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Competition and Regulation in the Healthcare Sector – Note by the United States

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United States

1. Introduction

1. The Federal Trade Commission ("FTC") and the Antitrust Division of the U.S. Department of Justice ("Division") (collectively, the "Agencies") are pleased to offer this joint submission in response to Working Party No. 2's consideration of regulation in the healthcare sector with a focus on healthcare facilities, providers, and health insurance.

2. Healthcare accounts for over 17 percent of U.S. GDP,[1] but still too many Americans are unable to obtain the care they need at prices they can afford.[2] For years, anticompetitive conduct, consolidation, and regulations throughout the healthcare industry have resulted in higher prices, lower quality, reduced access to care, and slower innovation.[3] Rural Americans, seniors, and veterans have been particularly hard hit by these changes, especially in terms of affordable and convenient access to care.[4]

3. Recognizing that healthcare is critically important to Americans, the Agencies have undertaken numerous initiatives using all possible tools to promote competition throughout the healthcare industry. In their primary role as law enforcers, the Agencies have pursued enforcement actions and obtained settlements to preserve or restore price, quality, and innovation competition throughout the healthcare industry.[5] A sample of the Agencies' recent actions include:

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[1] OECD, HEALTH AT A GLANCE: OECD INDICATORS Fig. 7.1 (2025), https://doi.org/10.1787/8f9e3f98-en. By comparison, OECD countries spend about 9.3% of their GDP on healthcare. *Id.*

[2] Memorandum from Andrew N. Ferguson, Chairman, Fed. Trade Comm'n, on Directive Regarding Healthcare Task Force 1 (Mar. 20, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/Memorandum-Ferguson-re-Healthcare-Task-Force.pdf.

[3] *Id.*

[4] *Id.*

[5] *See, e.g.*, Press Release, Fed. Trade Comm'n, FTC Takes Action to Prevent Anticompetitive Healthcare Services Merger (Jan. 30, 2026), https://www.ftc.gov/news-events/news/press-releases/2026/01/ftc-takes-action-prevent-anticompetitive-healthcare-services-merger (announcing a settlement to preserve access and quality competition in the market for the provision of services to individuals with intellectual and development disabilities in intermediate care facilities); Press Release, Fed. Trade Comm'n, FTC Stops Proposed Merger of Leading Cataract-Surgery Device Makers (Mar. 17, 2026), https://www.ftc.gov/news-events/news/press-releases/2026/03/ftc-stops-proposed-merger-leading-cataract-surgery-device-makers (explaining that Lensar abandoned its proposed acquisition of Alcon, two manufacturers of laser systems used in cataracts surgery, after staff found evidence that the merger likely would result in decreased price and innovation competition); Press Release, Fed. Trade Comm'n, FTC Bureau of Competition Statement on Termination of Healthcare Managed Services Merger (Dec. 5, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/12/ftc-bureau-competition-statement-termination-healthcare-managed-services-merger (explaining that Aya Healthcare abandoned its acquisition of Cross Country Healthcare after staff developed evidence that the transaction would eliminate head-to-head competition between two of the largest providers of software used by hospitals to find, hire, and manage nurses and other healthcare workers).

- **Preserving price and quality competition for outpatient surgeries.** Earlier this month, the FTC settled allegations that Ascension Health Alliance's ("Ascension") acquisition of AmSurg LLC would reduce price and quality competition in several local markets for outpatient surgical services performed by gastroenterologists, ophthalmologists, and orthopedists.[6] Under the settlement, Ascension must divest seven ambulatory surgery centers across Florida, Kansas, Oklahoma, Tennessee, and Texas.
- **Reducing the price of prescription drugs.** In February, the FTC obtained a landmark settlement with Express Scripts ("ESI") to reduce prescription drug prices for Americans and resolve allegations that ESI had artificially inflated the list price of insulin by using anticompetitive and unfair rebating practices. The settlement requires ESI to adopt fundamental changes to its business practices that increase transparency, and those changes are expected to reduce Americans' out-of-pocket costs for drugs like insulin by up to $7 billion over the next 10 years.[7]
- **Ensuring price and innovation competition for medical devices.** In January, the FTC successfully challenged Edwards Lifesciences' proposed acquisition of JenaValve, which would have combined the only two companies with ongoing clinical trials for devices designed to treat aortic regurgitation, a potentially fatal heart condition.[8] By blocking the transaction, the FTC preserved price, quality, and innovation competition between these two medical device manufacturers.
- **Reducing healthcare costs by allowing patients and employers to choose lower cost healthcare options.** In February 2026, the Division, together with the Attorney General of Ohio, filed a civil antitrust lawsuit against OhioHealth Corporation ("OhioHealth") for imposing anticompetitive contract restrictions that force Columbus-area patients to pay higher prices for healthcare and imposed limits on the cost information that insurers can provide to patients.[9] The Division alleged that these anticompetitive contract restrictions impede or completely prevent insurers from offering innovative and money-saving health-insurance plans or plan features and severely limit consumers' access to price information. Without these lower cost and innovative plan options and cost information that empower patients to save money by selecting lower-cost providers who provide high-quality care, patients and employers are faced with fewer health plan choices and higher costs.

