MERCATUS SPECIAL STUDY

HEALTHCARE OPENNESS AND ACCESS PROJECT: METHODOLOGY

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Kofi Ampaabeng and Liam Sigaud, "Healthcare Openness and Access Project: Methodology," Mercatus Special Study, Mercatus Center at George Mason University, Arlington, VA, October 2022.

ABSTRACT

Government regulations influence virtually every interaction between a health care provider and a patient in the United States. Yet researchers have often struggled to capture the systematic role healthcare regulations play in health outcomes. The Healthcare Openness and Access Project (HOAP), launched in 2016 by the Mercatus Center at George Mason University, seeks to fill this gap by measuring the openness and access of healthcare regulations across states. In this paper, we present the evidence-based framework that underpins HOAP's methodology. Each state is assigned a score on 42 indicators across six categories: professional regulations, healthcare-delivery regulations, patient regulations, payments regulations, institutional regulations, and pharmaceutical regulations.

JEL codes: I18, J08, R59

Keywords: access, health, openness, policy, regulation

Healthcare in the United States is expensive and complex, partly because of the extensive set of government regulations that influence virtually every interaction between a healthcare provider and a patient. Although the United States reports the highest per-capita health spending in the world, the pace of innovation and access to services in the healthcare sector lag behind similar countries across the Organisation for Economic Co-operation and Development (OECD).[1] While federal regulations play a significant role in dictating how—and by whom—healthcare is delivered in the United States, state policies also contribute to the outcomes we observe. On a host of issues ranging from provider licensing to pharmaceutical pricing, states have adopted widely diverging policies. With the Healthcare Openness and Access Project (HOAP), we seek to outline these state-level policies as manifested in regulations and summarize the theoretical and empirical research on their effects on health expenditures, quality of care, health outcomes, and other metrics.

The Mercatus Center introduced the HOAP Index in 2016 to encourage states to reform their healthcare laws, with the goal of ensuring innovation that would lead to better access to healthcare. To date, we have published three editions of HOAP: 2016, 2018, and 2020. With each edition we have made changes to the methodology, most notably by adding or removing indicators or even categories. Our choices of indicators and categories are intuitively reasonable—too many professional regulations restrict access and limit innovation; restrictive delivery regulations only deprive patients of care, especially when there are shortages of healthcare professionals; and so on. This methodological paper is not the publication of a new edition of HOAP. Rather, we provide here the

1. Gregg Girvan and Avik Roy, "Key Findings from the 2021 FREOPP World Index of Healthcare Innovation," Foundation for Research on Equal Opportunity, June 25, 2021, https://freopp.org/key-findings-from-the-freopp-world-index-of-healthcare-innovation-cda78938c047.

empirical justification for the inclusion of various indicators in the construction of HOAP.

Our original objective was to assign each indicator a weight on the basis of the research literature. Indicators with stronger evidentiary support and broader impacts would have received heavier weights. Unfortunately, we found the literature insufficient to justify precise quantification, so we weigh indicators and categories equally. We encourage readers to develop their own weighting methodology using their own needs and preferences.

The rest of the paper proceeds as follows. First, in Section I, we describe the HOAP Index, the importance of healthcare openness and access, and how state laws can be inimical to such access. We then discuss the data and methodology for constructing the index. A detailed discussion of each indicator follows in Section II. In this section, we present the empirical evidence that supports the inclusion of each indicator in HOAP. In Section III, we briefly discuss the construction of the index and other supporting documents. Finally, we conclude in Section IV by noting some of the weaknesses of the methodology and outlining the next steps for the HOAP Index.

I. WHAT IS HOAP?

Why Healthcare Openness?

Openness—the freedom to try innovative approaches and pursue innovative solutions—gives providers flexibility to take care of their patients. While regulations are intended to shield patients from harm, they also impede the process of discovering novel treatments and improving established practices. Policymakers must seek to manage the tension between these objectives. We believe state and federal policymakers have often chosen to impose too many restrictions on the healthcare sector, stifling the capacity of patients and providers to find the best solutions.

Why Healthcare Access?

Over the years, access to healthcare has been reduced in people's minds to insurance coverage. Although insurance coverage provides financial protection and can make it easier for patients to get the care they need in a timely manner, the two are far from synonymous. Insurance coverage has a rightful place in any discussion of access to care, but we believe policymakers should recognize that

other factors matter, too. To better capture how state policies affect access to healthcare services, we examine the following categories of regulations:

- Professional Regulations—including scope-of-practice restrictions and occupational-licensing rules.
- Healthcare-Delivery Regulations—including restrictions on alternative payment structures and telehealth.
- Patient Regulations—including restrictions on over-the-counter medicines and taxes on e-cigarettes.
- Payment Regulations—including mandates on private insurers and limits on health savings accounts (HSAs).
- Institutional Regulations—including certificate-of-need laws that require bureaucratic reviews of health-infrastructure projects and rules that limit retail health clinics.
- Pharmaceutical Regulations—including rules that impose price controls on pharmaceutical manufacturers.

II. DATA AND METHODOLOGY

In this section, we describe the processes for including indicators, their data sources, and the formula for creating the index.

Selecting Indicators and Sources

We only included indicators that have robust evidentiary support. For each indicator, we began by examining the peer-reviewed literature for relevant systematic reviews or meta-analyses. If none exist, we considered other peer-reviewed papers. If the scholarly literature is sparse or absent, we consulted the gray literature (government reports, white papers from research institutes, etc.). In the absence of convincing empirical evidence, we were guided by basic economic principles, particularly those that promote market mechanisms. To be included as contributing empirical evidence for an indicator, a paper had to address how the indicator affects health outcomes, healthcare inputs, or healthcare access. It is important to note that we did not conduct a systematic review of the literature on each indicator included in the HOAP Index but rather relied, whenever possible, on existing systematic reviews.

We strived to use the most recent and accurate data available. Because each indicator had a different data source, the recency of each variable was different.

Some data sources used in this project are kept continuously up to date by the trade association or by researchers who compile the data, whereas others are based on reports that are published yearly or less frequently. Details on each data source are available upon request.

Scoring States on Each Indicator

On the basis of the relevant data source, a Likert scale ranging from 1 to 5 was created for each indicator. Many of these scales have already been created for previous versions of HOAP, but some new scales have been developed for new or substantially changed variables.

A score of 1 represents the state allowing little or no flexibility and openness on that issue; a score of 5 represents the state allowing a full or high level of flexibility and openness on that issue. Some indicators lend themselves to very finely grained scales (e.g., possible scores of 1, 2, 3, 4, or 5), while other indicators are amenable only to coarser scales (e.g., possible scores of 1, 3, or 5, or even just 1 or 5). In some cases, scores are scaled to fit the five-point structure of the index. The appropriate choice of scale is driven by the availability and format of the data and the issue in question.

Category Scores and Overall Scores

The category score for each state is the unweighted arithmetic mean of the scores of all the indicators in that category. In categories with fewer numbers of variables (such as Pharmaceutical, with just two indicators), each indicator exerts a greater influence on the overall score than in categories with larger numbers of indicators (such as Professional, with 13 indicators).

Weights

Consistent with previous editions of HOAP, no special weighting was applied to the indicators or categories to calculate overall state scores and determine state rankings. Each state's score overall is the simple average of its scores across all six categories (i.e., each one contributing one-sixth toward the state's overall score). Using the spreadsheets that accompany the HOAP report, readers are invited to impose different weights if they feel that a particular policy area deserves emphasis. We considered a weighting scheme that is informed by the evidence from the systematic literature review. Unfortunately, we could not implement

such a scheme because very few articles of the peer-reviewed literature we relied upon included a reliable estimate of the effects of the policy variable.

Construction of HOAP

The HOAP Index is constructed hierarchically. The index is calculated on the basis of scores in six categories, each containing individual indicators.

We first computed the score for each indicator and then created the category score as the arithmetical average of the indicator scores in that category. Specifically, for a category C, the index is as follows:

$$C = \frac{\sum_{j=1}^{N} w_j i_j}{N}$$

where $w \in [0,1]$ is the weight given to the indicator j. In our construction, all indicators are equally weighted ($w = 1$). N is the number of indicators in a category.

Similarly, the final index score for each state S is defined as

$$S = \frac{\sum_{k=1}^{N} x_k C_k}{N}$$

where $x \in [0,1]$ is the weight given to the category k. In our construction, all categories are equally weighted ($x = 1$). N is the number of categories in the index (in our case, $N = 6$).

HOAP Indicators

HOAP score is composed of 42 indicators that are further grouped into six main categories: professional regulations, healthcare-delivery regulations, patient regulations, payment regulations, institutional regulations, and pharmaceutical regulations. We address each of these categories in subsequent sections.

Professional Regulations

The professional-regulation category analyzes how onerous a state's laws are to individuals seeking to practice in one of several medical professions. It includes scope-of-practice restrictions, excessive licensing burdens, or policies related to charity care. Healthcare practitioners ought to have the latitude to offer their professional skills and services without facing undue legal barriers. Lowering

the barriers that keep providers out of states' healthcare systems will increase the systems' openness and accessibility to patients as well as providers.

