorher], [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-regarding-michigan-senate-bill-268-which-would-create-limited-exception-current/150511michiganautocycle.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-michigan-senate-bill-268-which-would-create-limited-exception-current/150511michiganautocycle.pdf) [<https://perma.cc/2XM3-T9WV>]. A workshop was also held on January 19, 2016, to explore these and broader issues related to the reform of state automobile regulations to adapt to new automotive technologies and innovation in distribution methods. See *Auto Distribution: Current Issues and Trends*, FED. TRADE COMMISSION, <https://www.ftc.gov/news-events/events-calendar/2016/01/auto-distribution-current-issues-future-trends> [<https://perma.cc/7WFE-MMND>] (last visited Feb. 5, 2016). For a description of the issues to be addressed at the workshop, see Tara Isa Koslov & James Frost, *The FTC Opens the Hood on Automobile Distribution*, FED. TRADE COMMISSION (Dec. 14, 2015, 5:38 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/12/ftc-opens-hood-automobile-distribution> [<https://perma.cc/GU9B-THTJ>].

48. For one definition, see *The Power of Connection: Peer-to-Peer Businesses: Hearing Before the H. Comm. on Small Bus.*, 113th Cong. 1 (2014), [http://smallbusiness.house.gov/uploadedfiles/1-15-2014\\_revised\\_sundararajan\\_testimony.pdf](http://smallbusiness.house.gov/uploadedfiles/1-15-2014_revised_sundararajan_testimony.pdf) [<https://perma.cc/W3VU-W67W>] (written statement of Arun Sundararajan, Professor and NEC Faculty Fellow, New York University Stern School of Business). The FTC conducted a workshop to explore competition issues in the "sharing economy" in June 2015. See *The "Sharing" Economy: Issues Facing Platforms, Participants, and Regulators*, FED. TRADE COMMISSION, <https://www.ftc.gov/news-events/events-calendar/2015/06/sharing-economy-issues-facing-platforms-participants-regulators> [<https://perma.cc/ZE47-FAHC>] (last visited Feb. 5, 2016).

49. See, e.g., Letter from Fed. Trade Comm'n Staff to Brendan Reilly, Alderman, Chi. City Council (Apr. 15, 2014) [hereinafter FTC Letter to Brendan Reilly], [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-brendan-reilly-concerning-chicago-proposed-ordinance-o2014-1367/140421chicagoridesharing.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-honorable-brendan-reilly-concerning-chicago-proposed-ordinance-o2014-1367/140421chicagoridesharing.pdf) [<https://perma.cc/52J9-PETX>] (encouraging the City of Chicago to adopt regulations that would facilitate, not inhibit, the operation of ride-sharing services); Letter from Fed. Trade Comm'n Staff

have sought to employ the regulatory process to impede new rivals. As is discussed at length in Section II.B, today's health care markets, especially those related to health care professionals, exhibit many if not all of these characteristics.

### 1. *Pervasive Historical Regulation*

First and foremost, these markets are already subject to detailed and pervasive regulation. Such regulation heightens the incentives of industry participants not only to become well-versed in the features and requirements of the regulatory system, but also to view it as a vehicle for promoting their self-interest. Economists have labelled the possible end result "regulatory capture," which can transform regulation in whole or part from a method of serving the public to one focused on serving the interests of the regulated.<sup>51</sup> The threat to competition from capture can be amplified when government authorities assign the task of interpreting and enforcing regulations to self-interested industry participants.<sup>52</sup>

This is especially true in health care markets. As has already been discussed, health care professionals of many types have long been the focus of comprehensive regulation to protect the public from unqualified or unethical professionals. Typically, such regulations establish the terms of entry into a business, trade or profession, including the requirements for education, training, and certification or licensure. In

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to Jacques P. Lerner, Gen. Counsel, D.C. Taxicab Comm'n (June 7, 2013), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comments-district-columbia-taxicab-commission-concerning-proposed-rulemakings-passenger/130612dctaxicab.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comments-district-columbia-taxicab-commission-concerning-proposed-rulemakings-passenger/130612dctaxicab.pdf) [<https://perma.cc/3SFE-H9BZ>] (encouraging District of Columbia to adopt forward-looking regulations that would facilitate development of new transportation services).

50. See, e.g., Klint Finley, *Chattanooga Is Offering Internet Faster than Google Fiber*, WIRED (Oct. 15, 2015, 4:56 PM), <http://www.wired.com/2015/10/chattanooga-is-offering-internet-faster-than-google-fiber/> [<https://perma.cc/3432-YLPV>] (noting efforts by Comcast to block lower cost, higher quality municipally-supplied broadband services); see also James Surowiecki, *The Wait-for-Google-to-Do-It Strategy*, MIT TECH. REV. (June 23, 2015), <http://www.technologyreview.com/review/538411/the-wait-for-google-to-do-it-strategy> [<https://perma.cc/XN55-AUUC>] (describing antiquated regulatory framework for broadband and the competitive impact of Google Fiber's entry).

51. See generally DENNIS W. CARLTON & JEFFREY M. PERLOFF, MODERN INDUSTRIAL ORGANIZATION 687–91 (4th ed. 2005) (describing and explaining capture theory). As Carlton and Perloff explain, because "various interest groups are affected differently by regulation and compete to influence legislation. . . . Those that are the best organized and most affected by regulation spend the most money attempting to promote their own interest through legislation and sympathetic regulators." *Id.* at 687; see also Gavil, *supra* note 7, at 1911–12 (discussing the effect of capture theory on regulated trades and professions).

52. This was a concern of the Supreme Court in *North Carolina State Board of Dental Examiners*. See *supra* note 8.

competition terms, “conditions of entry” are typically established and evaluated by regulation.<sup>53</sup>

Existing regulations also may be structured in a very particular way that can itself exacerbate their impact on competition. For example, and as observed in Section I.C, the varied service providers in the health care fields typically have been regulated in discrete silos that promote a perception of distinctiveness, both with respect to function and competence. As a result, different types of health care professionals appear to be walled off from each other even though their competencies can overlap. This has the effect of creating and perpetuating the perception by service consumers that the professions are entirely distinct.<sup>54</sup>

## 2. *Existing Regulations Reflect a Dominant “Legacy” Business Model*

A second common characteristic is that the existing regulatory scheme is grounded in a specific and dominant business model, often one that developed over decades or longer. Such regulatory schemes encode policy priorities and compromises that reflect past assessments of the marketplace, methods of doing business, and the public interest.<sup>55</sup> They will thus tend to reflect static notions of what was required to protect public health and safety based on the practices, research, and understandings of their time. These regulations may also consciously or

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53. See, e.g., FTC APRN POLICY PAPER, *supra* note 36, at 12 (“Licensure is, by its nature, a process that establishes the conditions for entry into an occupation.”).

54. This is true in other industries, as well. For example, motor vehicle transportation is often regulated through local codes that separately address “taxis,” “sedans,” and “limousines,” and these silos tend to be created in such a way as to maintain the perception of distinctiveness of the three despite the obvious potential for competitive overlap. See, e.g., FTC Letter to Brendan Reilly, *supra* note 49; see also *Modernizing Regulation in the Canadian Taxi Industry*, COMPETITION BUREAU CAN., <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04007.html> [<https://perma.cc/9ZRZ-VVUA>] (last updated Nov. 26, 2015).

55. See, e.g., FED. TRADE COMM’N, POSSIBLE ANTICOMPETITIVE BARRIERS TO E-COMMERCE: WINE (2003), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-report-concerning-possible-anticompetitive-barriers-e-commerce-wine/winereport2.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-report-concerning-possible-anticompetitive-barriers-e-commerce-wine/winereport2.pdf) [<https://perma.cc/5MKX-SDBQ>] (discussing long-standing state regulatory impediments to the interstate sale of wines directly by producers to consumers). Another example is the case of electrical power distribution regulations that reflect the technologies and past integration of generation and distribution. See *supra* note 46. Yet another is the regulation of motor vehicle transportation services. As is true of health care professions, many local jurisdictions have long divided these services into seemingly distinct silos, treating “taxi,” “sedan” or “black car,” and “limousine” services as distinct, in effect limiting the degree to which they might compete. The competitive constraints of this approach have been exposed by the advent of smartphone-based applications that provide for a variety of services. See *supra* note 54.

unconsciously reflect the social mores of their times, including implicit assumptions about the likely gender and race of various service providers and the role they should play in the delivery of services. In this way, regulation can create, promote, and reinforce a sense of normalcy around a particular hierarchy of professionals.<sup>56</sup> Such a hierarchy, especially once codified by laws and regulations, can itself be difficult to dislodge, even when it no longer appears justified or well-adapted to changed circumstances and times. In many ways, therefore, legacy regulations capture but a snapshot of the way things worked at the time of their origin; unless and until the regulations are challenged, they can perpetuate an approach that has become dated.

From a competition policy perspective, legacy regulations can be profoundly stifling for innovation and they can slow the pace of change. They tend to entrench a specific business model and can forestall the development of new business models, even when not designed to do so intentionally. The consequence, however, is the same as if the regulations had been adopted to exclude alternatives: the entire regulatory scheme develops around a specific perception of how products should be produced or services should be provided, and it embeds that model as the only approach that can satisfy the regulations' requirements.<sup>57</sup>

### 3. *Market Conditions Are Changing*

In the well-established literature on cartel formation, cartel-like stability is largely dependent on the ability of cartel members to control for changing market conditions.<sup>58</sup> In many product and service markets,

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56. While the sociology of gender-based stereotypes is beyond the scope of this Article, it is worth noting that the existing hierarchy of health care professionals likely is tied to historical gender roles, whereby most physicians were male and most nurses were female. Even today, gender biases persist: according to one respected source, over eighty percent of professional active nurses in the United States are female. *Total Number of Professionally Active Nurses, by Gender*, HENRY J. KAISER FAMILY FOUND., <http://kff.org/other/state-indicator/total-number-of-professionally-active-nurses-by-gender/#table> [<https://perma.cc/3WYQ-BL54>] (last visited Feb. 5, 2016); see also U.S. CENSUS BUREAU, MEN IN NURSING OCCUPATIONS: AMERICAN COMMUNITY SURVEY HIGHLIGHT REPORT 2 (2013), [http://www.census.gov/people/io/files/Men\\_in\\_Nursing\\_Occupations.pdf](http://www.census.gov/people/io/files/Men_in_Nursing_Occupations.pdf) [<https://perma.cc/6PCX-WMA5>] (reporting that as of 2011, approximately ninety-one percent of employed nurses in the United States were female). See generally Ann V. Bell et al., *The (Stalled) Progress of Interprofessional Collaboration: The Role of Gender*, 28 J. INTERPROFESSIONAL CARE 98 (2014) (arguing that interprofessional collaboration in furtherance of team-oriented health care delivery is hindered by gender-based occupational status hierarchy, combined with persistent underrepresentation of women in the physician workforce).