[6] Press Release, Fed. Trade Comm'n, FTC Requires Divestiture of Ambulatory Surgery Centers to Protect Patients from Anticompetitive Effects of Ascension Health-AmSurg Deal (June 2, 2026), https://www.ftc.gov/news-events/news/press-releases/2026/06/ftc-requires-divestiture-ambulatory-surgery-centers-protect-patients-anticompetitive-effects.

[7] Press Release, Fed. Trade Comm'n, FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients (Feb. 4, 2026), https://www.ftc.gov/news-events/news/press-releases/2026/02/ftc-secures-landmark-settlement-express-scripts-lower-drug-costs-american-patients.

[8] Press Release, Fed. Trade Comm'n, Statement on FTC Victory Halting Anticompetitive Medical Device Deal (Jan. 12, 2026), https://www.ftc.gov/news-events/news/press-releases/2026/01/statement-ftc-victory-halting-anticompetitive-medical-device-deal.

[9] Press Release, U.S. Dep't of Just., Antitrust Div., Justice Department Sues OhioHealth for Anticompetitive Healthcare Contracts That Increase Costs for Ohio Patients (Feb. 20, 2026), https://www.justice.gov/opa/pr/justice-department-sues-ohiohealth-anticompetitive-healthcare-contracts-increase-costs-ohio.

- Similarly, in March 2026, the Division sued to enjoin The New York and Presbyterian Hospital ("New York-Presbyterian") from imposing anticompetitive contract restrictions.[10] The Division alleged that New York-Presbyterian's contractual restrictions preclude insurers and employers from offering New Yorkers budget-conscious health insurance plans, denying consumers the choice of lower cost healthcare options.
- **Ensuring quality home health and hospice services and competitive nursing wages and employment terms.** In December 2025, the Division, together with the Attorneys General of Maryland, Illinois, New Jersey, and New York, obtained the largest divestiture of outpatient healthcare services to resolve the merger challenge to UnitedHealth Group Incorporated's $3.3 billion acquisition of Amedisys Inc.[11] This acquisition would have combined two of the largest home health and hospice providers in the United States.[12] The Division also imposed a $1.1 million civil penalty against Amedisys for falsely certifying compliance with its obligations under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.[13]
- **Securing criminal fines, restitution, and forfeiture for fixing nurses wages.** In April 2025, the Division's criminal program obtained its first wage-fixing conspiracy win.[14] In *U.S. v. Lopez*, a federal jury convicted the defendant for participating in a three-year conspiracy to fix the wages for home healthcare nurses in Las Vegas and for fraudulently failing to disclose the criminal antitrust investigation during the sale of his home healthcare staffing company.[15] A federal district court in Nevada sentenced the defendant to 40 months in custody and $550,000 in criminal fines.[16] The defendant also must pay $2,496,101 in criminal

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[10] Press Release, U.S. Dep't of Just., Antitrust Div., Justice Department Sues New York-Presbyterian Hospital for Anticompetitive Contracts That Increase Healthcare Costs for New Yorkers (Mar. 26, 2026), https://www.justice.gov/opa/pr/justice-department-sues-new-york-presbyterian-hospital-anticompetitive-contracts-increase.

[11] Press Release, U.S. Dep't of Just., Antitrust Div., Court Approves Justice Department's Settlement in UnitedHealth Group and Amedisys Merger (Dec. 10, 2025), https://www.justice.gov/opa/pr/court-approves-justice-departments-settlement-unitedhealth-group-and-amedisys-merger.

[12] Press Release, U.S. Dep't of Just., Antitrust Div., Justice Department Sues to Block UnitedHealth Group's Acquisition of Home Health and Hospice Provider Amedisys (Nov. 12, 2024), https://www.justice.gov/archives/opa/pr/justice-department-sues-block-unitedhealth-groups-acquisition-home-health-and-hospice.

[13] Press Release, U.S. Dep't of Just., Antitrust Div., Court Approves Justice Department's Settlement in UnitedHealth Group and Amedisys Merger (Dec. 10, 2025), https://www.justice.gov/opa/pr/court-approves-justice-departments-settlement-unitedhealth-group-and-amedisys-merger.

[14] Press Release, U.S. Dep't of Just., Antitrust Div., Jury Convicts Home Health Agency Executive of Fixing Wages and Fraudulently Concealing Criminal Investigation (Apr. 14, 2025), https://www.justice.gov/opa/pr/jury-convicts-home-health-agency-executive-fixing-wages-and-fraudulently-concealing-criminal.

[15] *Id.*

[16] Press Release, U.S. Dep't of Just., Antitrust Div., White-Collar Executive Incarcerated for Fixing Nurse Wages and Fraud (Nov. 21, 2025), https://www.justice.gov/opa/pr/white-collar-executive-incarcerated-fixing-nurse-wages-and-fraud.

restitution to the defrauded purchaser of his home healthcare company and forfeit $10,459,000 from the fraudulent sale of his home healthcare company.[17]

4. In addition to vigorous enforcement, the Agencies use other tools to promote price and non-price competition in the healthcare industry. Chief among these tools—and most relevant to this roundtable—are the Agencies' use of their deep expertise in healthcare markets to identify and advocate against proposed federal and state legislation and regulations that unnecessarily impede healthcare competition. The Agencies often receive requests from state legislators to review potential competitive effects of proposed legislation or regulations. The Agencies—both jointly and separately—may provide perspectives based on their expertise.