Scope of Practice. Scope-of-practice laws are state-specific restrictions that determine what tasks nonphysician medical professionals, including nurses, nurse practitioners, physician assistants, pharmacists, and other healthcare providers, may perform while caring for patients.[2] For example, some states prohibit nurse practitioners from prescribing drugs without physician oversight. Other states limit pharmacists' ability to administer vaccines to certain age groups or prevent dental hygienists from initiating treatment without specific authorization from a dentist.

Often these laws prevent workers from practicing to the full extent of their education and training, although many nonphysician medical professionals are highly trained. This needlessly restricts the supply of health services and deters entry into these professions. Meanwhile, many states are confronting shortages of primary-care providers, particularly in rural communities, resulting in higher costs, longer wait times, and longer drives for patients seeking access to care.

Within the political sphere, expanding practice scope for nonphysician medical professionals is highly fraught and divisive, with opposition coming mainly from physicians who argue that patients would be worse off under the proposed changes.[3] Nevertheless, states continue to expand scope of practice, and a review of the literature shows that expansion does not negatively affect patient outcomes. In fact, in some cases, expanded practice scope leads to better outcomes for patients.

Effects of Scope-of-Practice Restrictions. Despite some research indicating that advanced-practice clinicians may be more prone to performing unnecessary imaging than primary-care physicians,[4] a growing body of evidence indicates that scope-of-practice restrictions do not improve quality of care.[5] On the contrary, many studies have shown that expanded practice scope does not lead to a

2. Julie A. Fairman et al., "Broadening the Scope of Nursing Practice," *New England Journal of Medicine* 364, no. 3 (January 2011): 193–96.
3. Andis Robeznieks, "Why Expanding APRN Scope of Practice Is Bad Idea," American Medical Association, October 30, 2020, https://www.ama-assn.org/practice-management/scope-practice/why-expanding-aprn-scope-practice-bad-idea.
4. Danny R. Hughes, Miao Jiang, and Richard Duszak, "A Comparison of Diagnostic Imaging Ordering Patterns Between Advanced Practice Clinicians and Primary Care Physicians Following Office-Based Evaluation and Management Visits," *JAMA Internal Medicine* 175, no. 1 (January 2015): 101–7.
5. Sara Markowitz et al., "Competitive Effects of Scope of Practice Restrictions: Public Health or Public Harm?," *Journal of Health Economics* 55 (September 2017): 201–18.

reduction in the quality of care or lead to adverse health outcomes.[6] A study of Medicare and Medicaid patients found that states with broad scope-of-practice authority for nurse practitioners performed significantly better than states with restrictive regulations.[7] A systematic review of the literature found that states granting nurse practitioners greater scope-of-practice authority exhibited an increase in the number of nurse practitioners and saw expanded healthcare utilization, especially among rural and vulnerable populations. The authors concluded, "Removing restrictions on [nurse practitioner scope-of-practice] regulations could be a viable and effective strategy to increase primary care capacity."[8] Indeed, it is estimated that allowing nurse practitioners full practice authority nationwide would save $810 million per year in retail clinic settings alone.[9] As midlevel providers, nurse practitioners are trained to assess patient needs, order and interpret laboratory tests, diagnose illnesses, and formulate treatment plans. Many nurse practitioners receive specialized training in neonatal care, women's health, or treatment of psychiatric conditions.

A systematic review of the literature found that physician assistants help to alleviate rural health shortages and have larger positive effects on outcomes when given broad scope of practice.[10] In a randomized experiment, nurse practitioners achieved the same clinical outcomes as physicians. Similarly, states that support independent midwifery practices have a larger midwifery workforce, a greater proportion of births attended by certified nurse midwives, and better birth outcomes.[11] A study in Washington state found that births attended by licensed midwives outside of a hospital setting had a significantly lower risk for low birthweight infants than those attended in hospital by certified nurse midwives, but no significant differences were observed between licensed midwives and any of the comparison groups on any other outcomes examined (low five-

6. Mary O. Mundinger et al., "Primary Care Outcomes in Patients Treated by Nurse Practitioners or Physicians: A Randomized Trial," *JAMA* 283, no. 1 (January 2000): 59–68.
7. Gina M. Oliver et al., "Impact of Nurse Practitioners on Health Outcomes of Medicare and Medicaid Patients," *Nursing Outlook* 62, no. 6 (November 2014): 440–47.
8. Ying Xue et al., "Impact of State Nurse Practitioner Scope-of-Practice Regulation on Health Care Delivery: Systematic Review," *Nursing Outlook* 64, no. 1 (January 2016): 71–85.
9. Joanne Spetz et al., "Scope-Of-Practice Laws For Nurse Practitioners Limit Cost Savings That Can Be Achieved In Retail Clinics," *Health Affairs* 32, no. 11 (November 2013): 1977–84.
10. Lisa Henry, Roderick S. Hooker, and Kathryn Yates, "The Role of Physician Assistants in Rural Health Care: A Systematic Review of the Literature," *The Journal of Rural Health* 27 (March 1, 2011): 220–29.
11. Y. Tony Yang, Laura B. Attanasio, and Katy B. Kozhimannil, "State Scope of Practice Laws, Nurse-Midwifery Workforce, and Childbirth Procedures and Outcomes," *Women's Health Issues* 26, no. 3 (May 2016): 262–67.

minute Apgar scores and neonatal and postneonatal mortality).[12] When Burnaby Hospital—a community hospital in British Columbia, Canada, with approximately 300 inpatient beds—implemented expanded scope of practice for its pharmacists, researchers found that patient-related clinical outcomes improved, pharmacists' satisfaction grew, and healthcare costs decreased.[13]

In states with expanded scope of practice for dental hygienists, adult residents reported better oral health.[14] A more expansive dental hygiene scope of practice is also positively and significantly associated with favorable children's oral health among those with recent dental-office visits.[15] Many states remain opposed to dental therapy, a midlevel dental position similar to that of nurse practitioners or physician assistants in medicine. Dental therapists provide preventive and routine restorative care, including filling cavities, placing temporary crowns, and performing simple extractions. These dental providers are especially needed in areas underserved by dentists. Rather than protecting patients from unqualified providers, many states' scope-of-practice restrictions harm public health by limiting access to care.

By loosening their scope-of-practice restrictions, states could dramatically reduce the cost of care and expand access to health services for their residents, especially for low-income families. Several studies have found that expanding pharmacists' prescribing authority and ability to order laboratory tests improves community glycemic control,[16] increases detection of chronic kidney disease,[17] and reduces risk factors for cardiovascular disease.[18]

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12. Patricia A. Janssen, Victoria L Holt, and Susan J. Myers, "Licensed Midwife-Attended, Out-of-Hospital Births in Washington State: Are They Safe?," *Birth* 21, no. 3 (September 1994): 141–48.
13. Soomi Hwang, Tamar Koleba, and Vincent H Mabasa, "Assessing the Impact of an Expanded Scope of Practice for Pharmacists at a Community Hospital," *Canadian Journal of Hospital Pharmacy* 66, no. 5 (October 2013): 304–9.
14. Margaret Langelier et al., "Expanded Scopes Of Practice For Dental Hygienists Associated With Improved Oral Health Outcomes For Adults," *Health Affairs* 35, no. 12 (December 2016): 2207–15.
15. Jean Moore et al., "Expanded Scope of Practice for Dental Hygienists Associated with Favorable Children's Oral Health" (paper presented at the American Public Health Association Annual Meeting and Expo, Philadelphia, PA, November 2019).
16. Yazid N. Al Hamarneh et al., "Pharmacist Intervention for Glycaemic Control in the Community (the RxING Study)," *BMJ Open* 3, no. 9 (September 2013): e003154.
17. Yazid N. Al Hamarneh et al., "Community Pharmacist Targeted Screening for Chronic Kidney Disease," *Canadian Pharmacists Journal/Revue Des Pharmaciens Du Canada (CPJ/ RPC)* 149, no. 1 (January 2016): 13–17.
18. Ross T. Tsuyuki et al., "The Effectiveness of Pharmacist Interventions on Cardiovascular Risk," *Journal of the American College of Cardiology* 67, no. 24 (June 2016): 2846–54.

Indicators

- State grants nurse practitioners broad scope of practice
- State grants behavioral health providers broad scope of practice
- State grants midwives broad scope of practice
- State grants pharmacists broad scope of practice
- State grants dental hygienists broad scope of practice
- State allows dental therapists to practice
- State grants optometrists broad scope of practice
- State grants physician assistants broad scope of practice

Restrictive Occupational Licensing. Occupational-licensing laws have expanded significantly in the last 50 years. Today, states impose education and training requirements for virtually all healthcare professions. In some cases, licensing can be appropriate to promote the public's health and safety. However, a growing body of evidence suggests that restrictive licensing regimes raise the price of healthcare services, exacerbate provider shortages, reduce access to care, and do little—if anything—to improve the quality of patients' care.