57. For further discussion of the challenge of adapting such legacy regulatory systems to industries facing disruptive technologies, see Gavil, *supra* note 7, at 1911–17.

58. See generally ANDREW I. GAVIL ET AL., ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS

these conditions include significant fluctuations in market demand, as well as entry by new firms or the expansion of output by existing ones, which can be facilitated by new technologies.<sup>59</sup> Commentators have explained, therefore, that exclusion can be and often is an essential feature of successful cartelization: to achieve stability, a cartel must be able to control for and respond effectively to new competitive challenges that might destabilize the cartel and trigger outbreaks of competition.<sup>60</sup> Faced with new competition, incumbents have two obvious choices: embrace or exclude. Incumbents can invite the new rival to join the cartel, or impede it from entering the market.<sup>61</sup>

Exclusionary regulation can substitute for this kind of exclusionary conduct in heavily regulated industries. Long-term and pervasive regulation can create cartel-like conditions—stability in price, innovation, and other dimensions of competition, including the persistence of the dominant business model itself—even when there is a substantial number of suppliers.<sup>62</sup> As noted above, regulation particularly affects conditions of new entry or expansion. New business models can present competitive challenges to such a staid and stable industry and, therefore, may tend to disrupt cartel conditions. Technology or other factors, such as increased demand, also can play a role, sometimes prompting or facilitating the development and emergence of new products, services, and business models that challenge the existing order. When “the new,” whatever it may be, does not align closely with the existing business model, its emergence generates friction with incumbent service providers, who may seek the

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AND PROBLEMS IN COMPETITION POLICY 235–47 (2d ed. 2008) (discussing economic analysis of cartel formation).

59. *Id.*

60. See, e.g., Jonathan B. Baker, *Exclusion as a Core Competition Concern*, 78 ANTITRUST L.J. 527, 558 (2013) (“Colluding firms may need to exclude in order for their collusive arrangement to succeed. They may find it necessary to deter a cheating member through exclusionary conduct, or to exclude fringe rivals or new entrants in order to prevent new competition from undermining their collusive arrangement.” (footnotes omitted)); see also GAVIL ET AL., *supra* note 58, at 235–36.

61. An illustration of this phenomenon is *JTC Petroleum Co. v. Piasa Motor Fuels, Inc.*, 190 F.3d 775 (7th Cir. 1999), in which a cartel of road pavers allegedly recruited and compensated asphalt producers to refuse to deal with a new, lower-priced road-paving entrant. See also *infra* notes 99–100 (citing additional cases and examples).

62. The regulation of motor vehicle transportation services is a prime example. For one recent account of the efforts of the incumbent taxi industry in New York City to use decades-old regulations to impede the entry and expansion of software application-based transportation services such as Uber, Lyft, and Sidecar, see Andrew J. Hawkins, *Uber Is on a Collision Course with New York City’s Mayor Again*, VERGE (Dec. 4, 2015, 3:51 PM), <http://www.theverge.com/2015/12/4/9851000/uber-nyc-bill-de-blasio-report-investigation-cap-tax-cuomo> [https://perma.cc/8FEW-YRFP]. For a description of the economic consequences of limiting entry into the industry, see CARLTON & PERLOFF, *supra* note 51, at 717–18. See also *supra* note 54.

support of regulators, especially if they perceive “the new” to be a significant competitive threat.<sup>63</sup>

Even when the competitive threat is not direct, the weight of legacy regulation can be sufficient to suppress a new business model. Inertia alone will tend to favor the incumbent. The crucial question then becomes whether the new model fits within, lies wholly outside, or simply cannot be squared with the existing regulations.

#### 4. *New Services, Products, or Business Models Are Incompatible with Legacy Regulations*

Regulatory incompatibility is often a path to exclusion. It can be apparent when a new business model obviously falls within the scope of existing regulations, but does not share all of its characteristics. In that case, it will often be argued that the new model is not in compliance with accepted regulatory norms. In other cases, the new business model may fall within, but challenge the rationale for, existing regulations, revealing a need for adaptation and evolution in the regulatory scheme.<sup>64</sup> Incompatibility also can be “manufactured” if the new model seems to fall outside of the current scheme, prompting calls for the extension of regulations to bring it within the fold.<sup>65</sup> Changing circumstances thus

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63. Many of the kinds of regulations that fit this exclusionary profile are also local or regional, the product of a long-standing allocation of regulatory authority among federal, state, and local governing authorities. In some cases, incompatibilities develop when new national or even international business models emerge that inherently challenge the notion of local regulation. This type of challenge may be the case in the emerging practice of telehealth. *See, e.g.,* Daniel J. Gilman, *Physician Licensure and Telemedicine: Some Competitive Issues Raised by the Prospect of Practicing Globally While Regulating Locally*, 14 J. HEALTH CARE L. & POL’Y 87, 89 (2011) (noting that the burgeoning field of telemedicine “promises in various ways to reduce the costs and extend the reach of many health care services,” but observing that “the advantages of remote and networked expertise may be poorly accommodated by licensing schemes that were developed to regulate local medical practices—practices historically dominated by face-to-face encounters between a physician and her patient” (footnotes omitted)). Localized regulations alone can also raise the cost of entry, as challengers seek to analyze and comply with myriad regulations across jurisdictions.

64. For example, in 2008 the North Carolina State Bar sued LegalZoom, arguing that the company participated in the unlicensed practice of law when it provided a variety of prepaid legal services, including legal document templates. LegalZoom responded with an antitrust suit directed at the Bar and accusing it of using its authority to impede new forms of competition. The Bar and LegalZoom reached a settlement in 2015 that includes a promise by the Bar to support revisions to its definition of the practice of law. *See* Terry Carter, *LegalZoom Resolves \$10.5M Antitrust Suit Against North Carolina State Bar*, ABA J. (Oct. 23, 2015, 3:15 PM), [http://www.abajournal.com/news/article/legalzoom\\_resolves\\_10.5m\\_antitrust\\_suit\\_against\\_north\\_carolina\\_state\\_bar](http://www.abajournal.com/news/article/legalzoom_resolves_10.5m_antitrust_suit_against_north_carolina_state_bar) [https://perma.cc/55KG-4U56].

65. For a possible example, see *Teladoc, Inc. v. Texas Medical Board*, No. 1–15–CV–343 RP, 2015 WL 4103658 (W.D. Tex. May 29, 2015), granting a motion preliminarily enjoining a new provision that required face-to-face physical examination of patients by a physician prior to

may highlight not only exclusionary aspects of existing regulations, but also prompt efforts to create or fortify incompatibilities. In either event, incompatibility is the lever most typically used to impede new rivalry. Rivals may advocate for change; incumbents for the status quo.

Incompatibility is a matter of degree. The regulator has several options available for responding to regulatory incompatibility. Some approaches inevitably amplify the incompatibility in ways that are more likely to impede competition. Others may allow for, or even facilitate, evolution and innovation in the marketplace, leading to a new order that may be more conducive to evolution and more responsive to consumer demands.

##### 5. *Incentives for Incumbent Firms to Seek Protectionist Regulation*

When these four factors are present, incumbent service providers may well have the incentive to seek regulatory protection as an alternative to launching a market-based competitive response to new sources of competition. Operating as if they were a covert cartel—but with the “cover” of the public regulatory process—incumbents may seek to address the changed market conditions and consequent competitive challenge through exclusionary regulation. If successful, they may be able to entirely bar the new professional or business model, slow its impact on incumbent operations, or perhaps just erect impediments to its acceptance. In short, incumbent firms may have the incentive to use legislators, regulators, and regulations to obtain protections they cannot lawfully secure for themselves.<sup>66</sup> The negative consequences can be substantial and durable. Consumers may face higher prices, lower quality, reduced access, and a loss of innovation.<sup>67</sup>

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prescribing any dangerous drug or controlled substance, effectively barring some of the telephonic health care services offered by the plaintiff. Another example is the effort by automobile dealers and their associations in a number of states to oppose efforts by electric vehicle manufacturer Tesla to sell its vehicles directly to consumers. *See supra* note 47.

66. For other examinations of the challenges, viewed through the lens of the FTC’s competition advocacy program, see James C. Cooper et al., *Theory and Practice of Competition Advocacy at the FTC*, 72 ANTITRUST L.J. 1091 (2005), and Tara Isa Koslov, *Competition Advocacy at the Federal Trade Commission: Recent Developments Build on Past Successes*, CPI ANTITRUST CHRON., Aug. 2012, at 1, <https://www.competitionpolicyinternational.com/file/view/6732> [<https://perma.cc/HS9C-LQVK>].

67. For example, for a discussion of how this is unfolding in the electric power industry, see John Seesel & Jim Mongoven, *Competition Sparks Improvements in Local Electricity Markets*, FED. TRADE COMMISSION (Dec. 1, 2015, 12:59 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/12/competition-sparks-improvements-local-electricity> [<https://perma.cc/64M8-GLPF>].

Our discussion of the five characteristics of markets conducive to exclusionary regulation is not hypothetical: these five characteristics are evident in the examples already discussed and are ubiquitous in today's regulated health care professional markets. In Part II, we discuss a number of examples that illustrate how incumbents have sought to use regulation to insulate themselves from competition, by reducing competition among existing health care providers and impeding entry or encroachment by new types of providers. So long as reform eludes the decades-old legacy framework, health care professionals will have the incentive to use regulations in this way to stifle competition.

## II. REGULATORY MECHANISMS FOR CONSTRAINING SERVICE OVERLAP COMPETITION

When faced with new competition, incumbents in heavily regulated industries have frequently urged regulators to react with hostility or at least extreme caution.<sup>68</sup> As we have noted, such anticompetitive regulatory responses can take the form of either interpretations of existing regulations or the promotion and adoption of new ones more specifically targeted at limiting new competition.<sup>69</sup> The effects can range from total exclusion of the new competition, to requirements that force it to adapt to existing regulatory models in ways that can deprive it of its competitive advantage, to the imposition of new requirements that can create or amplify incompatibility with the regulatory scheme. In this Part, we examine some specific examples of such regulatory responses and the economic impact they can have on new entry or the expansion of the provision of health care services.

Health care markets, however, should not be treated as unique so that they become disconnected from the broader principles that guide antitrust enforcement and competition policy more generally.<sup>70</sup> To

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68. For discussion of contemporary examples drawn from a variety of industries, see *supra* Section I.D.

69. *Supra* Section I.D.