5. This submission is organized as follows: Part II provides examples of how the U.S. healthcare system is subject to both federal and state regulations; Part III describes the Agencies' ongoing review of federal regulations that may unnecessarily restrict competition; and each of the remaining Part summarizes the Agencies' advocacy efforts to streamline regulations within a specific segment of the healthcare industry, including healthcare facilities, such as hospitals and ambulatory clinics; providers, namely physicians and nurses; and health insurance.

2. Federal and State Regulations of Healthcare Can Overlap

6. In the United States, the federal government and state governments regulate healthcare. These regulations establish, for example, the criteria under which healthcare facilities and providers may participate in federal healthcare programs and provide care to patients. For instance, hospitals must meet federal Conditions of Participation to participate in Medicare.[18] At the same time, hospitals must satisfy various state regulations, including obtaining licenses and, in some states, meeting or disclosing certain operational and quality standards.[19]

7. Though the regulation of pharmaceuticals goes beyond the scope of this roundtable, the pharmaceutical industry provides another example of how federal and state regulations in healthcare can interact. The federal Food and Drug Administration ("FDA") regulates the approval, manufacture, and labeling of pharmaceuticals.[20] States regulate, among other

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[17] *Id.*

[18] 42 C.F.R. § 482.1(a)(1) (2024). Medicare is the U.S. federal health insurance program that provides hospital, medical, and prescription drug coverage to Americans aged 65 and older, as well as certain individuals with qualifying disabilities or specific health conditions. Medicare Program – General Information, CMS, https://www.cms.gov/about-cms/what-we-do/medicare (last visited June 2, 2026).

[19] *E.g.*, Health Care Facility Licensing and Certification, CAL. DEP'T OF PUBLIC HEALTH, https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/ApplyForLicensure.aspx (last accessed May 4, 2026) (licensing process for healthcare facilities in California); Office of Health Care Quality, MD. DEP'T OF HEALTH, https://health.maryland.gov/ohcq/pages/home.aspx (last accessed May 4, 2026) (Maryland conducts surveys of healthcare facilities to determine compliance with regulations on minimum standards of care); ILL. DEP'T OF PUBLIC HEALTH, Clarification Document: Illinois Hospital Nurse Staffing Data Collection Guidelines (Mar. 2012), https://dph.illinois.gov/content/dam/soi/en/web/idph/files/publications/drafthrcadatacollectguidelines100.pdf (Illinois requires hospitals to disclose information about nurse staffing levels).

[20] *Development & Approval Process for Drugs*, FDA, https://www.fda.gov/drugs/development-approval-process-drugs (last visited June 2, 2026).

things, the dispensing of pharmaceuticals. For instance, some states require pharmacies to dispense a generic version where available.[21] Other states permit pharmacists to dispense a generic version instead of the brand-name drug, but they differ in terms of whether pharmacists must obtain express consent from patients for the substitution or merely provide notice.[22]

8. The Agencies have substantial experience navigating both federal and state healthcare laws to promote competition. Some of the Agencies' efforts last multiple years, but the payoff is high: enduring competition that benefits Americans through lower prices, higher quality, faster innovation, and more convenience.

9. The FTC's work to encourage competition for hearing aids is a clear example. In 2017, the FTC organized a workshop on competition, innovation, and consumer protection in hearing healthcare to address obstacles that tens of millions of hearing-impaired Americans faced in obtaining hearing aids.[23] The panelists provided evidence that many Americans could not obtain hearing aids because of high prices and restricted distribution channels that limited their choices. The workshop's record eventually supported the FDA's efforts to make hearing aids more accessible and to increase competition, reduce prices, and improve innovation. Specifically, in 2021, the FDA proposed a rule to permit the sale of over-the-counter ("OTC") hearing aids to consumers and preempt contrary state laws and regulations.[24] Relying on information collected from the 2017 workshop, the FTC submitted a comment supporting the proposed rule, explaining that it would likely foster entry of lower priced safe and effective hearing aids, new distribution channels, and increased choices for consumers.[25] The FDA finalized the rule in 2022. Now, consumers with mild and moderate hearing loss may purchase OTC hearing aids in retail stores or online without seeing a physician or other hearing healthcare professional.[26]

3. Ongoing Review of Anticompetitive Federal Regulations

10. Revitalizing and expanding the economy for all Americans is one of President Trump's top priorities. To help accomplish this goal, he issued several Executive Orders in early 2025, directing all executive agencies to eliminate unlawful, unnecessary, and anticompetitive regulations that obstruct businesses and entrepreneurs. For example, to help remove the massive regulatory burden that restricts economic growth, Executive Order

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[21] Chana A. Sacks et al., *Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions*, 181 JAMA INTERNAL MED. 16, 18 (2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769770#247630880.

[22] *Id.*

[23] Press Release, Fed. Trade Comm'n, FTC Announces Workshop on Hearing Health and Technology (Jan. 4, 2017), https://www.ftc.gov/news-events/news/press-releases/2017/01/ftc-announces-workshop-hearing-health-technology.

[24] Fed. Trade Comm'n, FTC Staff Comment Letter on Proposed Rule to Establishing Over-the-Counter Hearing Aids Under the FDA Reauthorization Act of 2017 (Jan. 18, 2022), https://www.ftc.gov/legal-library/browse/advocacy-filings/ftc-staff-comment-food-drug-administration-docket-no-fda-2021-n-0555-concerning-over-counter-hearing.