By erecting barriers to entry, licensing reduces the supply of workers in a profession and stifles competition, resulting in higher prices. According to a review of the literature, "State nurse practitioner licensing is estimated to increase the price of a well-child checkup by 3 to 16 percent, dental hygienist and dental assistant licensing is estimated to increase the price of a dental visit by 7 to 11 percent, and optometry licensing is estimated to increase the price of eye care by 5 to 13 percent."[19] One study estimated that licensing results in 2.8 million fewer jobs in the US economy, costing consumers $203 billion annually.[20] The maze of state licensing requirements also discourages healthcare providers from relocating from one jurisdiction to another, making it difficult to move workers to areas where they are needed most.[21] This is especially true of foreign-educated health workers, who are often required to repeat years of training to obtain a

19. Patrick A. McLaughlin, Matthew Mitchell, and Anne Philpot, "The Effects of Occupational Licensure on Competition, Consumers, and the Workforce" (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, November 2017), https://www.mercatus.org/publications/corporate-welfare/effects-occupational-licensure-competition-consumers-and-workforce.
20. Morris Kleiner, Alan Krueger, and Alexandre Mas, "A Proposal to Encourage States to Rationalize Occupational Licensing Practices" (Brookings Institution, Washington, DC, April 2011), 8.
21. Janna E. Johnson and Morris M. Kleiner, "Is Occupational Licensing a Barrier to Interstate Migration?," *American Economic Journal: Economic Policy* 12, no. 3 (2020): 347–73.

license in the United States despite no evidence that graduates of international medical schools deliver lower-quality care than US-trained physicians.[22]

The traditional defense of licensing laws is that by enforcing minimum competency standards, governments protect consumers from poorly trained practitioners who would otherwise provide low-quality services. Yet there is little empirical evidence to support this view. According to a report led by the Council of Economic Advisers, "Overall, the empirical research does not find large improvements in quality or health and safety from more stringent licensing. In fact, in only two of the 12 studies was greater licensing associated with quality improvements."[23] A separate review of 19 studies on the effect of licensing on quality found that the most common finding was neutral, mixed, or unclear. Three studies found that occupational licensure positively affected quality while four found that it negatively affected quality.[24]

There are several reasons excessive licensing requirements in the healthcare sector could be detrimental to patient outcomes. First, by erecting barriers to entry, licensing reduces the supply of workers in a profession and stifles competition, thereby removing a powerful incentive for licensed workers to deliver high-quality services. Government licensing boards are supposed to provide oversight and monitor quality, but disciplinary action against negligent licensees is rare. Second, when consumers are unable to hire a professional to provide a service—either because they can't afford the higher prices caused by licensing requirements or because there are too few workers to satisfy demand—they are likely to turn to lower-quality substitutes. For instance, instead of hiring a professional electrician, a homeowner may try to fix a faulty circuit by himself and risk electrocution.[25]

Indicators

- State has less restrictive licensing of certified registered nurse anesthetists and nurse practitioners[26]

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22. John J. Norcini et al., "Evaluating The Quality Of Care Provided By Graduates Of International Medical Schools," *Health Affairs* 29, no. 8 (August 2010): 1461–68.
23. U.S. Department of the Treasury Office of Economic Policy, Council of Economic Advisers, and U.S. Department of Labor, *Occupational Licensing: A Framework for Policymakers*, July 2015.
24. McLaughlin, Mitchell, and Philpot, "The Effects of Occupational Licensure on Competition."
25. Sidney L. Carroll and Robert J. Gaston, "Occupational Restrictions and the Quality of Service Received: Some Evidence," *Southern Economic Journal* 47, no. 4 (April 1981): 959–76.
26. This indicator overlaps somewhat with another indicator related to occupational licensing, "State has lower volume of occupational license restrictions." Despite this, we believe that including an indicator focused specifically on advanced practice nurses is appropriate. The measures of the volume of occupational license restrictions from the Mercatus Center's RegData are based on two- to

- State has less restrictive licensing of foreign-trained health workers
- State allows healthcare licensure reciprocity with other states
- State has lower volume of occupational-license restrictions (based on Healthcare RegData and Occupational Licensing RegData)

Liability Protection for Charity Caregivers. Many retired and practicing physicians want to volunteer their time and expertise in caring for underserved populations. However, the cost of malpractice insurance is prohibitive, acting as an effective barrier to increasing a volunteer physician workforce that would expand access for impoverished patients. Some states have sought to mitigate this risk by enacting protective liability legislation for physician volunteers. Empirical evidence suggests that these laws encourage volunteering and expand access to care. A study found a large and positive correlation between legal immunity and volunteering (though it did not focus specifically on healthcare).[27] In a large survey of physicians approaching retirement age, 62 percent reported that concern about malpractice lawsuits discouraged them from providing charity care.[28] A study of Florida's charity-care program, which offers sovereign-immunity protections to providers while they are volunteering, found that participation is high, administrative costs are low, and the value of care provided averages about $250 million per year.[29]

Indicator

- State limits liability for charity caregivers

Healthcare Delivery Regulations

The delivery-regulation category assesses how conducive each state's environment is to the establishment of new and diverse models of healthcare delivery

four-digit Standard Occupational Classification (SOC) codes, which do allow identification of specific advanced practice nursing occupations. Our review of the literature, cited above, reveals that advanced practice nurses play a key role in ensuring patient access to high-quality care.
27. Jill R. Horwitz and Joseph Mead, "Letting Good Deeds Go Unpunished: Volunteer Immunity Laws and Tort Deterrence," *Journal of Empirical Legal Studies* 6, no. 3 (September 2009): 585–635.
28. Philip D. Sloane et al., "Brief Communication: Physician Interest in Volunteer Service during Retirement," *Annals of Internal Medicine* 149, no. 5 (September 2008): 317–22.
29. Patrick Ishmael and Jonathan Ingram, "Volunteer Care: Affordable Health Care without Growing Government," Foundation for Government Accountability (October 2015), 11, https://thefga.org/paper/volunteer-care-affordable-health-care-without-growing-government/.

and emphasizes the importance of telemedicine, which has the potential to make healthcare more open and accessible.

Telehealth. *Telehealth*—the use of telecommunications technology for the remote diagnosis and treatment of patients—has the potential to transform healthcare delivery.[30] Increasingly, practitioners are finding that telehealth can be used as a supplement or substitute for face-to-face contact between patients and providers and that care delivered via telecommunications technology often can be of the same quality as care delivered in the traditional way.[31] Many observers believe that increased use of telehealth could also lower healthcare-system costs while improving healthcare accessibility for many patient populations, especially residents of rural communities and patients with limited mobility.

In telehealth's early days, opponents argued with some justification that there was insufficient evidence that telemedicine was safe, secure, and effective. Pioneers, however, have shown that in a variety of clinical areas (including psychiatry and the management of diabetes and other chronic diseases),[32] it is possible to deliver good care using telehealth.[33]

Although nearly all states reimburse providers for some forms of telemedicine through Medicaid, some states set lower reimbursement rates for comparable services delivered through telehealth. While private insurers should have the ability to independently set their reimbursement schedules within a competitive environment, the lack of parity on the part of government payers has hindered telehealth's adoption. Physicians and clinicians who participate in Medicaid ought to be able to use current technologies and techniques and receive usual and customary payment when they do. Four Medicaid-related policies are particularly significant:

- Store-and-forward telehealth, in which clinical data is transmitted to a clinician and reviewed asynchronously, can be cost-effective, improves

30. Sanjay Sood et al., "What Is Telemedicine? A Collection of 104 Peer-Reviewed Perspectives and Theoretical Underpinnings," *Telemedicine and E-Health* 13, no. 5 (October 2007): 573–90.
31. Rashid L. Bashshur, "On the Definition and Evaluation of Telemedicine," *Telemedicine Journal* 1, no. 1 (January 1995): 19–30.
32. William R. Hersh et al., "Diagnosis, Access and Outcomes: Update of a Systematic Review of Telemedicine Services," *Journal of Telemedicine and Telecare* 12, no. 2 (September 2006): 3–31.
33. Ines Hungerbuehler et al., "Home-Based Psychiatric Outpatient Care Through Videoconferencing for Depression: A Randomized Controlled Follow-Up Trial," *JMIR Mental Health* 3, no. 3 (August 2016): e36.

access to specialists, delivers high-quality outcomes,[34] and is preferred by patients over traditional face-to-face care.[35]

- Remote monitoring services, in which clinicians track a patient's vital signs and activities at a distance, is associated with improved outcomes and cost-effectiveness in patients with diabetes mellitus and heart disease,[36] lower healthcare costs and mortality rates,[37] and significant gains in patient satisfaction.[38]
- State Medicaid policies vary regarding the types of providers that are eligible for payment for services delivered through telehealth. While states have an interest in ensuring that clinicians are operating within their scope of practice, preventing certain providers from accessing reimbursement for telemedicine services creates needless barriers to care for Medicaid patients.

Beyond the Medicaid policies they adopt, states regulate telehealth in other ways. Some states limit physicians' ability to prescribe a drug to a patient on the basis of an online encounter. To protect against misuse or abuse, all states require that physicians and patients must establish a relationship before the physician may write a prescription; however, states vary in what they require and whether they allow the relationship to be established using telemedicine. Some states do not allow online prescribing at all. We argue that having fewer limitations on online prescribing is best for maximizing convenience and patient autonomy.