70. See, for example, Edith Ramirez, *Antitrust Enforcement in Health Care—Controlling Costs, Improving Quality*, 371 *NEW ENG. J. MED.* 2245 (2014), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1408009> [<https://perma.cc/V6LJ-UYZN>]:

The FTC supports the key aims of health care reform, and we recognize that collaborative and innovative arrangements among providers can reduce costs, improve quality, and benefit consumers. But these goals are best achieved when there is healthy competition in provider markets fostering the sort of dynamic, high-quality, and innovative health care that practitioners seek and patients deserve.

*Id.* at 2247; see also FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, *IMPROVING HEALTH CARE: A DOSE OF COMPETITION* 4 (2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department->

anchor the analysis of anticompetitive regulation as it affects competition in the delivery of health care services, the discussion first locates it within the broader context of competition policy. The analysis of exclusionary regulations can be informed by reference to three well-established areas of antitrust law enforcement: exclusion, the suppression of innovation, and coordination by trade groups. As we shall demonstrate, all three areas share characteristics in common with efforts to use regulation to eliminate or dampen competition from new business models and expanded services in the health care industry. Although the means of exclusion can vary, the economic mechanisms are the same whether they are a product of private conduct or regulation.<sup>71</sup> This well-developed framework for assessing anticompetitive conduct, therefore, can help to identify, analyze, and examine specific instances of potentially exclusionary regulation.

A. *Analogizing Regulatory Exclusion to Coordinated Exclusionary Conduct*

The common concern of almost all antitrust and competition law is the prevention of conduct that has the actual or probable effect of creating, maintaining, or protecting from erosion, market power.<sup>72</sup> Anticompetitive collusion can do so by directly reducing competition between rival firms that coordinate their activity, whereas anticompetitive exclusion does so indirectly by obstructing the ability of rival firms to compete in such a way as to facilitate the exercise of

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justice/040723healthcarerpt.pdf [https://perma.cc/CLU7-NZ2G] (discussing benefits of competition in health care markets).

71. Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power over Price*, 96 YALE L.J. 209, 230 n.73 (1986) (collecting authorities and noting that the article's economic analysis of raising rivals' costs "represents a synthesis of a large number of economics articles on the subjects of cost-raising and rent-seeking strategies generally, as well as several articles on vertical integration, vertical foreclosure, exclusive dealing, and special interest regulation" (emphasis added)); see also CARLTON & PERLOFF, *supra* note 51, at 372 ("A firm may raise its rivals' costs through government regulation.").

72. The Supreme Court has defined "market power" for antitrust law purposes as "the ability to raise prices above those that would be charged in a competitive market." NCAA v. Bd. of Regents, 468 U.S. 85, 109 n.38 (1984); see also CARLTON & PERLOFF, *supra* note 51, at 642 ("A firm (or group of firms acting together) has market power if it is profitably able to charge a price above that which would prevail under competition, which is usually taken to be marginal cost."). The Supreme Court has acknowledged, however, that price is just one dimension of competition. See Nat'l Soc. of Prof'l Eng'rs v. United States, 435 U.S. 679, 695 (1978) ("The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.").

market power.<sup>73</sup> Although collusion has been described as the “supreme evil” of antitrust,<sup>74</sup> as Professor Jonathan Baker has persuasively argued, “anticompetitive exclusion, like anticompetitive collusion, must be understood as a core concern of competition policy.”<sup>75</sup> Other commentators have similarly argued that exclusionary strategies that are likely to harm competition and unlikely to present any procompetitive benefits ought to “be at the core of an enforcement agenda that challenges exclusionary conduct.”<sup>76</sup> As Baker points out, however, collusion and exclusion often go hand-in-hand.<sup>77</sup> Many of the most well-known and successful antitrust cases have involved allegations of exclusion,<sup>78</sup> and many of the formative Supreme Court cases that are often thought of as involving collusion also have involved exclusion.<sup>79</sup> Indeed, Baker argues that successful exclusion may be a prerequisite for successful collusion.<sup>80</sup> That is often the case with efforts by incumbent firms to use regulation to insulate themselves from competition by excluding rival service providers, but exclusion can benefit incumbent firms even when they are not colluding and even when they individually lack market power.

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73. Professors Areeda and Hovenkamp offer this general definition of “anticompetitive exclusion”:

[A]cts that . . .

- (1) are reasonably capable of creating enlarging or prolonging monopoly power by impairing the opportunities of rivals; and
- (2) either (2a) do not benefit consumers at all, or (2b) are unnecessary for the particular consumer benefits claimed for them, or (2c) produce harms disproportionate to any resulting benefits.

3 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 651a, at 98 (4th ed. 2015).

74. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004).

75. Baker, *supra* note 60, at 532. For an explanation of the economic relationship between collusion and exclusion, see *id.* at 556–58.

76. Susan A. Creighton et al., *Cheap Exclusion*, 72 ANTITRUST L.J. 975, 978 (2005).

77. Baker, *supra* note 60, at 536 (“Exclusionary conduct allegations are also central to other antitrust decisions commonly thought of as alleging collusion.”).

78. *Id.* at 535–36.

79. *Id.* at 535–37.

80. *Id.* Baker cites as examples *California Dental Association v. FTC*, 526 U.S. 756 (1999) (broad prohibitions on professional advertising were enforced through threats of sanctions and expulsion), *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1986) (ban on competitive bidding was implemented through a Code of Ethics and those members who violated the ban could be threatened with disciplinary action), and *NCAA v. Board of Regents*, 468 U.S. 85 (1984) (NCAA member schools who deviate from the association’s agreement to restrict the output of televised college football games faced expulsion from the NCAA). This has also been true of some important cases initiated by the government enforcement agencies. See, e.g., *Realcomp II, Ltd. v. FTC*, 635 F.3d 815 (6th Cir. 2011) (association of real estate brokers violated the antitrust laws when its members adopted anticompetitive website policies that prohibited nontraditional listings from being included in the association’s multiple listing service for residential real estate).

### 1. *The Law and Economics of Exclusion as Foundation*

The most typical forms of exclusion involve conduct that impedes a rival's access either to inputs (sometimes called "input foreclosure") or to distribution or customers (sometimes called "customer foreclosure"). In either event, the focus of the inquiry is on whether the challenged conduct raises the costs for some competitors, reduces their output capacity or raises their costs of expansion, or reduces their revenues in such a way as to eliminate them or make them less effective competitors.<sup>81</sup> This raising rivals' costs (RRC) theory of exclusion generally describes conduct to raise the costs of competitors with the purpose and effect of causing them to raise their prices or reduce their output or fail to expand, thereby allowing the excluding firm or group of firms to profit by setting a supracompetitive price.<sup>82</sup> Total exclusion from the market is not required to secure this kind of anticompetitive advantage.<sup>83</sup>

RRC theory has been influential in a number of the most prominent modern cases involving allegations of exclusionary conduct.<sup>84</sup> For example, it was an important component of the Justice Department's 1998 case against Microsoft,<sup>85</sup> and more recently was invoked by the Eleventh Circuit in a case involving exclusive dealing that was brought by the Federal Trade Commission.<sup>86</sup> Both of these cases involved

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81. Krattenmaker & Salop, *supra* note 71, at 213–14 (“[C]laims of anticompetitive exclusion should be judged according to whether the challenged practice places rival competitors at a cost disadvantage sufficient to allow the defendant firm to exercise monopoly power by raising its price.”).

82. See Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 315 (2006). The economic theory underlying the theory of raising rivals' costs was developed in Steven C. Salop & David T. Scheffman, *Raising Rivals' Costs*, 73 AM. ECON. REV. 267 (1983); see also CARLTON & PERLOFF, *supra* note 51, at 371–79.

83. See, e.g., AREEDA & HOVENKAMP, *supra* note 73, ¶ 651b5, at 110, 111 (“RRC theories show that certain practices that have traditionally been subject to antitrust scrutiny can be anticompetitive even though they do not literally involve the destruction of rivals . . . [T]he law has never required complete market exclusion as a prerequisite to suit.”).

84. For a more complete discussion, see GAVIL ET AL., *supra* note 58, at 592–98.

85. *United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (“[A]lthough Microsoft did not bar its rivals from all means of distribution, it did bar them from the cost-efficient ones.”). For an explication of the theory of the government's case in *Microsoft*, see ANDREW I. GAVIL & HARRY FIRST, *THE MICROSOFT ANTITRUST CASES: COMPETITION POLICY FOR THE TWENTY-FIRST CENTURY* 61–66 (2014).

86. See *McWane, Inc. v. FTC*, 783 F.3d 814, 832 (11th Cir. 2015) (“[A]n exclusive dealing arrangement can be harmful when it allows a monopolist to maintain its monopoly power by raising its rivals' costs sufficiently to prevent them from growing into effective competitors.”). For an analysis of the exclusionary effects at issue in the FTC's *McWane* decision, see Steven C. Salop et al., *The Appropriate Legal Standard and Sufficient Economic Evidence for Exclusive Dealing Under Section 2: The FTC's McWane Case* (Georgetown Univ. Law Ctr. Working Paper No. 1365,

successful challenges to conduct that sought to deprive rivals of cost-effective access to distribution and thus are analogous to regulations that interfere with a service provider's ability to reach customers—or, as Section II.B discusses, in the health care industry, patients.

As the *United States v. Microsoft*<sup>87</sup> court recognized, “the means of illicit exclusion, like the means of legitimate competition, are myriad.”<sup>88</sup> Various commentators have noted this range of conduct and offered alternative ways to synthesize the cases into identifiable patterns.<sup>89</sup> Regardless of their form, however, anticompetitive strategies utilize a common economic mechanism: by raising rival's costs, they can in some circumstances facilitate the exercise of market power or otherwise insulate a dominant firm or group of incumbent firms from competition. As Professors Hemphill and Wu have explained:

When harmful, these [exclusionary] methods may weaken the rival, for example, by preventing it from achieving the economies of scale required to offer a competitive price. Lack of scale may also preclude a rival from gaining enough consumer adoption for a virtuous cycle to kick in, whereby widespread adoption makes the product more attractive for all users. The weakened competitor might also find it difficult to finance, either from external capital markets or retained earnings, the research and development needed to better displace the incumbent in the future. In the limit, these tactics may prevent entry entirely.<sup>90</sup>

Exclusionary regulation fits comfortably within this conceptual framework. In almost all of its forms, the probability that it will harm competition depends in the first instance on its tendency to successfully impede a rival firm's or a class of rival firms' access to inputs or customers by imposing additional costs on, or erecting other barriers to,

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2014), <http://scholarship.law.georgetown.edu/facpub/1365/>; <http://scholarship.law.georgetown.edu/facpub/1365/> [https://perma.cc/PC39-4CNF]; see also AREEDA & HOVENKAMP, *supra* note 73, ¶ 651b5, at 110 n.36 (collecting cases that have acknowledged the raising rival's costs theory).