[25] *Id.*

[26] Jack Stebbins, *Best Buy to Sell Over-the-Counter Hearing Devices This Fall Following Change in FDA Regulation*, CNBC (Aug. 17, 2022, 12:43 PM), https://www.cnbc.com/2022/08/17/best-buy-to-sell-otc-hearing-aid-devices-after-fda-regulation.html.

14192 instructed agencies to identify at least 10 existing regulations for removal for each new regulation adopted.[27] Executive Order 14267, "Reducing Anti-Competitive Regulatory Barriers," called on the FTC Chairman and Attorney General to lead a government-wide effort to identify and review anticompetitive regulations that create or facilitate monopolies, raise unnecessary barriers to entry for new market participants, or otherwise impose restraints that distort the free market.[28]

11. In response to those orders, the Agencies established processes to seek input from other federal government agencies and the public regarding potentially anticompetitive regulations. The Agencies received hundreds of submissions that aided their work to facilitate the reduction of anticompetitive regulatory barriers. After consulting other agencies and considering public input, the Agencies identified over 125 anticompetitive regulations that distort markets and stifle competition.[29] On September 16, 2025, the FTC Chairman submitted to the White House Office of Management and Budget ("OMB") a report summarizing those regulations that warrant rescission or modification. The OMB Director, through the Administrator of the Office of Information and Regulatory Affairs, will consult with the FTC, the Division, the White House, and the relevant agency heads to decide whether to incorporate the proposed rescissions or modifications into the Unified Agenda of Regulatory and Deregulatory Actions, a semi-annual report on the actions executive agencies plan to issue in the near and long term.

12. The 125 regulations identified last September represent an initial tranche of anticompetitive regulations, as the Agencies continue to receive responses identifying other potentially anticompetitive regulations.[30] After consulting with relevant government agencies, the Agencies will submit supplemental reports containing additional recommendations for the deletion or modification of anticompetitive regulations. Those supplemental reports may contain recommendations to eliminate or modify anticompetitive regulations affecting the healthcare industry.

4. Preventing Anticompetitive Regulations of Healthcare Facilities

13. "Certificate of Need" and "Certificate of Public Advantage" laws are two schemes that some U.S. states use to regulate healthcare facilities, such as hospitals and ambulatory clinics. The Agencies have substantial experience advocating against these laws because they hinder competition.

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[27] Exec. Order No. 14192, 90 Fed. Reg. 9065 (Jan. 31, 2025).

[28] Exec. Order No. 14267, 90 Fed. Reg. 15629 (Apr. 9, 2025).

[29] Press Release, Fed. Trade Comm'n, FTC Recommends Anticompetitive Regulations for Deletion or Revision

(Sept. 17, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/09/ftc-recommends-anticompetitive-regulations-deletion-or-revision; Press Release, U.S. Dep't of Just., Antitrust Division, Antitrust Division Contributes to Historic Efforts to Unleash Prosperity Through Deregulation (Sept. 17, 2025), https://www.justice.gov/opa/pr/antitrust-division-contributes-historic-efforts-unleash-prosperity-through-deregulation.

[30] Letter from Andrew N. Ferguson, Chairman, Fed. Trade Comm'n, to Russell Vought, Director, Office of Mgmt. & Budget (Sept. 16, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/Anticompetitive-Regulations-Ferguson-Letter.pdf.

4.1. Certificates of Need

14. A Certificate of Need ("CON") is a regulatory tool in some U.S. states that requires state agency approval before a health care provider, such as a hospital or ambulatory clinic, can enter a market or make certain capital improvements.[31] They typically cover the construction of new facilities, expansion of existing ones, equipment purchases, or the launch of certain types of medical services.[32] Healthcare providers seeking CONs typically must demonstrate to the state government that the project serves a genuine community need and will not duplicate existing resources or increase costs unnecessarily.[33] As of 2025, approximately 35 states and the District of Columbia had CON laws.[34]

15. Many states enacted CON laws with the goal of reducing healthcare costs and improving access to healthcare. But CON laws undermine those goals by obstructing competition. Through costs, delays, and potential rejections, CON laws can be a major barrier for firms that seek to enter or expand into healthcare markets. CON laws can even deter or block firms that seek to add competition to concentrated markets with new, lower cost, higher quality, or more convenient healthcare services.[35] Incumbent healthcare providers may exploit the CON process to protect their market positions. Indeed, over the years, the Agencies have observed that some incumbent firms have challenged or commented on a potential competitor's CON application to block or delay competition.[36]

16. The Agencies have a long history of advocating against CON laws.[37] For example, in 2017, when Alaska considered legislation that would repeal the state's CON law, the

[31] Fed. Trade Comm'n & U.S. Dep't of Just., Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250, at 6 (Jan. 11, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-certificate-need-laws-south-carolina-house-bill-3250/160111ftc-doj-sclaw.pdf.

[32] *Id.*

[33] U.S. DEP'T OF JUST. & FED. TRADE COMM'N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION ch. 8, pp. 1–2 (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

[34] Adney Rakotoniaina & Johanna Butler, *50-State Scan of State Certificate-of-Need Programs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Dec. 10, 2025), https://nashp.org/state-tracker/50-state-scan-of-state-certificate-of-need-programs.