Several states either prohibit or restrict online eye exams. Until recently, these examinations could only be done in person, but now innovative mobile apps make it possible to conduct routine vision tests online. While online exams are no substitute for comprehensive on-site visits that allow clinicians to screen for conditions such as cataracts and glaucoma, their convenience and low cost

34. Hon Pak et al., "Store-and-Forward Teledermatology Results in Similar Clinical Outcomes to Conventional Clinic-Based Care," *Journal of Telemedicine and Telecare* 13, no. 1 (January 2007): 26–30.
35. John D. Whited et al., "Patient and Clinician Satisfaction with a Store-and-Forward Teledermatology Consult System," *Telemedicine Journal and E-Health* 10, no. 4 (December 2004): 422–31.
36. Eric L. Wallace et al., "Remote Patient Management for Home Dialysis Patients," *Kidney International Reports* 2, no. 6 (November 2017): 1009–17.
37. Adam Darkins et al., "Reduced Cost and Mortality Using Home Telehealth to Promote Self-Management of Complex Chronic Conditions: A Retrospective Matched Cohort Study of 4,999 Veteran Patients," *Telemedicine and E-Health* 21, no. 1 (January 2015): 70–76.
38. Leslie A. Grant, Todd Rockwood, and Leif Stennes, "Client Satisfaction with Telehealth Services in Home Health Care Agencies," *Journal of Telemedicine and Telecare* 21, no. 2 (March 2015): 88–92.

make them attractive to many individuals who simply need to update their prescription for corrective lenses. Moreover, for the millions of residents of the 800 counties that reported no optometrist offices or optical-goods stores in 2016, online eye exams can help improve access to care.[39]

Finally, some states mandate that private insurers reimburse telemedicine at parity with comparable on-site services. Although government payers like Medicaid should not exhibit favoritism for one delivery model over another, parity laws for private insurers can stifle competition, raise costs in the health system, and impede the creation of treatment plans that meet the needs of individual patients.[40] Since telehealth encounters generally cost less in terms of equipment, facility costs, and physicians' time than on-site visits, payment-parity mandates serve as price controls and lead to inefficiency. When insurers are allowed to negotiate separate rates, reimbursement rates for telehealth tend to be lower than those for the same service provided in person.[41] For example, one study estimates that a telehealth visit costs $50 for a commercially insured patient, whereas a physician office visit costs nearly $100.[42] Payment-parity mandates disadvantage patients by preventing any cost savings related to telehealth from being passed along to them in the form of lower premiums or more favorable cost-sharing provisions.

Indicators

- State has broad definition of telehealth
- State does not restrict the types of providers that can offer telehealth services
- State does not restrict services that can be offered via telehealth
- State does not impose mandates on private insurers related to telehealth coverage and reimbursement

39. Elliott Long and Michael Mandel, *The Case for Online Vision Tests* (Washington, DC: Progressive Policy Institute, March 2018), https://www.progressivepolicy.org/publication/case-online-vision-tests-2/.
40. Katherine Restrepo, *The Case Against Telemedicine Parity Laws: Let the Market Thrive in America's Most Regulated Industry* (Raleigh, NC: John Locke Foundation, December 2017), https://www.johnlocke.org/wp-content/uploads/2018/01/The_Case_Against_Telemedicine_Parity_Laws.pdf.
41. Angela K. Dills, "Telehealth Payment Parity Laws at the State Level" (Mercatus Policy Brief, Mercatus Center at George Mason University, Arlington, VA, November 2021), https://www.mercatus.org/publications/healthcare/telehealth-payment-parity-laws-state-level.
42. Dale H. Yamamoto, *Assessment of the Feasibility and Cost of Replacing In-Person Care with Acute Care Telehealth Services* (Wathington, DC: Alliance for Connected Care, 2014), 17, https://connectwithcare.org/assessment-of-the-feasibility-and-cost-of-replacing-in-person-care-with-acute-care-telehealth-services/.

Patient Regulations

The patient-regulation category analyzes to what extent states allow patients to access certain classes of drugs and whether information on drug treatments is freely available. It also analyzes which states allow residents the easiest access to e-cigarettes, which can help smokers quit, and naloxone, a life-saving antidote to opioid overdose.

Pharmaceutical Access. Many states impede patients' ability to make decisions about the pharmaceutical drugs they take or the technology they use to interact with their pharmacists. By limiting access, these laws strip consumers of autonomy and can lead to negative health outcomes.

Some states restrict *telepharmacy*, the practice of using telecommunications technology to deliver pharmaceutical services at a distance. Telepharmacy can benefit patients in many different settings, but it can be especially beneficial for rural patients. As the number of independently owned rural pharmacies falls, enabling a pharmacist to support clinical services, provide patient education, provide medication reconciliation, or provide other services at a distance can be an efficient way to deliver high-quality care.[43] Telepharmacy has been used effectively to improve outcomes in asthma patients living in a rural community.[44] Another study found that the quality of medication used at telepharmacies that serve rural areas was no worse than at traditional pharmacies.[45] Despite this evidence, some states place geographic limitations on telepharmacy, preventing it from coexisting and competing with traditional pharmacies.

Some states limit access to specific pharmaceuticals, such as contraceptives. Oral contraceptives are a safe and reliable method for preventing unwanted pregnancy. Using this method of birth control entails obtaining a packet of birth-control pills (which usually contains a one-month supply) and taking one pill daily. Some states allow pharmacists to prescribe contraceptives after a brief health screening, whereas other states require a prescription to be filled out by a physician. States with the latter policy in effect put in place an unnecessary access barrier for women. Empirical evidence suggests that making oral contraceptives available without a physician's prescription increases their use,

43. George Tzanetakos, Fred Ullrich, and Keith Meuller, "Telepharmacy Rules and Statutes: A 50-State Survey," *Rural Policy Brief*, April 1, 2017, 1–4.
44. Wendy Brown et al., "Impact of Telepharmacy Services as a Way to Increase Access to Asthma Care," *Journal of Asthma* 54, no. 9 (October 2017): 961–67.
45. Shweta Pathak et al., "Telepharmacy and Quality of Medication Use in Rural Areas, 2013–2019," *Preventing Chronic Disease* 17 (September 2020): 200012.

improves medication adherence,[46] and reduces unwanted pregnancies.[47] Benefits to adolescents are particularly large.[48]

One of the most effective public-health tools to mitigate the effects of opioid addiction and overdose is naloxone, a medicine that is safe and easy to administer and can rapidly reverse an opioid overdose.[49] Unfortunately, naloxone is too often unavailable when it is needed most. Although states have taken steps to make naloxone more widely available to emergency medical technicians, firefighters, police officers, school staff, and others who are frequently the first to intervene in an overdose, naloxone's status as a prescription drug is a significant barrier to access, especially given the social stigma many drug users feel. Research has shown that nonmedical personnel can safely administer naloxone.[50] Given the scale of America's current opioid crisis, making naloxone available as an over-the-counter medicine nationwide could save hundreds or thousands of lives each year.[51]

Obtaining Food and Drug Administration (FDA) approval for a specific health indication for a particular drug that has already been approved for another purpose can be a lengthy and costly process.[52] Clinical experience and science can be decades ahead in showing that a drug works for different diseases or health issues than the uses originally approved by the FDA. This practice, known as *off-label use*, accounts for about 20 percent of all prescriptions written in the United States. Some states, however, prohibit pharmaceutical manufacturers from sharing true, accurate information related to off-label use of their products. By restricting access to the most current medical data about a particular drug, these laws limit providers' knowledge and deprive patients of effective treatments.

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46. Joseph E. Potter et al., "Continuation of Prescribed Compared With Over-the-Counter Oral Contraceptives," *Obstetrics & Gynecology* 117, no. 3 (March 2011): 551–57.
47. Diana G. Foster et al., "Potential Public Sector Cost-Savings from Over-the-Counter Access to Oral Contraceptives," *Contraception* 91, no. 5 (May 2015): 373–79.
48. Krishna K. Upadhya et al., "Over-the-Counter Access to Oral Contraceptives for Adolescents," *Journal of Adolescent Health* 60, no. 6 (June 2017): 634–40.
49. Lisa Chimbar and Yvette Moleta, "Naloxone Effectiveness: A Systematic Review," *Journal of Addictions Nursing* 29, no. 3 (July 2018): 167–71.
50. Alexander R. Bazazi et al., "Preventing Opiate Overdose Deaths: Examining Objections to Take-Home Naloxone," *Journal of Health Care for the Poor and Underserved* 21, no. 4 (November 2010): 1108–13.
51. Corey S. Davis and Derek Carr, "Over the Counter Naloxone Needed to Save Lives in the United States," *Preventive Medicine* 130 (January 2020): 105932.
52. Joseph A. DiMasi, "Innovating by Developing New Uses of Already-Approved Drugs: Trends in the Marketing Approval of Supplemental Indications," *Clinical Therapeutics* 35, no. 6 (June 2013): 808–18.