87. 253 F.3d 34, 64 (D.C. Cir. 2001).

88. *Id.* at 58; see also C. Scott Hemphill & Tim Wu, *Parallel Exclusion*, 122 YALE L.J. 1182, 1200 (2013) (“Anticompetitive exclusion can occur by a wide variety of means.”).

89. See, e.g., Baker, *supra* note 60, at 538–43 (identifying three types of practices that courts have identified as potentially exclusionary: constraints imposed on rival conduct, the purchase of exclusionary rights, and commitments to tough competition); see also Hemphill & Wu, *supra* note 88, at 1200–09 (classifying conduct that unreasonably forecloses competition into six categories that have been recognized in the case law: simple exclusion, recruiting agents, overbuying an input, tying and bundling, resale price maintenance, and most favored nation provisions).

90. Hemphill & Wu, *supra* note 88, at 1200.

entry.<sup>91</sup> In doing so, such regulations can help perpetuate the market power of incumbent firms or the collective market power of groups of small firms and otherwise insulate them from all dimensions of competition, not only price, but also quality and innovation. Not surprisingly, therefore, as illustrated in Section I.D, such restrictive regulations are often advocated by incumbent firms either in parallel or through explicit coordination.<sup>92</sup> And whether accomplished through private conduct or regulation, RRC can impede innovation in the marketplace, especially when it is targeted at the new business models or service delivery methods used by service providers.

Before turning back to an examination of specific examples from the health care services field, however, it is valuable to consider how RRC relates to two additional areas of antitrust law enforcement: (1) the suppression of innovation, and (2) trade association activity. An examination of these cases lends further context to the analysis of exclusionary regulations and completes the framework for identifying and analyzing anticompetitive instances of regulation.

## 2. *Protecting Innovation and Innovation Competition*

The protection of competition sparked by innovation has long been a concern of antitrust law.<sup>93</sup> That concern has been evident in cases involving both collusion and exclusion to suppress innovation.<sup>94</sup> It has taken on even greater importance in today's technology-driven and dynamic economy, where new products and new business methods can pose substantial competitive challenges to status quo firms. As we observed in Section I.D, the competitive threat of such changes in the marketplace can lead incumbent firms to respond with exclusionary strategies.<sup>95</sup> Indeed, one of the paradigmatic early cases on exclusion

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91. See, e.g., FTC APRN POLICY PAPER, *supra* note 36, at 33 (“To the extent that rigid APRN supervision requirements may inhibit the growth of APRN-staffed retail clinics or prevent alternative settings from operating at all, such restrictions may deny consumers important price and non-price benefits of innovation in health care delivery.”).

92. Collective efforts to petition or lobby the government for such anticompetitive regulations may be beyond the reach of antitrust enforcement. For a discussion, see Gavil, *supra* note 7, at 1916–17.

93. See generally GAVIL ET AL., *supra* note 58, at 1162–72 (discussing various ways in which antitrust law has sought to deter conduct that suppresses innovation); see also Timothy Wu, *Taking Innovation Seriously: Antitrust Enforcement If Innovation Mattered Most*, 78 ANTITRUST L.J. 313 (2012) (arguing for a broader commitment to using antitrust law to promote innovation).

94. For recent discussions, see Baker, *supra* note 60, at 559–62; Hemphill & Wu, *supra* note 88, at 1210–13 (discussing what they describe as “anticompetitive parallel exclusion” and emphasizing the importance of its impact on innovation).

95. As Professors Hemphill and Wu argue, “[w]here the innovative product is a serious

involved efforts by a dominant local newspaper to squelch the competitive threat of then new technology: over-the-air AM radio.<sup>96</sup> Similarly and more recently, in *Realcomp II, Ltd. v. FTC*<sup>97</sup> the FTC successfully challenged coordinated efforts by a local board of realtors to suppress competition from new, internet-based and lower-cost sales models.<sup>98</sup> Many other examples from the annals of antitrust history can be cited to illustrate how incumbent firms can pursue exclusionary strategies rather than competitive ones in response to new products, services, and business models that challenge the status quo.<sup>99</sup>

### 3. *Trade Associations as Facilitators*

Strategies to suppress innovation are often pursued by professionals in cooperation with other members of their trade, sometimes through private standard setting, trade association rules including codes of conduct, and government regulation.<sup>100</sup> A number of such cases have arisen in the health care industry, often in connection with the activity of

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existential threat to members of the oligopoly, the incentive to block or co-opt the entrant can (understandably) be strong.” Hemphill & Wu, *supra* note 88, at 1212.

96. *Lorain Journal Co. v. United States*, 342 U.S. 143 (1951) (incumbent newspaper refused to accept advertisements from its customers who also placed advertisements with new radio station). For an analysis of *Lorain Journal* through the lens of modern exclusion theory, see GAVIL ET AL., *supra* note 58, at 596–98.

97. 635 F.3d 815 (6th Cir. 2011).

98. *Id.* at 829–34 (finding substantial evidence that Realcomp’s “website policy,” which restricted consumer access to discounted online and limited service business models, was unreasonably anticompetitive).

99. *See, e.g., Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500–01 (1988) (use of private industry standard-setting process to exclude new competitive threat); *Am. Soc’y of Mech. Eng’rs v. Hydrolevel Corp.*, 456 U.S. 556 (1982) (concluding that non-profit standard-setting group could be held liable under the antitrust laws for allowing its members to manipulate its standards to exclude their rival’s product); *United States v. Visa USA, Inc.*, 344 F.3d 229, 241 (2d Cir. 2003) (finding no error in the district court’s finding “that product innovation and output has been stunted by the challenged policies”); *United States v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001) (“[I]t would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will—particularly in industries marked by rapid technological advance and frequent paradigm shifts.”). For a discussion of the exclusionary theories in both *Visa* and *Allied Tube*, see Hemphill & Wu, *supra* note 88, at 1191–93. For an additional discussion of the exclusionary possibilities in the context of private standard-setting organizations, such as those involved in *Allied Tube* and *American Society of Mechanical Engineers*, see Creighton et al., *supra* note 76, at 987–88.

100. *See supra* note 99; *see also Radiant Burners, Inc. v. Peoples Gas Light & Coke Co.*, 364 U.S. 656 (1961) (holding that a gas burner manufacturer stated an antitrust claim for relief against trade association and its gas supplier members who refused to approve manufacturer’s burner for use by gas utilities); *Fashion Originators’ Guild of Am. v. FTC*, 312 U.S. 457 (1941) (condemning boycott by designers and manufacturers of women’s garments directed at retailers who also resold allegedly “pirated” designs of lower cost rival manufacturers).

trade associations.<sup>101</sup> Indeed, trade groups of various kinds have frequently been, and continue to be, a persistent focus of antitrust enforcement. The pervasiveness of such groups in the health care trades draws attention to the connection between the anticompetitive acts of trade groups and those of self-interested state boards charged with enforcing professional regulations, a connection that the Supreme Court recently acknowledged:

In important regards, agencies controlled by market participants are more similar to private trade associations vested by States with regulatory authority than to the agencies [*Town of Hallie v. City of Eau Claire*, 471 U.S. 34 (1985)] considered. And as the Court observed three years after *Hallie*, “[t]here is no doubt that the members of such associations often have economic incentives to restrain competition and that the product standards set by such associations have a serious potential for anticompetitive harm.”<sup>102</sup>

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101. One example is *American Medical Ass’n v. FTC*, 638 F.2d 443 (2d Cir. 1980), which also illustrates the relationship between collusion and exclusion. The FTC prevailed in its challenge to certain AMA ethical rules that restrained advertising, including the dissemination of price information, and solicitation. *Id.* at 450. The FTC also successfully challenged the AMA’s prohibitions of various kinds of contractual arrangements between physicians and non-physicians, restrictions that limited the business models available to physicians. *Id.* at 451–52. The case can be understood, therefore, as an additional illustration of the interdependence of collusion and exclusion. *See also* *Cal. Dental Ass’n v. FTC*, 526 U.S. 756 (1999) (holding that, although FTC’s use of abbreviated rule of reason analysis in connection with certain prohibitions on professional advertising was improper, the prohibitions were enforced by the association through threats of sanctions and expulsion of advertising members). For a more recent example, see *Kissing Camels Surgery Center, LLC v. Centura Health Corp.*, 111 F. Supp. 3d 1180 (D. Colo. 2015), denying a motion to dismiss an antitrust claim that a trade association, hospitals with surgery centers, and insurers conspired to refuse to enter into necessary transfer agreements with non-hospital ambulatory surgical centers which had the effect of impeding their ability to compete.

102. *N.C. State Bd. of Dental Exm’rs v. FTC*, 574 U.S. \_\_\_, 135 S. Ct. 1101, 1114 (2015) (second alteration in original) (quoting *Allied Tube & Conduit Corp.*, 486 U.S. at 500) (rejecting application of state action doctrine to state board of dental examiners, which sought to eliminate competition from low-cost teeth whitening services provided by non-dentists); *see also* *S.C. State Bd. of Dentistry v. FTC*, 455 F.3d 436 (4th Cir. 2006) (holding that the board was not insulated from antitrust liability for its efforts to prevent dental hygienists from providing basic dental care services to underserved populations). Indeed, knowing that conduct by the trade group may violate the antitrust laws could provide the needed incentive for group members to instead turn to government regulation to achieve the same, prohibited ends without incurring the risk of personal liability. *See also* Memorandum from Fed. Trade Comm’n, FTC Staff Guidance on Active Supervision of State Boards Controlled by Market Participants (Oct. 2015), [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active\\_supervision\\_of\\_state\\_boards.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/active_supervision_of_state_boards.pdf) [<https://perma.cc/5BWS-9T8L>] (providing additional guidance for states on compliance with the Supreme Court’s decision in *North Carolina State Board of Dental Examiners*); Blair & Durrance, *supra* note 31, at 31–32 (modeling the harm to competition and consumers that can occur when licensure and related regulations are used by one group of health care providers to exclude a competing group of providers, with no offsetting quality of care benefits).

In assessing how regulation can be used to impede competition, therefore, it can be revealing to examine the economic underpinnings of antitrust law enforcement actions that have been directed at anticompetitive conduct by trade groups. That economic analysis is instructive whether those actions were adopted and implemented by self-interested boards, as in *North Carolina State Board of Dental Examiners v. FTC*,<sup>103</sup> or are the product of trade group conduct.<sup>104</sup> Such cost-raising strategies are common in examples of regulations that impede competition.