[35] A DOSE OF COMPETITION, *supra* note 33, at 1–2.

[36] Fed. Trade Comm'n & U.S. Dep't of Just., Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice Regarding Certificate-of-Need Laws and Alaska Senate Bill 62 at 6–7 (Apr. 12, 2017), https://www.justice.gov/archives/opa/press-release/file/957186/dl.

[37] In additional to advocacy letters, the Agencies also provided testimony on CON laws jointly and separately to states legislatures. *E.g.*, Mark J. Botti, U.S. Dep't of Just., Competition in Healthcare and Certificates of Need (Feb. 23, 2007), https://www.justice.gov/sites/default/files/atr/legacy/2007/06/05/223754.pdf; U.S. Dep't of Just. & Fed. Trade Comm'n, Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform (Sept. 15, 2008), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-and-department-justice-written-testimony-illinois-task-force-health-planning-reform-concerning/v080018illconlaws.pdf.

Agencies issued a joint statement supporting repeal.[38] Under Alaska's CON law, a person or entity seeking to spend $1.5 million or more to construct a healthcare facility, alter the bed capacity of a healthcare facility, or add health services provided at a healthcare facility had to obtain a CON from the state.[39] The Agencies explained that such CON laws suppress competition by limiting entry and expansion.[40] Moreover, the Agencies noted that evidence showed that CON laws generally fail to control healthcare costs, improve quality, or expand access—supposed benefits that proponents of CON laws typically tout.[41]

17. More recently, in 2023, the Division issued another letter to the Alaska Legislature addressing why newer justifications for CON laws also fail to reach their intended goals.[42] Proponents of CON laws argue that CON laws ensure access to care in rural areas by shielding rural hospitals from competitive pressures and distribute access to care.[43] However, the Division explained that CON laws do not have a meaningful effect on access to care in rural areas, despite such access, especially in rural areas, being an important public policy goal.[44] Instead, they act as a barrier to entry, leading to lower access to care and less innovation.[45] Accordingly, the Division encouraged states, including Alaska, to pursue other means to ensure access to healthcare.[46]

18. In 2025, the FTC responded to a request from Governor Dan McKee of Rhode Island, who sought the FTC's views on the competitive implications of legislation that would narrow the circumstances under which healthcare providers would need to obtain a CON from the Rhode Island Department of Health.[47] Specifically, the legislation would, among other things, remove several types of healthcare facilities and services subject to CON review, as well as increase the capital expenditure threshold that triggers review.[48] The FTC's response reiterated its "consistent, bipartisan advocacy that states can improve

[38] *Id.*

[39] *Id.* at 4 (internal quotation marks and citations omitted).

[40] *Id.* at 5–6.

[41] *Id.* at 12–13.

[42] Letter from Karina Lubell, Chief, Competition Pol'y & Advoc. Section, U.S. Dep't of Just., Antitrust Div. to David Wilson, Alaska State Sen., Alaska State Leg. Regarding Proposed Repeal of Alaska's Certificate-of-Need Laws (May 23, 2023), https://www.justice.gov/d9/2023-08/415865.pdf.

[43] *Id.* at 3–5.

[44] *Id.* at 5.

[45] *Id.* 3–5.

[46] *Id.* at 5.

[47] Letter from FTC Staff to Dan McKee, Governor of R.I., Proposed Reforms to Rhode Island's Certificate of Need Process (Apr. 16, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/ftc-letter-to-ri-gov-mckee-on-proposed-con-amendments.pdf.

[48] The proposed legislation would remove home health, hospice, outpatient rehabilitation, substance use disorder treatment facilities, outpatient surgical centers, and independent surgical practices from CON review, and it would increase the capital expenditure threshold from $5-7 million to $50 million. *Id.* at 3.

healthcare competition 'by repealing or curtailing their certificate of need laws.'"[49] In an April 2026 letter to Tennessee legislators, the FTC again emphasized that "CON laws prevent the efficient functioning of healthcare markets" and "create barriers to entry and expansion, thus limiting consumer choice and stifling innovation."[50]

4.2. Certificates of Public Advantage

19. Distinct from CON laws, many states have enacted Certificate of Public Advantage ("COPA") laws. In these states, hospitals seeking to merge may seek a COPA from the state government. In granting a COPA, the state government purports to immunize the merger from federal antitrust laws by replacing competition with government oversight.[51] To receive a COPA, the merging hospitals typically must persuade the state government that the merger would benefit the public, such as through lower prices, higher quality, or improved access to care.[52] As of 2022, at least 19 states had COPA laws.[53] Since then, several states have repealed their COPA laws.

20. In 2022, FTC staff issued a report entitled, "FTC Policy Perspectives on Certificates of Public Advantage."[54] This report was informed by the FTC's lengthy history of investigating and challenging anticompetitive hospital mergers. The FTC has accumulated considerable experience evaluating whether a hospital merger is likely to substantially lessen competition, and therefore raise healthcare prices, reduce quality of care, limit access to healthcare services, or depress wage growth for hospital employees. The staff report details why competition produces better outcomes than mergers subject to COPA-related state oversight and rebuts common but flawed arguments made by hospitals seeking COPAs. Crucially, the report provides many case examples where COPAs failed to prevent hospitals from exploiting their market power to the detriment of American patients.