Generic substitution occurs when a pharmacist dispenses a cheaper drug that is bioequivalent to, but different from, a more expensive drug that is prescribed by a physician. This possibility arises because once a drug goes off patent, cheaper generic versions of that drug can come onto the market and compete alongside the branded version, but the branded version tends to be better known by name to patients and physicians. To reduce overall spending on healthcare, some states require pharmacists to substitute generics for branded drugs. There is evidence that mandatory generic-substitution laws reduce spending on pharmaceuticals,[53] but making substitution mandatory overrides physicians' and patients' choices and can leave consumers with little legal recourse if adverse events result from product design defects. In some cases, generic substitution has been associated with negative health effects. A review of the literature found that although in many cases generics may represent an appropriate alternative to branded products, mandating genetic substitution can trigger unintended consequences:

> Specifically, several studies suggested that switching may negatively impact medication adherence, whereas other studies found that generic switching was associated with poorer clinical outcomes and more adverse events. In some instances, switching accomplished cost savings but did so at increased total cost of care because of increased physician visits or hospitalizations.[54]

Indicators

- State allows online pharmacy services
- State allows access to oral contraceptives without physician prescription
- State allows access to naloxone
- State does not restrict off-label use of pharmaceuticals
- State encourages, but does not require, generic substitution

53. Karolina A. Andersson et al., "Influence of Mandatory Generic Substitution on Pharmaceutical Sales Patterns: A National Study over Five Years," *BMC Health Services Research* 8, no. 1 (December 2008): 50.
54. Robert J. Straka, Denis J. Keohane, and Larry Z. Liu, "Potential Clinical and Economic Impact of Switching Branded Medications to Generics," *American Journal of Therapeutics* 24, no. 3 (May 2017): e278–89.

E-Cigarette Taxes. E-cigarettes have grown rapidly in popularity over the last decade. Recent surveys reveal that 4.5 percent of adults,[55] 19.6 percent of high school students, and 4.7 percent of middle school students[56] use e-cigarettes. Some public-health officials fear e-cigarettes may promote nicotine addiction, increased youth access, and a renormalization of smoking. However, multiple clinical studies suggest that e-cigarettes are significantly less harmful than combustible cigarettes and may decrease smoking-related morbidity and mortality by offering smokers a safer alternative. Researchers have estimated that if combustible cigarettes were largely replaced by vaping products over a 10-year period, at least 1.6 million premature deaths could be averted in the United States.[57]

States often use taxation as a means of penalizing use of a particular product deemed unhealthy or undesirable for the public good. Many states have begun to tax e-cigarettes to restrict residents' access to them. Raising the price of e-cigarettes and making combustible cigarettes more affordable by comparison, however, may do more harm than good. Data from Minnesota, one of the first states to adopt e-cigarette taxes, suggests that e-cigarette taxes increase adult smoking and reduce smoking cessation.[58]

Indicator

- State has lower excise taxes on e-cigarettes

Payment Regulations

The payment-regulation category measures the extent to which states liberate or restrict payment arrangements between various actors in the healthcare system. This category includes how much states intervene to determine what kind of insurance coverage individuals can buy, how freely individuals can save for their own future medical expenses, whether pharmaceutical companies can offer coupons to consumers, and more. Payment restrictions impede openness and access by making it harder for consumers to find products and plans that meet their needs and preferences.

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55. Monica E. Cornelius, "Tobacco Product Use Among Adults—United States, 2019," *Morbidity and Mortality Weekly Report* 69, no. 46 (2020): 1736–42.
56. Teresa W. Wang, "E-Cigarette Use Among Middle and High School Students—United States, 2020," *Morbidity and Mortality Weekly Report* 69, no. 37 (2020): 1310–12.
57. David T. Levy et al., "Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes," *Tobacco Control* 27, no. 1 (January 2018): 18–25.
58. Henry Saffer et al., "E-Cigarettes and Adult Smoking: Evidence from Minnesota," *Journal of Risk and Uncertainty* 60, no. 3 (June 2020): 207–28.

Alternative Payment Systems. For many Americans, private health insurance—obtained either through an employer or on the individual market—is growing increasingly expensive and out of touch with their needs. Restrictive state and federal regulations have limited the scope of insurance products and contributed to escalating premiums, leaving many consumers dissatisfied with the options available. In 2018, a Gallup poll found that nearly a third of US adults (31 percent) rated their healthcare coverage as less than "good"—a proportion that has remained fairly stable since 2001.[59] By focusing on expanding health-insurance coverage as the solution to America's healthcare woes, policymakers have persistently ignored alternative payment mechanisms that may be better suited to patients' needs.

Many states restrict the sale of noninsurance health plans—such as plans run by organizations that support farmers and ranchers (called Farm Bureaus), plans run by health-sharing ministries, and direct-primary-care arrangements—out of concerns that these products do not provide sufficient financial protection against high-cost events.[60] To be sure, these products offer less comprehensive coverage than conventional insurance, exposing enrollees to more risk. It is plausible that some consumers may not fully realize this fact, leading to poor choices and unpleasant surprises. Yet relaxing regulations surrounding these alternative payment systems allows companies to reduce prices, better target consumer preferences, and give patients more control over their healthcare.

Farm Bureau plans, which are generally offered by state Farm Bureaus to their members, serve as a backstop to many rural residents for whom traditional insurance is too expensive. It is estimated that 83 percent of Iowans with Farm Bureau coverage would otherwise be uninsured. In Tennessee, which became the first state to authorize Farm Bureau plans in 1993, a typical family of four can save approximately $800 per month with a Farm Bureau plan compared to a similar plan on the individual market. Despite the lack of government mandates, Tennessee Farm Bureau plans all offer prescription-drug coverage and easy access to specialists, and they do not impose limits on coverage amounts.[61]

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59. Justin McCarthy, "Most Americans Still Rate Their Healthcare Quite Positively," Gallup.com, December 7, 2018, https://news.gallup.com/poll/245195/americans-rate-healthcare-quite-positively.aspx.
60. Sarah Lueck, "Key Flaws of Short-Term Health Plans Pose Risks to Consumers," Center on Budget and Policy Priorities, September 20, 2018, https://www.cbpp.org/research/health/key-flaws-of-short-term-health-plans-pose-risks-to-consumers.
61. Hayden Dublois and Josh Archambault, "Farm Bureau Plans: Affordable Health Coverage Options for Americans," Foundation for Government Accountability, January 14, 2021, https://thefga.org/briefs/farm-bureau-plans/.

Healthcare sharing ministries (HCSMs), in which healthcare costs are shared among members with common religious beliefs, are also popular and effective alternatives to traditional insurance. A 2010 analysis by the Citizens' Council on Health Care found that the cost of HCSM membership was similar to the cost of a health-insurance policy with similar levels of coverage, while other comparisons suggest HCSM prices are up to 60 percent less expensive.[62] Moreover, many HCSMs offer more favorable cost-sharing protections and freer access to specialists than insurance plans.[63]

Direct primary care (DPC), a practice model in which physicians charge patients a regular fee to provide routine primary-care services, is another promising alternative to traditional insurance—one that some states needlessly stifle. By abandoning third-party, fee-for-service payment, DPC practices keep administrative costs low and nurture more productive doctor-patient relationships. Once a fringe phenomenon, DPC has grown rapidly in recent years, driven by doctors and patients increasingly dissatisfied with the impersonal, industrialized tenor of modern medicine. Monthly costs range from $40 to $85, according to a 2020 study.[64] Research suggests that DPC improves patient outcomes and reduces preventable downstream expenses. One study found that urgent and avoidable hospital admissions were 62 percent lower among DPC patients compared to patients with traditional insurance.[65] Some states treat DPC practices as health insurers, subjecting them to onerous regulations—such as financial reserve requirements, reporting mandates, and administrative fees—that were never designed or intended for small medical practices. Other states limit the ability of DPC practices to dispense prescriptions from their offices or to bill patients directly for laboratory services. These restrictions undermine the convenience and independence that have contributed to the DPC model's success.

Indicators

- State allows group (Farm Bureau) health plans
- State allows health care sharing ministries plans

62. Benjamin Boyd, "Health Care Sharing Ministries: Scam or Solution?," *Journal of Law and Health* 26, no. 2 (2013): 219.
63. Boyd, "Health Care Sharing Ministries."
64. Fritz Busch, Dustin Grzeskowiak, and Erik Huth, *Direct Primary Care: Evaluating a New Model of Delivery and Financing* (Schaumburg, IL: Society of Actuaries, 2020), https://www.soa.org/globalassets/assets/files/resources/research-report/2020/direct-primary-care-eval-model.pdf.
65. Andrea Klemes et al., "Personalized Preventive Care Leads to Significant Reductions in Hospital Utilization," *The American Journal of Managed Care* 18, no. 12 (December 2012): 453–60.