This Section provided an analytical framework that can be applied to specific recent examples of exclusionary regulation in the health care professions. To construct that framework, it drew upon three well-established areas of antitrust: the law and economics of anticompetitive exclusion, suppression of innovation, and trade group and association activity that eliminated competition. In the illustrations that follow, exclusionary regulation often lies at the intersection of these three areas of antitrust. Virtually all of the examples that follow illustrate how industry incumbents in the health care industry, either in parallel or through coordination, have sought to use regulation to impede the access of their perceived rival service providers to patients and other purchasers of their services. In some instances, the rival providers were attempting to expand competitive overlap with incumbent service providers by advancing new and innovative service or business models. The successful exclusion of such new providers in turn can diminish the opportunity and incentives for future innovations in service delivery. Regardless of context, in each instance the conduct's anticompetitive effect can be attributed to its tendency to alter the conditions of entry into the field by raising the costs, or reducing the revenues, of the targeted rival group, without substantial justification.<sup>105</sup> With this foundation in place, the next Section turns to a sampling of recent illustrations.

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103. *N.C. State Bd. of Dental Examiners*, 135 S. Ct. 1101.

104. *See, e.g., Wilk v. Am. Med. Ass'n*, 719 F.2d 207, 212–15 (7th Cir. 1984) (remanding an antitrust challenge by chiropractors against various medical trade groups alleging conduct that impaired their ability to compete with medical doctors).

105. For a general discussion of the consequences of regulations that limit entry, see CARLTON & PERLOFF, *supra* note 51, at 716–18.

B. *Anticompetitive Regulation in the Health Care Industry: A Sampling*

To make our analysis more concrete, we next identify specific examples of health care professional regulations that may impede competition. When evaluated in the context of the overlap areas in Figure 1 above, the exclusionary nature of these regulations becomes apparent: they make it impossible to fully realize the competitive benefits that arise when different types of health care providers can safely and effectively perform at least some of the same services. Further, the public safety arguments proffered to justify the specific restrictions at issue appeared to be either exaggerated or unsupported.

All of these examples are drawn from advocacy comments filed by FTC staff in recent years. As an important component of the agency's competition mission, upon request FTC staff regularly engages in competition advocacy by filing comments that analyze the competitive effects of proposed state legislation or regulations.<sup>106</sup> From January 2010 through November 2015, FTC staff sent more than fifteen advocacy comments to state legislators regarding scope-of-practice restrictions,<sup>107</sup> and also published a March 2014 staff policy paper, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses*.<sup>108</sup>

The FTC staff policy paper, drawing from and expanding upon prior FTC staff comments, focuses on various forms of mandatory physician supervision of APRNs.<sup>109</sup> Slightly more than half the states currently

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106. *Advocacy Filings*, FED. TRADE COMMISSION, <https://www.ftc.gov/policy/advocacy/advocacy-filings> [<https://perma.cc/FLB5-ZKRN>] (last visited Feb. 20, 2016) (“When government bodies and other organizations consider cases or policy decisions that affect consumers or competition, the FTC may offer insight and expertise to decision makers by filing an advocacy letter.”); see also Gavil, *supra* note 7, at 1902–05 (discussing sources of FTC’s authority to engage in competition advocacy); Cooper et al., *supra* note 66, at 1092–99 (describing history of FTC advocacy comments from 1974–2004); Koslov, *supra* note 66, at 6–8 (describing examples of FTC competition advocacy comments involving intellectual property, innovation, and health care).

107. To access FTC staff competition advocacy comments, see *Advocacy Filings*, *supra* note 106.

108. FTC APRN POLICY PAPER, *supra* note 36. Ms. Koslov was one of two principal authors of the policy paper (with Daniel J. Gilman), and Professor Gavil supervised the project as then-Director of the FTC’s Office of Policy Planning. See also Daniel J. Gilman & Julie Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice*, 24 HEALTH MATRIX: J.L.-MED. 143, 171–206 (2014) (discussing and evaluating FTC staff competition advocacies affecting various health care professionals).

109. Similar issues have arisen with supervision requirements imposed on dental hygienists. See, e.g., Letter from Fed. Trade Comm’n Staff to Valencia Seay, Senator, Ga. State Senate (Jan. 29, 2016) [hereinafter FTC Letter to Valencia Seay], [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-georgia-state-senator-valencia-seay-concerning-georgia-house-bill-684/160201gadentaladvocacy.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-georgia-state-senator-valencia-seay-concerning-georgia-house-bill-684/160201gadentaladvocacy.pdf) [<https://perma.cc/9Y5P-J6ME>] (supporting proposed legislation that would broaden settings where dental hygienists can provide preventive dental care

restrict otherwise qualified APRNs from practicing to the top of their license,<sup>110</sup> unless they also satisfy an additional layer of physician supervision requirements that may include, for example, mandatory chart review, specified numbers or types of physician consultations, or physician approval of practice plans or protocols.<sup>111</sup> They may also include mandatory “collaborative practice agreements,” whereby an APRN must secure (and often pay for) a written agreement with a physician, in which the physician specifies acceptable terms for the APRN’s practice.<sup>112</sup> In many of these states, such supervision is a general prerequisite to licensed APRN practice; in some states, these or other restrictions pertain to large parts of practice, such as prescribing medications or diagnosing illnesses. The physician becomes a “gatekeeper” for the APRN’s entry and continued access to the profession—“effectively giv[ing] one group of health care professionals the ability to restrict access to the market by another, competing group of health care professionals, thereby denying health care consumers the benefits of greater competition.”<sup>113</sup>

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services without direct in-person supervision by a dentist, which likely would enhance competition and expand access to care); Letter from Fed. Trade Comm’n Staff to Teneale E. Johnson, Exec. Sec’y, Bd. of Dental Exam’rs (Nov. 16, 2011), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-maine-board-dental-examiners-concerning-proposed-rules-allow-independent-practice/111125mainedental.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-maine-board-dental-examiners-concerning-proposed-rules-allow-independent-practice/111125mainedental.pdf) [<https://perma.cc/7VYX-6LMP>] (concerning proposed rules to allow independent practice dental hygienists to take x-rays in underserved areas); Letter from Fed. Trade Comm’n Staff to Randall Vaughn, Sec’y of State, Ga. Bd. of Dentistry (Dec. 30, 2010), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-georgia-board-dentistry-concerning-proposed-amendments-board-rule-150.5-0.3-governing-supervision-dental-hygienists/101230gaboarddentistryletter.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-georgia-board-dentistry-concerning-proposed-amendments-board-rule-150.5-0.3-governing-supervision-dental-hygienists/101230gaboarddentistryletter.pdf) [<https://perma.cc/SC4E-UYK7>] (concerning proposed amendments to Board rule 150-5-0.3 governing supervision of dental hygienists).

110. See *AANP State Practice Environment Data*, *supra* note 35 (summarizing the APRN practice environment in each state, including comparative characterizations of “full,” “reduced,” or “restricted” practice).

111. FTC APRN POLICY PAPER, *supra* note 36, at 28. For a general (albeit somewhat outdated) summary of state-by-state supervisory requirements, see IOM FUTURE OF NURSING REPORT, *supra* note 11, at 157–61, tbl.3-A1. See also GRANT R. MARTSOLF ET AL., THE IMPACT OF FULL PRACTICE AUTHORITY FOR NURSE PRACTITIONERS AND OTHER ADVANCED PRACTICE REGISTERED NURSES IN OHIO (2015), [http://www.rand.org/content/dam/rand/pubs/research\\_reports/RR800/RR848/RAND\\_RR848.pdf](http://www.rand.org/content/dam/rand/pubs/research_reports/RR800/RR848/RAND_RR848.pdf) [<https://perma.cc/43G2-3SZP>].

112. FTC APRN POLICY PAPER, *supra* note 36, at 28. Of the ten most populous states, six are listed in the “restricted” category (California, Texas, Florida, Georgia, North Carolina, and Michigan) and the other four are in the “reduced” category (New York, Illinois, Pennsylvania, and Ohio). *AANP State Practice Environment Data*, *supra* note 35; see *Resident Population Data*, U.S. CENSUS BUREAU, <http://www.census.gov/2010census/data/apportionment-dens-text.php> [<https://perma.cc/2X39-K5ZE>] (last visited Feb. 22, 2016).

113. FTC APRN POLICY PAPER, *supra* note 36, at 2; see also FTC Letter to Valencia Seay, *supra* note 109, at 3 (“By increasing the availability of dental hygienists’ services outside of dentists’ offices, these initiatives can increase the number of suppliers of preventive dental care. The

A subset of related regulations restrict the ability of APRNs to write prescriptions independently—typically for controlled substances<sup>114</sup> used for pain relief, but sometimes even for basic drugs like antibiotics. When these restrictions are in place, an APRN can only write prescriptions subject to a collaborative practice agreement or another form of physician supervision, such as the physician’s “delegation” to the APRN of prescribing authority.<sup>115</sup> These regulations needlessly reserve for physicians the power to prescribe, even though credible evidence establishes that APRNs can safely and effectively prescribe a variety of medications, and no credible countervailing evidence negates this conclusion.<sup>116</sup> Even with respect to more controversial pain medications, where scope of practice variations among states create a natural experiment, it appears that APRNs safely and effectively prescribe controlled substances in a number of states,<sup>117</sup> which calls into question the legitimacy of other states’ restrictions.

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initiatives thereby promote greater competition in the provision of oral health services. Greater competition may, in turn, enhance access to affordable preventive services, mitigate the broader health consequences of dentist shortages, and facilitate the development of innovative models for delivering care.”).

114. “Drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential.” *Drug Scheduling*, U.S. DRUG ENFORCEMENT ADMIN., <http://www.dea.gov/druginfo/ds.shtml> [<https://perma.cc/A3TA-S2RA>] (last visited Feb. 20, 2016); see also Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2012)); 21 U.S.C. § 812 (“Schedules of controlled substances”).

115. Many states restrict prescribing authority by requiring such authority to be explicitly included in a mandatory collaborative practice agreement, or by requiring an additional act of delegation that is specific to prescribing. See, e.g., S.C. CODE ANN. § 40-33-34(4)(C)–(D) (West, Westlaw through 2015 Reg. Sess.) (imposing requirements for written protocols and physician supervision; mandating that prescribing authority for all drugs, including non-controlled substances, must be delegated pursuant to written protocol and is limited to an APRN’s defined specialty role); see also *supra* note 30 (comparing prescribing authority in Wyoming and Texas). For an overview of each state’s prescribing rules for APRNs, see Laura A. Stokowski, *APRN Prescribing Law: A State-by-State Summary*, MEDSCAPE NURSES (June 9, 2015), <http://www.medscape.com/viewarticle/440315> [<https://perma.cc/8AMB-XAKY>].