21. In 2024, FTC staff submitted a comment urging the Indiana Department of Health ("IN DOH") to deny a COPA application that would permit Union Health and Terre Haute

[49] *Id*. at 1 (quoting Letter from FTC and Division staff to the Honorable Martin Daniel, Tennessee House of Representatives (Mar. 7, 2019), https://www.justice.gov/d9/pages/attachments/2019/03/20/363812.pdf.

[50] Letter from FTC Staff to the Honorable David Hawk, Tennessee House of Representatives (Apr. 1, 2026), https://www.ftc.gov/system/files/ftc_gov/pdf/FTC-Letter-re-TN-COPA-CON-Bills.pdf.

[51] The state action immunity doctrine permits U.S. states, under narrow circumstances, to regulate their economies by adopting measures that shield anticompetitive conduct from the reach of federal antitrust laws. Under this doctrine, a private actor's otherwise anticompetitive merger or conduct is immunized if (1) the actor is acting pursuant to a clearly articulated and affirmatively expressed state policy and (2) those actions are actively supervised by the state. N.C. Bd. of Dental Exam'rs v. FTC, 574 U.S. 494, 503–04 (2015). The first element seeks to ensure that the anticompetitive mechanisms adopted by the state operate because of a deliberate and intended state policy. The second element requiring state oversight seeks to ensure that private actors are acting pursuant to a state policy rather than their own private interests.

[52] FED. TRADE COMM'N, FTC POLICY PERSPECTIVES OF CERTIFICATES OF PUBLIC ADVANTAGE 1 (Aug. 15, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/COPA_Policy_Paper.pdf [hereinafter FTC COPA Study].

[53] Fred Ashton, *FTC Warns That Monopoly Hospitals Use State COPA Laws to Evade Antitrust Enforcement*, AM. ACTION FORUM (Sept. 27, 2022), https://www.americanactionforum.org/insight/ftc-warns-that-monopoly-hospitals-use-state-copa-laws-to-evade-antitrust-enforcement/.

[54] FTC COPA Study, *supra* note 52.

Regional Hospital to merge.[55] Staff's comment included extensive analysis of the proposed transaction, similar to how the FTC generally evaluates hospital mergers.[56] In particular, the comment evaluated the competitive dynamics in the hospitals' primary service area by examining diversion ratios, market shares and market concentration levels, and entry.[57] Additionally, staff's analysis demonstrated that the hospitals' claimed benefits for pricing, quality, and access to care were unsubstantiated or could have been achieved without the merger. The hospitals withdrew their COPA application after the FTC comment and resubmitted a new application with more significant commitments several months later. In response, FTC staff submitted a supplemental comment that emphasized that the improved commitments were still insufficient to prevent the risk of "higher costs and worse healthcare outcomes for Indiana consumers, as well as lower wage growth for hospital workers."[58] The IN DOH nonetheless approved the COPA after imposing more stringent oversight restrictions than the parties initially proposed. After the merger faced broad opposition, including from the FTC, Indiana enacted legislation that effectively ensured that no future hospital mergers in the state could receive COPA protection from antitrust scrutiny.[59]

5. Preventing Anticompetitive Regulation of Healthcare Workers

22. Healthcare providers, such as doctors and nurses, play a crucial role in providing patient care, and access to those providers plays an important role in promoting a healthy population. While some regulations and oversight may be needed to ensure patient safety, there are times when those regulations may go beyond what is necessary to achieve those goals and impact competition in the markets. In those situations, the Agencies may intervene to prevent such efforts. We discuss several examples below.

5.1. Advanced Practice Registered Nurses

23. An Advanced Practice Registered Nurse ("APRN") is a nurse practitioner with a graduate nursing degree, in addition to undergraduate nursing education and practice experience. While there are different types of APRNs, most are trained to provide a broad

[55] Press Release, Fed. Trade Comm'n, FTC Staff Opposes Proposed Indiana Hospital Merger (Sept. 5, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-staff-opposes-proposed-indiana-hospital-merger.

[56] FTC COPA Study, *supra* note 52, at 6.

[57] Fed. Trade Comm'n, Federal Trade Commission Staff Submission to Indiana Health Department Regarding the Certificate of Public Advantage Application of Union Health and Terre Haute Regional Hospital (Public Version) (Sept. 5, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/in_copa_comment_9-5-24_public_redacted.pdf.

[58] Fed. Trade Comm'n, Federal Trade Commission Supplemental Staff Submission to Indiana Health Department Regarding 2025 Certificate of Public Advantage Application of Union Health and Terre Haute Regional Hospital (Public Version), at 2 (Mar. 17, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/in-copa-comment-3-17-2025-public-redacted.pdf.