- State does not treat DPC as insurance
- State allows DPC drug dispensing
- State allows DPC wholesale lab pricing

Insurance Regulations. Health insurance allows people to mitigate their financial exposure through risk pooling. Unfortunately, as governments have expanded their role in regulating health insurance, health insurance has operated less and less as true insurance. For example, in contrast to suppliers of home or automotive insurance, health-insurance companies are not fully free to design their products to meet the demands of their customers. The prices the companies set typically do not reflect the actual expected costs associated with any given buyer, based on that buyer's actual risks and characteristics. Consequently, health insurance bears a much greater resemblance to a prepaid healthcare plan than to an actual insurance product. Although federal regulations—many of which flow out of the Affordable Care Act (ACA)—impose many constraints on health insurers, state policies remain influential.

According to federal law, despite the importance of accurate risk assessment, insurers may not sell coverage to people at different prices on the basis of their actual health-related behaviors and other relevant characteristics. Insurers are only allowed to take into consideration a limited number of factors—age, smoking status, and place of residence—when pricing coverage for an individual. Premiums may be higher for certain individuals only by certain ratios, such as 3:1 for older adults compared to younger adults. Some states go beyond the federally defined ratios and impose even narrower ranges that create significant misalignments between a person's actuarial risk and the premium rate. These regulations, which fall under the umbrella of "community rating," distort the market and cause healthier insurance enrollees to implicitly subsidize sicker enrollees. Consequently, low-risk people buy too little insurance, while high-risk people purchase too much.[66] Stricter community-rating policies tend to discourage younger and healthier people from purchasing insurance,[67] resulting in a larger proportion of the population choosing to remain uninsured.[68] A study in

66. Mark V. Pauly, "The Welfare Economics of Community Rating," *The Journal of Risk and Insurance* 37, no. 3 (September 1970): 407–18.
67. Anthony T. Lo Sasso and Ithai Z. Lurie, "Community Rating and the Market for Private Non-Group Health Insurance," *Journal of Public Economics* 93, no. 1–2 (February 2009): 264–79.
68. Bradley Herring and Mark Pauly, "The Effect of State Community Rating Regulations on Premiums and Coverage in the Individual Health Insurance Market" (NBER Working Paper No. 12504, National Bureau of Economic Research, Cambridge, MA, August 2006).

California also found that community rating produced large unintended transfers of wealth from poorer, rural communities to urban, wealthier regions. For example, high-income areas (including communities like Malibu, Santa Monica, Marina del Rey, and Beverly Hills) had per family expenditures that exceeded the countywide premium by $200 or more annually.[69]

Due to the elimination of the tax penalty associated with the ACA's individual mandate in 2019, states now have discretion to impose their own individual mandates and enforcement mechanisms. Mandating health coverage is problematic for philosophical and empirical reasons. Philosophically, these mandates interfere with individuals' decision-making autonomy. Empirically, while most studies find that individual mandates succeed in increasing enrollment (especially among young people)[70] and reducing average premiums, these effects are small and uncertain.[71] Most research does not support the view that individual mandates are needed to prevent the nongroup insurance market from being destabilized or collapsing.[72] Perhaps the main effect of individual mandates is to concentrate the expense of covering the chronically ill on younger, healthier workers while obscuring the troubling consequences (redistribution concerns and the impact on efficiency).[73]

Indicators

- State does not constrict age rating further than federal law
- State does not mandate that individuals buy health insurance

Copay Coupons. Manufacturer copay coupons (also known as manufacturer copay cards) are savings programs that are set up and run by drug manufacturers to help patients afford medications. Copay coupons are generally offered for brand-name drugs, not generics. Using the coupon lowers the out-of-pocket

69. Dana P. Goldman et al., "Redistributional Consequences of Community Rating," *Health Services Research* 32, no. 1 (April 1997): 71–86.
70. Matthew Fiedler, "The ACA's Individual Mandate In Retrospect: What Did It Do, and Where Do We Go From Here? A Review of Recent Research on the Insurance Coverage Effects of the Affordable Care Act's Individual Mandate," *Health Affairs* 39, no. 3 (March 2020): 429–35.
71. Ithai Z. Lurie, Daniel W. Sacks, and Bradley Heim, "Does the Individual Mandate Affect Insurance Coverage? Evidence from Tax Returns," *American Economic Journal: Economic Policy* 13, no. 2 (May 1, 2021): 378–407.
72. Vicki Fung et al., "Potential Effects of Eliminating the Individual Mandate Penalty in California," *Health Affairs* 38, no. 1 (January 2019): 147–54.
73. Chris Pope, *The Individual Mandate Is Unnecessary and Unfair* (New York: Manhattan Institute, October 2017), https://www.manhattan-institute.org/html/individual-mandate-unnecessary-and-unfair-10735.html.

cost for patients, enabling patients to stick with the brand-name drug that they may already know and trust. (Due to anti-kickback statutes, most copay coupons can only be used by individuals with private insurance, not individuals with Medicare or Medicaid.) Some states have passed laws against copay coupons because they argue that coupons allow drug companies to keep the out-of-pocket costs to patients low while they raise the list prices that they charge insurers, thus increasing overall healthcare spending (via higher premiums).[74] Others have raised concerns that copay coupons encourage the use of more expensive branded medications when clinically equivalent and lower-cost generics are available.[75] On the other hand, there is evidence that copay coupons lower patients' out-of-pocket expenses and improve medication adherence without increasing total drug costs.[76] As researchers studying the overall incentive picture, we recognize the possible short-term negative effects of these tactics but caution states against taking up the potentially legally perilous position of prohibiting companies from giving discounts on their own products. We would prefer pricing discipline on drug makers to be brought about more organically through competition.

Indicator

- State allows drug manufacturer copay coupons

Medical Taxation. States impose varying levels of taxation on medical devices, medical services, and medicines. In several states, all three of those categories are tax exempt, whereas in at least one state, sales taxes are applied to items in all three of those categories. Some states have a sales tax for a general category but exempt certain items, such as specific medical devices for which the consumer has a prescription. These exemptions can be broad or narrow (e.g., limited to just certain classes of items, such as ostomy items, prosthetics, and oxygen components and systems).

74. Leemore S. Dafny, Christopher J. Ody, and Matthew A. Schmitt, "Undermining Value-Based Purchasing—Lessons from the Pharmaceutical Industry," *New England Journal of Medicine* 375, no. 21 (November 2016): 2013–15.
75. Leemore Dafny, Christopher Ody, and Matthew Schmitt, "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization" (NBER Working Paper No. 22745, National Bureau of Economic Research, Cambridge, MA, October 2016), 56.
76. Matthew Daubresse et al., "Effect of Prescription Drug Coupons on Statin Utilization and Expenditures: A Retrospective Cohort Study," *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy* 37, no. 1 (January 2017): 12–24.

These taxes reduce access to medical devices by raising their costs to patients. Patients who forgo certain treatments because of the higher cost may develop more serious health needs —some of which may require uncompensated care—that might have been avoided if the original cost had been more affordable.

Indicator

- State has less medical taxation

Health Savings Account Taxes. Health savings accounts (HSAs) are tax-favored accounts individuals can use to save money for medical expenses. Paired with a high-deductible health-insurance policy, an HSA can be an important piece of responsible planning for healthcare expenses. With an HSA, individuals can save during their healthy years for unpredictable medical expenses in later years. HSAs form part of the foundation of the consumer-directed healthcare movement, as they "shift the locus of rights and responsibilities for financing healthcare from governments and employers toward consumers."[77] By putting patients more in control of their health spending, HSAs encourage comparison shopping and value-based decision-making. A review of the literature on consumer-driven health plans found that participants were more educated about their health coverage and spent less on medical services than participants in other models, such health maintenance organizations (HMOs) and preferred provider organizations (PPOs).[78] A large-scale study found that HSA enrollees spent about 5 to 7 percent less on health-related goods and services than non-HSA enrollees.[79] HSAs are undercut, however, when their tax-advantaged nature is either revoked or never granted in the first place. States impose varying levels of regulation and taxation on these financial tools.

Indicator

- State has fewer health savings account (HSA) taxes

77. James C. Robinson, "Health Savings Accounts—The Ownership Society in Health Care," *New England Journal of Medicine* 353, no. 12 (September 2005): 1199–202.
78. William Ferguson et al., "Potential Savings from Consumer-Driven Health Plans," *International Journal of Healthcare Management* 14, no. 4 (May 2020): 1457–62.
79. Anthony T. Lo Sasso, Mona Shah, and Bianca K. Frogner, "Health Savings Accounts and Health Care Spending," *Health Services Research* 45, no. 4 (August 2010): 1041–60.

Institutional Regulations

The institutional-regulation category measures the extent to which state laws liberate or restrict healthcare institutions such as hospitals, pharmacies, insurance companies, and so on. To maximize competition and innovation, these institutions should be able to make business investments and expansions as they see fit, including designing new services and lines of business. They would either profit by creating value or bear their own losses.

Certificate of Need. Certificate-of-need (CON) laws require healthcare providers to obtain authorization from state regulators before they offer new services, expand facilities, or invest in technology. CON laws commonly apply to nursing homes, psychiatric services, ambulatory surgical centers, imaging equipment, and hospital beds. CON proceedings can be expensive and may cause long delays; further, they are vulnerable to cronyism, manipulation by the politically connected, and lobbying by incumbent healthcare providers defending their turf.