116. See, e.g., FTC APRN POLICY PAPER, *supra* note 36; see also *infra* notes 141–43 and accompanying text (citing and interpreting various studies concluding that APRNs prescribe safely and effectively); Letter from Fed. Trade Comm’n Staff to Kent Leonhardt, Senator, Senate of W. Va. (Feb. 10, 2016), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-senate-west-virginia-concerning-competitive-impact-wv-senate-bill-516-regulation/160212westvirginia.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-senate-west-virginia-concerning-competitive-impact-wv-senate-bill-516-regulation/160212westvirginia.pdf) [<https://perma.cc/GJ9Q-76KD>] (expressing concerns about, inter alia, proposed legislation that would require certain APRNs to secure a separate prescribing license to gain independent prescribing authority, and would place control of that new licensure scheme entirely under the authority of the state’s Board of Medicine or Board of Osteopathy).

117. See, e.g., MARIA SCHIFF, NAT’L GOVERNORS ASS’N, THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE 12–13 (2012), <http://www.nga.org/cms/>

Also relevant to pain medication, FTC staff has filed several comments relating to scope-of-practice restrictions on certified registered nurse anesthetists (CRNAs), a type of advanced practice nurse with specialized training in anesthesia and pain management.<sup>118</sup> These restrictions complicate the problem of ensuring adequate access to pain management, which is a significant public health challenge, particularly in rural and other underserved communities.<sup>119</sup> Some states have adopted scope of practice laws that prohibit CRNAs from providing anesthesia and other inpatient pain management services (e.g., epidurals for labor and delivery) without in-person supervision by an anesthesiologist, thus undermining the ability of otherwise competent CRNAs to safely provide expanded access to care in areas with anesthesiologist shortages.<sup>120</sup> In addition, a number of states limit the ability of CRNAs to independently provide post-operative or chronic pain management in outpatient settings, without direct physician supervision.<sup>121</sup> Again, given the natural experiment of expanded CRNA practice in a number of states (including many where Medicare allows direct billing for CRNA-provided services)<sup>122</sup> with no evidence of differential safety concerns,<sup>123</sup> it becomes difficult to defend the more restrictive approach.

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home/nga-center-for-best-practices/center-publications/page-health-publications/col2-content/main-content-list/the-role-of-nurse-practitioners.html [https://perma.cc/L68J-GCJU] (identifying states in which APRNs may independently prescribe controlled substances).

118. See, e.g., Press Release, Fed. Trade Comm'n, FTC Staff: Massachusetts Should Consider Removing Physician Supervision Requirements for Nurse Practitioners and Nurse Anesthetists (Jan. 23, 2014), <https://www.ftc.gov/news-events/press-releases/2014/01/ftc-staff-massachusetts-should-consider-removing-physician> [https://perma.cc/S5R3-CYKX]; Press Release, Fed. Trade Comm'n, FTC Staff: Proposed Missouri Legislation May Reduce Patient Access to Pain Management Services and Increase Prices (Mar. 28, 2012) [hereinafter FTC Missouri Comment], <https://www.ftc.gov/news-events/press-releases/2012/03/ftc-staff-proposed-missouri-legislation-may-reduce-patient-access> [https://perma.cc/Z6K6-477Y].

119. See FTC Missouri Comment, *supra* note 118 (noting that some rural hospitals are located in counties in which there are no licensed anesthesiologists). See generally INST. OF MED., *supra* note 32, at 57 (providing recommendations to improve pain management practices in the United States, including a recognition that “state and federal policy makers, who must craft policies related to . . . regulation of clinicians’ scope of practice,” are among the sectors that should contribute to solving the public health challenge of pain management).

120. See, e.g., Letter from Fed. Trade Comm’n Staff to Heather A. Steans, Senator, Ill. State Senate (Apr. 19, 2013), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-honorable-heather.steans-illinois-state-senate-concerning-illinois-senate-bill-1662-and-regulation-certified/130424illinois-sb1662.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-heather.steans-illinois-state-senate-concerning-illinois-senate-bill-1662-and-regulation-certified/130424illinois-sb1662.pdf) [https://perma.cc/MM9R-ALJB].

121. *Id.*

122. Although Medicare imposes a supervision requirement for CRNAs, since 2001 individual states have been permitted to “opt out” of the supervision requirement. Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 66 Fed. Reg. 56,762 (Nov. 13, 2001) (codified at 42 C.F.R. § 416.42(d) (2016)). Effective November 13, 2001, CMS established an exemption for Certified Registered Nurse Anesthetists from the physician supervision

In recent years, FTC staff has expanded its scope of practice advocacy to address restrictions on an emerging profession: dental therapists, who, as discussed above,<sup>124</sup> are trained to provide some dental services traditionally provided only by licensed dentists. FTC staff commented on a type of restriction that arose at an “upstream” level: accreditation standards for dental therapy education programs.<sup>125</sup> When the Commission on Dental Accreditation (CODA) proposed draft accreditation standards, the proposed standards implicitly assumed that all dental therapy students would be trained to practice only under the direct supervision of dentists.<sup>126</sup> This framework all but guaranteed that graduates of dental therapy programs would be deemed to lack the training necessary to practice safely without direct supervision, which inevitably would influence scope of practice laws and constrain the discretion of states as they created licensing regimes for this new profession. Mandatory supervision would thwart one of the main

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requirement. “This exemption recognized a Governor’s written request to CMS attesting that he or she is aware of the State’s right to an exemption of the requirement and that is in the best interests of the State’s citizens to exercise this option.” *Conditions for Coverage (CfCs) & Conditions of Participations (CoPs): Spotlight*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Spotlight.html> [<https://perma.cc/LQS4-LDNE>] (last visited Feb. 20, 2016). In opt-out states, it is possible to bill Medicare directly for CRNA services, without requiring the signature of a supervising physician. At least seventeen states have opted out. *Id.* Governors often determine that expanded CRNA practice authority is particularly critical in rural areas where anesthesiologists are in short supply. Hospitals and other health care facilities otherwise might be unable to treat emergencies or schedule procedures requiring anesthesia, unless an anesthesiologist were physically present. *See generally Fact Sheet Concerning State Opt-Outs and November 13, 2001 CMS Rule*, AM. ASS’N NURSE ANESTHETISTS, <http://www.aana.com/advocacy/stategovernmentaffairs/Pages/Fact-Sheet-Concerning-State-Opt-Outs.aspx> [<https://perma.cc/8BCV-WXKR>] (last visited Feb. 13, 2016).

123. *See, e.g.*, Letter from Fed. Trade Comm’n Staff to Kay Khan, Representative, Mass. House of Representatives 8 & nn.67–68 (Jan. 17, 2014), [https://www.ftc.gov/sites/default/files/documents/advocacy\\_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf](https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-massachusetts-house-representatives-regarding-house-bill-6-h.2009-concerning-supervisory-requirements-nurse-practitioners-nurse-anesthetists/140123massachusettsnursesletter.pdf) [<https://perma.cc/2URB-4NXC>] (citing various sources from safety literature relating to CRNA practice, none of which provide evidence of patient harm).

124. *See supra* notes 40–41 and accompanying text.

125. FTC 2013 CODA Comment, *supra* note 41. FTC staff provided a follow-up comment a year later, commending CODA for its revisions and encouraging CODA to finalize and adopt accreditation standards without undue delay. Press Release, Fed. Trade Comm’n, FTC Staff Urges Dental Accreditation Commission to Adopt Dental Therapy Accreditation Standards (Dec. 1, 2014), <https://www.ftc.gov/news-events/press-releases/2014/12/ftc-staff-urges-dental-accreditation-commission-adopt-dental> [<https://perma.cc/QAE8-5BGD>].

126. FTC 2013 CODA Comment, *supra* note 41, at 1–2 (noting proposed standards stated that “diagnosis and treatment planning are the responsibility of a supervising dentist,” which “may deter the development of dental education programs that would train dental therapists to provide such services under the level of supervision required by each state . . . even when states determine that patient safety may not require [on-site supervision by a dentist]”).

purposes of dental therapists: to expand access to dental care, especially for underserved populations.<sup>127</sup> The FTC staff comment encouraged CODA to consider making the accreditation standards neutral with respect to the role of supervising dentists, and to develop accreditation standards that would train dental therapists to practice without an on-site supervising dentist, thus preserving individual states' flexibility to address supervision issues in their licensure and scope of practice laws.<sup>128</sup> In other words, the comment acknowledged the interest of regulators in addressing any genuine health and safety concerns, but encouraged them to do so without imposing unjustifiable barriers to entry and expansion of services.

Finally, in 2014, FTC staff commented on proposed Texas regulations that likely would have preserved the long-standing status quo approach by stifling the development of new business models for delivering dental services.<sup>129</sup> The proposed regulations would have prohibited dentists from entering into contracts with "unlicensed persons" for the provision of non-clinical services, such as administrative and business management functions.<sup>130</sup> The proposed regulations also would have expanded the Board's authority to take disciplinary actions against dentists that entered into such contracts.<sup>131</sup>

Although the draft regulations did not explicitly mention it, the proposals appeared to have been targeted at dental service organizations (DSOs), and would have had the effect of discouraging dentists from

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127. See, e.g., MINN. STAT. ANN. § 150A.105 (West, Westlaw through 2015 First Spec. Sess.) ("Limited practice settings. A dental therapist licensed under this chapter is limited to primarily practicing in settings that serve low-income, uninsured, and underserved patients or in a dental health professional shortage area."); FTC 2013 CODA Comment, *supra* note 41, at 5 & n.40 ("Dental therapists are likely to be most effective in expanding access to care, especially to the underserved, when they are allowed under appropriate circumstances to evaluate a patient and develop a treatment plan under the supervision of a remotely-located dentist."); *Dental Crisis in America: The Need to Expand Access: Hearing Before the Subcomm. on Primary Health & Aging of the S. Comm. on Health, Educ., Labor, & Pensions*, 112th Cong. 28 (2012) (statement of Christy Jo Fogarty, Registered Dental Hygienist, Master of Science, Oral Health Practitioner), <https://www.gpo.gov/fdsys/pkg/CHRG-112shrg89737/pdf/CHRG-112shrg89737.pdf> [<https://perma.cc/E5C2-9BJ6>] (if dental therapists must have a dentist on-site, they cannot "do much to improve access to care for vulnerable populations").

128. FTC 2013 CODA Comment, *supra* note 41, at 9.

129. Letter from Fed. Trade Comm'n Staff to Simone Salloum, Assistant Gen. Counsel, Tex. State Bd. of Dental Exam'rs (Oct. 6, 2014) [hereinafter FTC TX DSO Comment], [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-texas-state-board-dental-examiners/141006tsbdecomment1.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-texas-state-board-dental-examiners/141006tsbdecomment1.pdf) [<https://perma.cc/38MH-D67D>] (commenting on proposed law that would restrict ability of dentists to enter into agreements with non-dentists for the provision of administrative services).