[59] *See* Whitney Downard, *Braun Signs Ten Bills Into Law*, IND. CAPITAL CHRON. (Apr. 22, 2025, 2:55 PM), https://indianacapitalchronicle.com/briefs/braun-signs-ten-bills-into-law/ ("Senate Enrolled Act 119, prohibits submitting applications for a certificate of public advantage after May 13, 2025, part of an ongoing effort to reduce hospital mergers.").

range of primary care services, including the diagnosis and treatment of acute and chronic illnesses.[60] Most states recognize APRNs as a distinct category of nursing professional.[61]

24. APRNs, like other healthcare professionals, are subject to various state regulations. For example, APRNs face licensure requirements that determine who may enter the profession. Additionally, states set scope-of-practice rules that define the range of services that APRNs may provide and the extent to which they are permitted to practice independently.[62] These rules vary from state to state. Some scope-of-practice restrictions limit APRNs' ability to prescribe medicines, refer for, order, or perform certain tests or procedures, or treat certain indications.[63] Other restrictions focus on the types of patients APRNs may see; in some states, APRNs may not be allowed to examine new patients or patients who have had a major health change unless they have been recently examined by a supervising physician.[64] Finally, many states require APRNs to collaborate with or be supervised by physicians.[65] All of these types of regulations may unnecessarily impede access to care by restricting APRNs from practicing to the full extent of their abilities.[66] As a result, they may limit the availability of care in underserved areas and soften competition by obstructing healthcare consumers from being treated by providers who typically offer lower-cost care than physicians.[67]

25. Over the past year, the FTC has received two requests for input relating to proposed legislation affecting APRNs. Last year, a South Carolina state legislator asked the FTC to analyze two competing bills.[68] The first would permit nurse practitioners, certified nurse midwives, and clinical nurse specialists to transition to full autonomous practice after completing 2,000 hours of collaborative practice with a physician. The second bill, in contrast, would ban APRNs, and certain other non-physician providers, from practicing independently, thereby requiring them to practice as part of physician-led teams. Separately, earlier this year, a lawmaker from Mississippi asked the FTC to review proposed legislation that would authorize nurse midwives to practice as APRNs and deliver

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[60] FED. TRADE COMM'N, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (Mar. 2014), https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf.

[61] *Id.* at 7.

[62] *Id.* at 14.

[63] *Id.* at 9.

[64] *Id.* at 9–10.

[65] *Id.* at 11.

[66] *See generally id.*

[67] Letter from Clarke Edwards, Acting Director, Office of Policy Planning, Fed. Trade Comm'n, to Mississippi State Senator Juan Barnett Regarding H.B. 1057, at 3 (2025) (Jan. 5, 2026), https://www.ftc.gov/system/files/ftc_gov/pdf/LetterfromClarkeEdwardstoSenBarnett%281-5-26%29.pdf [hereinafter Barnett Letter]; *see also* Te-Ping Chen, *Nurse Practitioner Is Now the Hottest Job in Healthcare*, WALL ST. J. (May 16, 2026), https://www.wsj.com/health/healthcare/nurse-practitioner-is-now-the-hottest-job-in-healthcare-a98e0bc8.

[68] Letter from Clarke Edwards, Acting Director, Office of Policy Planning, Fed. Trade Comm'n, to South Carolina State Senator Brad Hutto Regarding S.45 / H.3580 and S.669 (Sept. 9, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/SC-APRNs-CoverLetterAdvocacy-9-9-25.pdf [hereinafter Hutto Letter].

babies of low-risk mothers without requiring a collaboration practice agreement with a physician.[69] The FTC responded to each request by summarizing its prior work advocating against anticompetitive healthcare regulations that exclude qualified professionals from the market and thwart competition between physicians and APRNs. In particular, the responses noted that FTC experience and research show that consumers benefit in the form of lower prices, improved access to care, and additional innovation when APRNs can effectively address the needs of patients.[70] The FTC explained that substantial evidence shows that APRNs can provide safe and effective care as independent healthcare providers.[71] The FTC also encouraged legislators "to consider the incentives of those who oppose" independent practice by APRNs, as it "may be in the economic self-interest of physicians to propose and advocate for restrictions on APRN licensure and scope of practice."[72]

5.2. Physicians

26. Physicians are also subject to state regulations and may choose to obtain board certification to practice medicine. Unlike state licensure, which sets minimal legal requirements to practice medicine generally, private organizations certify physicians upon meeting certain requirements. Although not legally required, physicians often seek board certification for several reasons.[73] Physicians seek board certification for various state law purposes, such as the ability to advertise themselves as having "board certification."[74] Healthcare employers, such as hospitals or insurers, often use board certification to identify skilled and qualified physicians for employment.[75] Separate from employment, hospitals also often require board certification to be granted hospital privileges, which is an authorization from the hospital to a physician to practice medicine in the hospital's facilities.[76]

27. In some instances, however, certifying bodies may impose more stringent requirements than necessary on physicians. Such unnecessary requirements can raise costs and constrain the supply of providers, thereby harming competition and increasing the cost of healthcare services to consumers.

28. Given these concerns, in 2018, the Division provided its views to the Maryland Legislature on whether the Maintenance of Certification ("MOC") program, a recertification requirement implemented by the American Board of Medical Specialties ("ABMS"), a certifying body, posed anticompetitive concerns for physicians who wish to

[69] Barnett Letter, *supra* note 67, at 1.

[70] *Id.* at 3; Hutto Letter, *supra* note 68, at 2–3.

[71] Barnett Letter, *supra* note 67, at 4.

[72] Barnett Letter, *supra* note 67, at 1 (internal citations omitted).