CON laws were first conceived nearly 60 years ago as policymakers grew concerned that an unfettered supply of hospital beds, diagnostic equipment, and healthcare services would drive up demand, contributing to higher healthcare spending and jeopardizing access to care for those who needed it most. The empirical evidence, however, is unambiguous: CON laws restrict access to healthcare (especially in rural communities[80]), make services more expensive,[81] and undermine the quality of care.[82] A review of 90 studies on the effects of CON laws concluded that their expected costs exceed their benefits.[83]

By limiting the supply of services, CON laws weaken competition in the healthcare sector, make it harder for innovators to gain a foothold, and allow incumbent providers to charge higher prices while facing fewer incentives to deliver high-quality care. One study noted, "CON appears to add 20.6 percent

80. Thomas Stratmann and Christopher Koopman, "Entry Regulation and Rural Health Care: Certificate-of-Need Laws, Ambulatory Surgical Centers, and Community Hospitals" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, February 2016), https://www.mercatus.org/publications/regulation/entry-regulation-and-rural-health-care-certificate-need-laws-ambulatory.
81. Matthew D. Mitchell, "Do Certificate-of-Need Laws Limit Spending?" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016), https://www.mercatus.org/publications/corporate-welfare/do-certificate-need-laws-limit-spending.
82. Thomas Stratmann and David Wille, "Certificate-of-Need Laws and Hospital Quality" (Mercatus Working Paper, Mercatus Center at George Mason University, Arlington, VA, September 2016), https://www.mercatus.org/publications/corporate-welfare/certificate-need-laws-and-hospital-quality.
83. Christopher J. Conover and James Bailey, "Certificate of Need Laws: A Systematic Review and Cost-Effectiveness Analysis," *BMC Health Services Research* 20, no. 1 (December 2020): 748.

to per capita hospital expenditures in the long run. This is consistent with the view that CON programs act to protect inefficient hospitals from competition."[84] Moreover, Medicare patients who live in states with CON laws on the books are 3.4 to 5.3 percent more likely to travel outside their home county to obtain imaging services than residents of non-CON states.[85]

Indicator

- State has fewer certificate-of-need restrictions

Retail Health Clinics. Retail health clinics have proliferated in recent years as Americans have shown a preference for convenient, timely, and low-cost healthcare. Today, more than 2,000 clinics operate within drugstores, supermarkets, and "big box" stores throughout the country. Typically staffed by a physician assistant or nurse practitioner, retail health clinics provide basic primary-care services, including treatments for colds and other infections, physical exams and screenings, lab work, and vaccinations. Thanks to their extended hours, short wait times, transparent pricing, and "walk-ins welcome" policy, retail health clinics increasingly serve as an alternative to the emergency room for patients with minor illnesses and injuries.

Research by the RAND Corporation suggests that retail-clinic use is heaviest among younger adults, minorities, and families with children. Many clinic users lack viable alternatives. Only 39 percent of patients who visit clinics have an established relationship with a primary-care provider (compared to 80 percent in the general population), and about 16 to 27 percent of retail-clinic users are uninsured.[86]

A 2009 analysis found that retail clinics generate significant costs savings for consumers and the health system as a whole. Over a six-month period, retail-clinic users had lower healthcare expenditures than nonusers by 14 percent ($347). Moreover, there was no evidence that care provided by retail clinics was lower in quality than care received in physicians' offices. The authors have estimated that banning retail clinics nationwide would reduce aggregate welfare by

84. Joyce A. Lanning, Michael A. Morrisey, and Robert L. Ohsfeldt, "Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures," *Journal of Regulatory Economics* 3, no. 2 (June 1991): 137–54.
85. Matthew C. Baker and Thomas Stratmann, "Barriers to Entry in the Healthcare Markets: Winners and Losers from Certificate-of-Need Laws," *Socio-Economic Planning Sciences* 77 (October 2021): 101007.
86. Robin M. Weinick et al., *Policy Implications of the Use of Retail Clinics* (Santa Monica, CA: RAND Corporation, 2010), 94, https://www.rand.org/pubs/technical_reports/TR810.html.

$433 million annually.[87] Given the substantial growth in the retail-clinic industry since 2009, these economic benefits have only increased.

Indicator

- State gives retail health clinics broad latitude in services offered

Competition. The quickening pace of hospital consolidations, insurer mergers, and other trends within the US healthcare system has resulted in unprecedented levels of market concentration. In 2016, a report found that "90 percent of metropolitan areas had highly concentrated hospital markets, 65 percent had highly concentrated specialist physician markets, 39 percent had highly concentrated primary-care physician markets, and 57 percent had highly concentrated insurance markets."[88] Although consolidation could theoretically yield benefits through economies of scale, the empirical evidence unequivocally demonstrates that the lack of competition contributes to higher prices and erodes incentives to provide innovative, high-quality care.[89] Although eliminating barriers to entry—such as scope-of-practice restrictions and CON laws—is an important step, states should consider more direct action to strengthen competition and prevent monopolistic behavior in the healthcare industry.

Pre-merger reviews—in which state authorities, typically the attorney general's staff, assess whether a proposed consolidation promotes cost containment, quality enhancement, and greater access to care—can help prevent anticompetitive practices. Although such reviews are not always successful in identifying mergers that are not in the public interest, they constitute an important safeguard against the most blatant—and harmful—consolidations of market power.[90]

Some states have also experimented with a promising regulatory structure, called *certificate of public advantage* (COPA), which gives regulators broad authority to limit the harmful effects of mergers (e.g., higher prices) while promoting their benefits (e.g., greater administrative efficiency). With a COPA, a

87. Stephen T. Parente and Robert J. Town, "The Impact of Retail Clinics on Cost, Utilization and Welfare" (NBER Working Paper, National Bureau of Economic Research, Cambridge, MA, October 2009), 34.
88. Brent D. Fulton, "Health Care Market Concentration Trends in the United States: Evidence and Policy Responses," *Health Affairs* 36, no. 9 (September 2017), 2.
89. Martin Gaynor, *What to Do about Health-Care Markets? Policies to Make Health-Care Markets Work* (Washington, DC: Brookings Institution, March 2020), 40.
90. Alexandra D. Montague, Katherine L. Gudiksen, and Jaime S. King, "State Action to Oversee Consolidation of Health Care Providers," Milbank Memorial Fund, August 5, 2021, https://www.milbank.org/publications/state-action-to-oversee-consolidation-of-health-care-providers/.

state permits the formation of a healthcare monopoly in exchange for ongoing state oversight and accountability, which is intended to replace the competition that has been lost. Often, the COPA imposes controls on the growth of healthcare prices the entity can charge, as well as caps on its profits.[91] In crafting these agreements, the factors state authorities have to consider can be numerous, conflicting, and not subject to empirical analysis or measurement. If properly designed and implemented, COPAs are a form of light-handed regulation, threading the needle between allowing unchecked market power (if a merger is permitted to proceed with no oversight) and forgoing the benefits of a merger to avoid greater costs (if a merger is blocked through an antitrust action).[92]

Finally, firms in the healthcare industry often negotiate anticompetitive contracts to reduce transparency and strengthen their market power.[93] Six contracting practices are particularly widespread: *most-favored-nations clauses*, which guarantee that a buyer of goods or services (e.g., an insurer) receives terms from a seller (e.g., a hospital) that are at least as favorable as those provided to any other buyer; *noncompete clauses*, which prohibit employees from competing against their current employer within a certain time frame; *all-or-nothing provisions*, which oblige insurers to contract with all facilities in a health system if they want to include any facilities under their plan; *exclusive dealing arrangements*, which bar insurers from contracting with other providers for services; *anti-tiering* and *anti-steering clauses*, which require insurers to place all physicians, hospitals, and other facilities associated with a hospital system in the most favorable tier (or lowest cost-sharing rate) of providers; and *gag clauses*, which prevent patients or employers from knowing the negotiated rates of healthcare services. While it is difficult to quantify the effects of these practices, the best evidence suggests that they lead to higher prices and may undermine quality of care.[94] States have adopted a wide range of policies related to these anticompetitive practices. In

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91. Erin C. Fuse Brown, "To Oversee or Not to Oversee? Lessons from the Repeal of North Carolina's Certificate of Public Advantage Law," Milbank Memorial Fund, January 17, 2019, 11, https://www.milbank.org/publications/to-oversee-or-not-to-oversee-lessons-from-the-repeal-of-north-carolinas-certificate-of-public-advantage-law/.

92. Randall R. Bovbjerg and Robert A. Berenson, "Certificates of Public Advantage," Urban Institute, February 2015, 45, https://www.urban.org/research/publication/certificates-public-advantage.

93. Katherine L. Gudiksen, Alexandra D. Montague, and Jaime S. King, "Mitigating the Price Impacts of Health Care Provider Consolidation," Milbank Memorial Fund, September 23, 2021, 18, https://www.milbank.org/publications/mitigating-the-price-impacts-of-health-care-provider-consolidation/.