130. *Id.* at 1, 4.

131. *Id.*

affiliating with them. The comment expressed the staff's concern that such restrictions could be anticompetitive:

Dentists generally have little training in administration, which means that carrying out administrative tasks can be time consuming. Relieving dentists of the need to perform administrative tasks could increase the amount of dentistry services dentists could provide, and lower the costs of providing dental services. In addition, DSOs may support entry into Texas, or prevent exit, by dentists who prefer to affiliate with a DSO. This new entry may lead to lower prices, expanded services, and improved access to dental services. Because the proposed rules may well deter licensed dentists from contracting with DSOs, the proposed rules appear likely to impede competition and deprive consumers of these potential benefits.<sup>132</sup>

This small sampling of the FTC staff's most recent competition advocacy work in the health care field continues long-standing efforts by the agency to, first, identify anticompetitive laws and regulations (both current and proposed) and, second, provide a framework that regulators and legislators can use to evaluate the potential for anticompetitive harm. As argued in Section II.A, all of the staff's analysis consistently focuses on entry-related regulations that impose costs on potential rivals and ensure that, even if they do successfully enter the market, revenues generated by their services will be shared with incumbent providers. The incumbent providers are often observable behind the scenes in these regulatory proposals. The competitive threat is always the same: by impeding change, including the emergence of innovative new delivery models, the troublesome regulations would have the effect of perpetuating the status quo and stifling competition in the marketplace.

### III. LOOKING TOWARD THE FUTURE OF HEALTH CARE WORKFORCE REGULATION

#### A. *Guiding Principles for Regulators*

As illustrated in Part II, regulations can favor incumbents to the detriment of competition in a number of ways. Some have completely barred competition, as by imposing unjustifiable limits on the scope of practice. Others, either working within existing regulatory schemes or by amending and expanding them, can alter the economic incentives of new service providers in a way that dampens their incentives to compete or

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132. *Id.* at 5 (footnote omitted). Efforts to restrict the ability of professionals to affiliate with non-professionals was also an issue in the FTC's 1980 case against the AMA. *See supra* note 101.

relegates them to being less aggressive and less effective competitors. Supervision requirements in both the medical and dental fields provide illustrations. Often, these regulations have the effect of depriving new rivals of the very competitive advantage that drives consumer interest in their products, services, or business models.

Regulators and health care industry stakeholders should consider a different path: evolutionary adaptation guided by some of the lessons of competition law enforcement and policy. We offer three guiding principles: (1) understand and integrate competition concerns into the consideration of regulation; (2) appreciate the self-perpetuating tendencies of regulations shaped by the business models of their time; and (3) consider reforms that move regulation away from approaches that lock-in particular business models to more flexible and adaptable standards that can account for continued change now and in the future, for example, by being explicitly subject to periodic review or by being crafted to allow for evolution without periodic revision.

As FTC staff has consistently asserted in its competition advocacies, regulators in the health care field should be attentive to the competition consequences of regulation and should integrate competition concerns into their analysis.<sup>133</sup> In repeating this point here, however, we mean to drive it home more specifically. Sound competition policy does not preclude some degree of regulation. Once the need for at least some regulation is established, however—as is often the case in the health care field—the discussion becomes more particularized. The inquiry shifts from asking “whether to regulate” to asking whether some very specific provision of a regulation is likely to harm competition *and how*. One valuable lesson learned from over a century of antitrust law enforcement is that competition policymakers must be attentive both to the characteristics of the specific market and to the unique economic mechanisms of harm at issue.

In the context of exclusionary regulation, regulators first must familiarize themselves with the basic characteristics of the marketplace. More particularly, as described in Section I.D, they must be well-aware of the circumstances that suggest a market is conducive to abuse of the regulatory process to protect incumbents, exclude new challengers, and sacrifice consumer interests. If the regulatory context suggests reasons to be wary, regulators ought to be especially attentive to the costs, justifications, and probable consequences of proposed conditions, especially if they are targeted at challengers and are being advocated by

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133. FTC APRN POLICY PAPER, *supra* note 36, at 17–18 (describing competition analysis of regulations that restrict competition).

long-entrenched incumbents. A series of questions can guide the analysis. First, does the proposed regulation (or interpretation) bar entry entirely? Second, if not, will compliance with the regulation (or interpretation) impose significant costs on market participants? Third, if it will impose significant costs, are those costs to be borne by all participants, or are they likely to impact solely the competitive challenger? Consistent with the teachings of cases and commentary based on the theory of raising rivals' costs, the final and critical question will be whether the impact on the challenger will help to facilitate the creation of, or perhaps perpetuate the exercise of, market power by incumbents.

The answers to these questions may suggest that there is a potential for competitive harm, but they do not end the inquiry. Competition principles and economic analysis also can help to evaluate the justifications offered for specific kinds of regulations that may be exclusionary. FTC staff, for example, has highlighted circumstances where the health and safety of the public, which is frequently invoked to justify various types of health care workforce regulation, are exaggerated or pretextual.<sup>134</sup> Similarly, they have consistently argued that, when some regulation is warranted, regulators ought to adopt the regulation that is best calibrated to serve a genuine and substantiated public concern, while minimizing any adverse impact on competition.<sup>135</sup> These have become bedrock principles of the FTC's competition advocacy program.

Especially in markets like health care that are undergoing significant evolution, regulators must also consider the impact of specific regulations on incentives to innovate, both for incumbents and new entrants. Regulators ought to carefully scrutinize requests for such regulations in markets that have been stagnant from the point of view of innovation, when the challenger threatens to disrupt the status quo, as by introducing new services or service models. These circumstances are especially vulnerable to exclusionary regulations and their effects can stifle the emergence of new services and service models for years to come.<sup>136</sup> Hence, it is also important to inquire whether there are less

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134. *See, e.g.*, FTC APRN POLICY PAPER, *supra* note 36, at 35–36.

135. *Id.* at 17 (urging regulators to consider whether regulations that appear likely to have an adverse impact on competition “are narrowly tailored to address [well-founded consumer protection concerns] without undue harm to competition, or whether less restrictive alternatives are available”).

136. For example, in the case of the emerging field of dental therapy, accreditation standards that anticipate on-site supervision by dentists could discourage the creation of education programs designed to produce independently practicing dental therapists. *See supra* notes 39–41, 124–28 and accompanying text. Similarly, if states continue to prohibit the sale of motor vehicles directly to

restrictive regulatory options that might secure the benefits, but with less adverse impact on incentives to innovate.<sup>137</sup> Exclusionary regulations can function like a moat, strategically placed around incumbent competitors in a protective perimeter that insulates them from attack from new rivals. They can be the product of collusion and have the effect of exclusion. A more complete understanding of the conditions under which such regulations can be sought, and an appreciation for the consequences of their adoption, will be essential to the health care work force of the future.

Finally, we note that antitrust enforcement agencies can serve a critical, dual function in supporting this first guiding principle, i.e., that competitive effects analysis should be an integral part of the policy calculus. First, when needed, the agencies can help to educate regulators and legislators by offering their competition expertise to assess the important characteristics of the industry and to identify and analyze potentially anticompetitive regulations. More specifically, they can flesh out the mechanism of exclusion, bringing to bear the kinds of principles and cases discussed above in Section II.A, to explain the particular ways in which regulation can hinder competition. In doing so, they can give voice to consumer interests that may otherwise go unheard or undervalued. Competition enforcement agencies, however, should neither be arrogant nor naïve. Local legislators and regulators may often fully appreciate the anticompetitive potential of regulations, but for political and other reasons nevertheless may be poised to adopt them in response to the urging of industry incumbents. In such circumstances, government advocacy can provide needed transparency and a useful “sunshine” function, helping to expose possible consumer harm and informing broader public debate.

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consumers, existing manufacturers will be discouraged from competing based on innovative new methods of internet-based sales. New entrants also may be discouraged from attempting to enter the market based on methods of distribution that do not rely upon independent dealers. *See* FTC Letter to Darwin L. Boorher, *supra* note 47, at 7–8 (“A direct sales ban deters experimentation with new and different methods of sales by current auto manufacturers, and also by future entrants to the market.”).

137. *See, e.g.*, FTC APRN POLICY PAPER, *supra* note 36, at 19 (“Regulatory choices that affect APRN scope of practice may have a direct impact on health care prices, quality, and innovation, often without countervailing benefits.”); *id.* at 38 (“APRN licensure and scope of practice restrictions, like other professional regulations, may advance important consumer interests. But when these restrictions restrain competition and are not closely tied to legitimate policy goals, they may do more harm than good.”); *see also* FTC TX DSO Comment, *supra* note 129, at 6–7 (“To the extent possible, restrictions should be narrowly tailored to minimize their potential anticompetitive effects, and to avoid unduly discouraging innovative and efficient models of practice that could compete against traditional providers without compromising safety or quality.”).

In the next and concluding Part, we turn to proposals for reform. Not the kinds of reforms that have infected the regulatory process and threatened the capacity of the health care work force to adapt to changing times. Rather, Section III.B suggests alternative models of regulation that would be less prone to ensconcing the status quo of particular business and service models for the delivery of health care, and more likely to prove attractive to challengers promoting safe, but innovative health care delivery models now or in the future.

### B. *Paths to Reform*

Implementation of the principles outlined in Section III.A should help to diminish the incidence of exclusionary regulations. Here we conclude by offering several broader, specific suggestions to reform the U.S. approach to professional regulation in the evolving health care marketplace. While all of these proposals may be theoretically appealing from a pure competition perspective, we recognize that some of these ideas are more provocative than others. We also acknowledge that, as a practical matter, some reforms are likely to be exceedingly difficult to implement given the highly politicized nature of state-based professional regulation and the complex interplay of various interest groups.