94. Katherine L. Gudiksen et al., *Preventing Anticompetitive Contracting Practices in Healthcare Markets* (San Francisco, CA: The Source on Healthcare Price & Competition, September 2020), 56, https://2zele1bn0sl2i91io41niae1-wpengine.netdna-ssl.com/wp-content/uploads/2020/09/Preventing-Anticompetitive-Contracting-Practices-in-Healthcare-Markets-FINAL.pdf.

some cases, a certain practice may be prohibited or subject to special oversight from a state authority.

Indicators

- State reviews provider and insurer mergers
- State encourages competition among healthcare providers

Compounding Pharmacies. Compounding pharmacies are laboratories in which pharmacists mix drugs to create custom medications for patients. They are an important part of the healthcare-delivery system. However, many states put restrictions on compounding practices, rather than allowing pharmacies to adopt or innovate new methods for producing drugs more efficiently and at lower costs. One such restriction is prohibiting facilities from making sterile office stock, which means pharmacists are not allowed to make more product than that for which they have orders at a given time. Advocates of these regulations point out that over the last two decades, improper handling at compounding pharmacies have led to a number of fatal disease outbreaks.[95] We believe improvements in training and safety procedures[96] can mitigate the risk of future public-health threats, rather than forcing pharmacists to make small batches of new product for each order. Making small batches is less efficient and more expensive than making larger batches and storing them to fill future orders.

Indicator

- State puts fewer restrictions on compounding pharmacies

Entrepreneurial Business Structures. Innovative business models are needed to improve the way healthcare is organized in the United States. Unfortunately, some states limit medical entrepreneurship through laws against what they call the *corporate practice of medicine* (CPOM). These laws arose out of early-20th-century efforts by the American Medical Association to professionalize medicine through the development of an ethical code for preventing quackery and

95. Nadine Shehab et al., "U.S. Compounding Pharmacy-Related Outbreaks, 2001–2013: Public Health and Patient Safety Lessons Learned," *Journal of Patient Safety* 14, no. 3 (September 2018): 164–73.
96. Catherine Staes et al., "Description of Outbreaks of Health-Care-Associated Infections Related to Compounding Pharmacies, 2000–12," *American Journal of Health-System Pharmacy* 70, no. 15 (August 2013): 1301–12.

the commercial exploitation of physicians.[97] Proponents argue that any person who practices medicine must be licensed by the government and that healthcare professionals may not assist unlicensed people or entities to practice medicine.[98] In effect, this inhibits the development of new business models that could potentially lower the cost and improve the quality of medical care. For example, these laws can prohibit a licensed physician and an unlicensed person from forming a limited liability company in which the doctor provides medical services and the unlicensed person handles business administration.[99] Even scholars who worry about the abuses of corporate power have increasingly acknowledged that the CPOM doctrine is too strict and needs revision.[100] We believe states should grant entrepreneurs and businesspeople flexibility with regard to ownership and business structure in the healthcare sector.

Indicator

- State allows entrepreneurial business structures

Pharmaceutical Regulations

The pharmaceutical-regulation category captures state policies that constrain market forces within the pharmaceutical industry, such as affordability boards vested with the power to sanction companies deemed to be charging excessive prices. Such price controls interfere with healthcare openness and accessibility by distorting incentives and discouraging innovation. We also consider whether states use reference pricing, a model that can effectively moderate price increases.

Drug Price Controls. Rising pharmaceutical costs are an ongoing concern for many Americans. In response, some states have taken steps such as adopting European-style price controls on drug manufacturers, levying taxes on drug manufacturers deemed to have increased a drug's price too rapidly (such as exceeding the rate of general inflation), or requiring pharmaceutical compa-

97. Nicole Huberfeld, "Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine," *Health Matrix: The Journal of Law-Medicine* 14, no. 2 (2004): 51.
98. Jeffrey F. Chase-Lubitz, "The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry," *Vanderbilt Law Review* 40, no. 2 (1987): 45.
99. Stuart I. Silverman, "In an Era of Healthcare Delivery Reforms, the Corporate Practice of Medicine Is a Matter That Requires Vigilance," *Health Law and Policy Brief* 9, no. 1 (2015): 24.
100. Sara D. Mars, "The Corporate Practice of Medicine: A Call for Action," *Health Matrix: The Journal of Law-Medicine* 7, no. 1 (1997): 61.

nies to disclose and justify price hikes. These misguided policies distort market incentives and fail to address the underlying cause of high drug prices: the prohibitive cost of drug development.

While price controls can provide short-term financial relief to some patients,[101] they also impose substantial long-term costs by discouraging drug makers from developing new medicines. A 2020 literature review found that 90 percent of the studies examined showed a significant negative relationship between drug price controls and investment in pharmaceutical research and development (R&D) or access to innovative drugs.[102] These disincentives are likely to be particularly acute in the United States, which remains the world's foremost source of pharmaceutical innovation. A 2005 study estimated that cutting pharmaceutical prices by 40 to 50 percent in the United States would lead to between 30 and 60 percent fewer early-stage R&D projects being undertaken.[103] Researchers have also documented that European reference-pricing policies lead to widespread launch delays for novel drugs; they estimate that repealing reference-pricing laws in Europe would reduce launch delays by up to 14 months per drug.[104] A report by the European Centre for International Political Economy concluded, "Ultimately, by dampening the price competition and by discouraging incremental innovation, [international reference pricing] may in the long run defeat its purpose and lead to increased medical expenses for the public healthcare sector."[105]

Targeting "unsupported" price increases or enacting bans on "price gouging" are more subtle forms of price controls, but their interference with market mechanisms is just as real. State regulators often lack the detailed knowledge to understand the myriad factors that contribute to a drug's price and may issue a ruling that undermines access and competition. Moreover, many of these restrictions fail to distinguish between a generic drug increasing its price from $1 to $2 (a 100 percent increase) and a brand-name drug increasing its price from $100 to

101. Joy Li-Yueh Lee et al., "A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending," *American Journal of Managed Care* 18, no. 11 (2012): 9.
102. Yanick Labrie, "Evidence That Regulating Pharmaceutical Prices Negatively Affects R&D and Access to New Medicines," *Canadian Health Policy* (June 2020): 1–10.
103. Thomas Abbott and John Vernon, "The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions" (NBER Working Paper No. 11114, National Bureau of Economic Research, Cambridge, MA, February 2005).
104. Luca Maini and Fabio Pammolli, "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market," last revised December 3, 2020, https://ssrn.com/abstract=3694471.
105. Lisa Brandt, "Price Tagging the Priceless: International Reference Pricing for Medicines in Theory and Practice," *European Centre for International Political Economy*, no. 3 (April 2013): 12.

$105 (a mere 5 percent increase). Consequently, these laws may punish generic manufacturers for small (in absolute magnitude) price hikes while allowing brand-name drug prices to escalate. This may undermine generic competition, one of the most reliable sources of drug-price reductions.[106]

Indicators

- State requires drug manufacturers to submit cost or price information (such as wholesale acquisition costs and price increases) to state regulators or the public
- State does not conduct drug-affordability reviews

III. DISCUSSION

The appendixes can be found on the Mercatus website. Appendix 1 contains the data sources and detailed methodology for constructing each of the indicators discussed above. Construction of the indicators proceeds as outlined in Section II. Using this approach, each state receives a score for each indicator and category and an overall HOAP score. This approach to constructing the index, as with all multicomponent indices, means the score at each level can be used independently. For example, states can be ranked only on professional regulation or scope of practice. Appendix 2 summarizes the evolution of HOAP indicators from the first edition (released in 2016) to the present.

IV. CONCLUSION

In this paper, we have outlined the empirical justification for the indicators included in the HOAP Index and the steps to construct the scores. With the empirical basis of HOAP established, we invite scholars to use the resulting index in their research, with the assurance that each indicator is carefully selected and has a strong evidentiary basis. Researchers have often struggled to examine the systematic role healthcare regulations play in health outcomes. HOAP seeks to fill this gap by providing a quantifiable measure of healthcare regulations and how they affect health outcomes, access, and inputs across US states.

106. Sean R. Dickson and Tyler Kent, "Association of Generic Competition With Price Decreases in Physician-Administered Drugs and Estimated Price Decreases for Biosimilar Competition," *JAMA Network Open* 4, no. 11 (November 2021): e2133451.

This methodological paper has some limitations, however. First, it is impossible to include every policy variable or regulation that influences health outcomes, healthcare access, or healthcare inputs. Further, to be included in the HOAP Index, there must be available data for the indicator. The upshot is that new indicators that meet the above-mentioned criteria can be included as necessary without changing the methodology. A second shortcoming of the methodology is use of unweighted averages. As mentioned earlier, categories that have few indicators have disproportionate influence on a state's score and subsequent ranking. Our raw data is amenable to a wide range of weighting approaches, and we hope that researchers will explore these possibilities.

Despite these shortcomings, we believe that HOAP offers an empirically robust measure of the healthcare regulatory landscape and how states vary in their approaches to regulating healthcare. We hope that, with the support of the scholarly community, HOAP can continue to inform important research.

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ACKNOWLEDGMENTS

The authors thank Robert Graboyes, Jared Rhoads, and Elise Amez-Droz for helpful comments. Justin Leventhal generously provided data assistance.

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