The easiest place to start—and, indeed, one of the purposes of this Article—is to encourage greater recognition that competition between different types of health care professionals does, in fact, exist and is likely to become increasingly common in the future. Such competition is a good thing—likely to reduce costs, expand access, improve quality, and drive innovation—and the value of these benefits should not be diminished. Too often, productive discussions about health care provider competition are suppressed with vague and exaggerated protests of safety concerns, claims of inadequate training for some types of providers, or other pretextual arguments.<sup>138</sup> Some health care

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138. See, e.g., AM. ACAD. OF FAMILY PHYSICIANS, PRIMARY CARE FOR THE 21ST CENTURY: ENSURING A QUALITY, PHYSICIAN-LED TEAM FOR EVERY PATIENT (2012); see also *id.* at i–ii (“This effort to have nurses practice independent of physicians comes at the very same moment that medical practice itself is changing to an integrated, team-based approach that includes physicians and other health professionals. These two approaches take the country and our health care system in opposite and conflicting directions.”); cf. *AANP Responds to the American Academy of Family Physicians Report*, AM. ASS’N NURSE PRAC. (Sept. 19, 2012), <https://www.aanp.org/component/content/article/28-press-room/2012-press-releases/1082-aanp-responds-to-aafp-report> [<https://perma.cc/VWA5-3SH8>] (“The American Academy of Nurse Practitioners strongly supports patient-centered and team-based care models. However, AANP believes that AAFP’s efforts to link these evolving models of care with the licensure of nurse practitioner (NP) practice are misdirected and out of step with today’s environment.”); FTC APRN POLICY PAPER, *supra* note 36, at 34–35 (refuting argument that physician supervision of APRNs is necessary to promote team-based care;

professionals seem reluctant to acknowledge that they care about losing income due to price competition, or that they would rather not have to compete on dimensions of quality or convenience if a larger pool of providers were authorized to offer certain services. As explained above, however, the triple aim goals are far more likely to be achieved—and the interests of consumers satisfied—if the idea of competition is more fully embraced and fostered.

A more ambitious, but still realistic, solution would involve heightened state-by-state legislative efforts to address fundamental conceptions (and misconceptions) about which types of providers can safely perform which categories of services. As FTC staff repeatedly has suggested,<sup>139</sup> state legislators who are drafting or reviewing specific scope of practice bills should carefully scrutinize purported safety justifications based on available empirical data as well as actual experience (including, where possible, experience in other states with less restrictive environments).

State legislators, along with the providers themselves, are not alone in needing to rethink too-rigid categorizations regarding who performs which services, and how well, and at what cost. In health care markets—as in all markets—people do what they are paid to do, and seek to maximize financial rewards. Therefore, we must also consider the critical role of health care payers, which include private health insurance companies, the federal government, and state governments. Ideally, reimbursement policies at all levels, both public and private, would become more agnostic regarding who has performed a given service, or even affirmatively promote expanded provision of services by lower-cost professionals, thus stimulating greater competition and creating

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explaining how collaboration routinely occurs among all health care providers, including in states without mandatory physician supervision of APRNs). *See generally* IOM FUTURE OF NURSING REPORT, *supra* note 11, at 110–14 (reviewing examples of, and reasons for, physician resistance to expanded nursing scope of practice; noting investment of significant lobbying resources “on the part of organized medicine to oppose boundary expansion and to defeat proposed legislation in several states to expand scope of practice for allied health care providers, including nurses. . . . [W]ith the assistance of a special full-time legislative attorney hired for the purpose, [an alliance of medical organizations] spearheaded several projects designed to obstruct expansion of scopes of practice for nurses and others”).

139. *See, e.g.*, Letter from Fed. Trade Comm’n Staff to Jenny A. Horne, Representative, S.C. House of Representatives 5 (Nov. 2, 2015), [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-south-carolina-representative-jenny.horne-regarding-house-bill-3508-3078-advanced-practice-registered-nurse-regulations/151103scaprn.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-south-carolina-representative-jenny.horne-regarding-house-bill-3508-3078-advanced-practice-registered-nurse-regulations/151103scaprn.pdf) [<https://perma.cc/N6D5-YHTF>] (“[The proposed bill] would maintain supervision requirements that many states have done without or eliminated, and would add a new layer of bureaucratic process to meeting those requirements. Accordingly, we encourage you to consider whether these requirements are necessary to assure patient safety in light of your own regulatory experience, the findings of the IOM and other expert bodies, and the experience of other states.”).

financial incentives to deploy the health care workforce more efficiently. The volume-to-value shift in payment models, as well as greater financial interdependence among all providers within a given health care system, likely will encourage this approach. But as long as most health care reimbursement follows a fee-for-service model, it will continue to matter greatly who performs a given service and at what billing rate, and reimbursement policy choices can act as powerful levers to change behavior.

In the longer term, we urge states to consider whether licensure for APRNs and similar professionals should be less rigid, and more like licensure for physicians. To recall the example above, general practice physicians are entrusted to decide, among other things, which services they are qualified to provide according to the standard of care and which patients should be referred to specialists.<sup>140</sup> Unless there is reason to believe that the ethical and other self-regulating incentives of APRNs differ from those of physicians, a similar approach could be taken. The empirical literature suggests that APRNs are highly competent at determining which patients they can treat safely and which patients should receive physician referrals.<sup>141</sup> A more flexible approach to APRN licensure would make it easier for the profession to adapt to changes in the standard of care over time, and also would facilitate taking full advantage of an individual professional's qualifications, without requiring constant legislative intervention. It might also become a model for reform in other, similar areas of service overlap.

Our most provocative suggestion is to consider national licensure for health care professionals, to insulate the licensure process from state-level politics and mitigate the effects of silo-based turf battles that must be fought jurisdiction-by-jurisdiction.<sup>142</sup> For the most part, each type of

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140. See *supra* notes 26–27 and accompanying text (explaining broad and undifferentiated practice authority for physicians under all states' medical practice acts); *supra* note 32 and accompanying text (providing an example of a general practitioner determining her own competency to read an x-ray and make a diagnosis).

141. See, e.g., NGA NP PAPER, *supra* note 16, at 7–8 (summarizing review of empirical literature regarding APRN safety, concluding that quality of care provided by APRNs is not a concern, and noting that “[m]ost studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures”). Inherent in these and related quality findings is an assumption that, when presented with issues beyond their skills or expertise, APRNs refer patients to physicians.

142. In addition, a shift to national licensure would greatly enhance workforce mobility, because state-based licensure makes it far more difficult for professionals to move from one state to another.

Many workers may choose their occupation with the understanding that it requires a State license, but life events can intervene to change their expectations about the need to make a cross-state move. For example, military spouses may have entered their field before marriage. Other events—like a local disaster or a health crisis for a parent—may mean that workers who

health care professional in this country is educated according to common curricular and training standards for that profession, and certified and licensed based on the results of a national examination.<sup>143</sup> National licensure also would promote interstate mobility as professionals move around the country, which would help to ease provider shortages in certain geographic areas. We recognize, however, that states rely on licensure fees as a source of revenue, which likely would skew states' financial incentives to cede their licensing authority, and Congress might be reluctant to preempt long-standing state authority.

## CONCLUSION

The health care marketplace is changing, and health care professionals at all levels of the system are an integral part of that change. If the national goals of lower cost, higher quality, and increased

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had never planned to move across State lines after receiving a license suddenly find themselves needing to do so. In such cases, the need to re-license is an important concern. If States don't offer a temporary license to practice (while re-certifying), then the financial barriers of licensing are even more significant.

DEP'T OF THE TREASURY, COUNCIL OF ECON. ADVISORS & DEP'T OF LABOR, OCCUPATIONAL LICENSING: A FRAMEWORK FOR POLICYMAKERS 39 (2015), [https://www.whitehouse.gov/sites/default/files/docs/licensing\\_report\\_final\\_nonembargo.pdf](https://www.whitehouse.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf) [<https://perma.cc/4ASJ-TMGP>]; *see also* KLEINER, *supra* note 33 (analyzing influence of occupational licensing on geographic mobility); *id.* at 20–21 (suggesting greater state-to-state reciprocity to reduce barriers to migration).

143. Using nursing as an example, all candidates for licensure as a registered nurse in the United States and Canada sit for the same examination, known as the National Council Licensure Examination (NCLEX-RN) and administered by the National Council of State Boards of Nursing, *NCLEX and Other Exams*, NAT'L COUNCIL ST. BOARDS NURSING, <https://www.ncsbn.org/nclex.htm> [<https://perma.cc/DG57-GFF4>] (last visited Feb. 20, 2016). While each state's board of nursing determines eligibility criteria to apply for RN licensure and sign up for the NCLEX, every RN student in the country is expected to take the same examination and uphold the same standards of care; therefore, nursing schools and nationally certified accreditation organizations focus on designing and approving curricula around common criteria for scope and quality. *See, e.g., Accreditation and Schools of Nursing*, NURSINGSCHOOL.ORG, <http://nursingschool.org/education/choosing/accreditation/> [<https://perma.cc/MMQ3-DY3S>] (last visited Feb. 20, 2016). In addition, a number of state legislatures have considered or adopted bills that would implement aspects of the APRN Consensus Model, which has been designed to align requirements for licensure, accreditation, certification, and education for advanced practice nurses in all states, and thereby facilitate licensure portability across state lines. *See APRN Consensus Model*, AM. NURSES ASS'N, <http://www.nursingworld.org/consensusmodel> [<https://perma.cc/HUU8-JSS9>] (last visited Feb. 20, 2016); APRN CONSENSUS WORK GRP. & NAT'L COUNCIL OF STATE BDS. OF NURSING APRN ADVISORY COMM., *CONSENSUS MODEL FOR APRN REGULATION: LICENSURE, ACCREDITATION, CERTIFICATION & EDUCATION* (2008), [https://www.ncsbn.org/Consensus\\_Model\\_for\\_APRN\\_Regulation\\_July\\_2008.pdf](https://www.ncsbn.org/Consensus_Model_for_APRN_Regulation_July_2008.pdf) [<https://perma.cc/JA6M-USDZ>]; *see also* IOM FUTURE OF NURSING REPORT, *supra* note 11, at 23 (most RNs must pass standardized licensing exam); *id.* at 196–97 (describing typical graduate-level education and certification requirements for APRNs); *Major Components of the Consensus Model by State*, NAT'L COUNCIL ST. BOARDS NURSING, [https://www.ncsbn.org/2014.07\\_18\\_Julymapwithpoints.pdf](https://www.ncsbn.org/2014.07_18_Julymapwithpoints.pdf) [<https://perma.cc/ESP4-RF48>] (last updated Dec. 2015).

access are to be achieved, the approach to regulating these varied professionals must also change, and competition principles must play an important role in any reformation. In the short term, responsible legislators and regulators should be informed of the competitive consequences of professional regulation. In particular, they should be wary of the self-interested claims of health care providers whose economic and professional sustainability are wedded to the status quo. Legislators and regulators also should carefully scrutinize unsubstantiated health and safety arguments that may mask anticompetitive motives. In the long-term, however, locally-sourced, silo-influenced, and highly specified regulations will need to give way to more flexible, more adaptable, and less easily manipulated performance and capability-based standards. Only then will we fully unleash the incentives most likely to facilitate the emergence of a health care services market tailored to the needs of the twenty-first century.