[73] Letter from Robert Potter, Chief, Competition Pol'y & Advoc. Section, U.S. Dep't of Just., Antitrust Div. to Dan K. Morhaim, M.D., Md. State Del., Md. H.D., at 4 (Sept. 10, 2018), https://www.justice.gov/archives/atr/page/file/1092791/dl?inline.

[74] *Id.* at 8.

[75] *Id.* at 3

[76] *Id.*

maintain their certification.[77] The Division encouraged the Maryland Legislature to consider ways to allow entry of additional, alternative certifying bodies to the dominant body, ABMS; continue allowing hospitals to independently evaluate a physician's MOC status; and consider redefining board certification for state law purposes to ensure physicians not participating in MOCs still quality as board-certified.[78] The Division also noted that while ABMS certification may not be legally required, physicians without MOC may face professional consequences.[79]

5.3. Optometrists

29. Like APRNs, states also promulgate scope-of-practice laws that define the range of services that optometrists may provide and the extent to which they are permitted to practice.

30. In 2016, the Agencies issued a joint statement encouraging the Massachusetts Legislature to consider expanding the services that optometrists can provide to glaucoma patients, subject to certain training and referral requirements, which is consistent with other states.[80] At the time, treatment of glaucoma in Massachusetts was limited to ophthalmologists. The Agencies explained that by expanding optometrists' scope-of-practice, patients could benefit from enhanced competition among glaucoma care providers, including greater access to timely and cost-competitive care.[81] The Agencies also noted that unnecessarily broad scope-of-practice restrictions "can impose significant competitive costs on health care consumers and other payors," and recommended that the legislature restrict optometrists' ability to treat glaucoma only to the extent necessary to ensure patient health and safety.[82]

31. Similarly, in that same year, the Agencies issued another joint statement encouraging the Puerto Rican Legislature to expand optometrists' scope-of-practice to diagnose and treat diseases of the eye upon taking additional training, also consistent with other states.[83] While recognizing that certain restrictions protect patient health and safety, the Agencies described the potential benefits to patients of enhanced competition among vision care providers, including greater access to timely and cost-effective care.[84] The Agencies also explained that unnecessarily restricting optometrists' scope-of-practice can

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[77] *See also* Letter from David B. Lawrence, Chief, Competition Pol'y & Advoc. Section, U.S. Dep't of Just., Antitrust Div. to Sam Rasoul, Va. State Del., Va. H.D. (Oct. 22, 2019), https://www.justice.gov/atr/page/file/1212231/dl?inline.

[78] *Id.*

[79] *Id.*

[80] Letter from Marina Lao, Director, Office of Pol'y Planning, Fed. Trade Comm'n & Robert Potter, Chief, Legal Pol'y Section, U.S. Dep't of Just., Antitrust Div. to, Bradley H. Jones, Jr, Mass. State Rep., Mass. H.R. (Feb. 18, 2016), https://www.justice.gov/archives/opa/file/826371/dl?inline=.

[81] *Id.*

[82] *Id.*

[83] Letter from Marina Lao, Director, Office of Pol'y Planning, Fed. Trade Comm'n & Robert Potter, Chief, Legal Pol'y Section, U.S. Dep't of Just., Antitrust Div. to Jose L. Báez Rivera, P.R. Rep., Cámara de Representantes (May 18, 2016), https://www.justice.gov/opa/file/852206/dl?inline=.

[84] *Id.*

limit the supply of qualified providers and therefore limit the number of patients who obtain care, limit price competition, and inhibit innovation.

6. Anticompetitive Laws Involving Health Insurance

32. Under federal law, the McCarran-Ferguson Act exempted activities from the federal antitrust laws if the activity fell under the "business of insurance," was regulated by state law, and did not involve "an agreement to boycott, coerce, or intimidate." At times, courts have struggled with interpreting the scope of the exemption and interpreted this broadly written immunity to allow a range of harmful anticompetitive conduct in health insurance markets to occur unimpeded by the antitrust laws.

33. The Division has engaged in advocacy efforts to minimize the risk that courts would immunize anticompetitive conduct.[85] For example, in 2020, the Division submitted an amicus brief in *Oscar Insurance Company of Florida v. Blue Cross and Blue Shield of Florida, et al.* arguing that the district court erred in holding that the appellee was immune from federal antitrust claims under the "business of insurance" exemption because the court disregarded Supreme Court precedent and protections of federal antitrust law.[86]

34. In 2020, Congress passed the Competitive Health Insurance Reform Act ("CHIRA"), H.R. 1418, 116th Cong. (2020), and President Trump signed the bill into law in 2021. CHIRA narrowed the broad federal antitrust exemption by subjecting the conduct of health insurers to the federal antitrust laws but carved out activities that improve health insurance services for consumers. The Division welcomed the passage of the bill on January 13, 2021.[87]

[85] Courts have been clear that the McCarran-Ferguson Act does not apply to merger transactions. The Division has been able to enforce the antitrust laws to the benefit of consumers with great success in those instances.

[86] Brief for the United States as Amicus Curiae Supporting Plaintiffs-Appellants and Reversal, Oscar Ins. Co. of Fl. v. Blue Cross & Blue Shield of Fl., (11th Cir. 2020) (No. 19-14096), *available at* https://www.justice.gov/atr/case-document/file/1232461/dl?inline.

[87] Press Release, U.S. Dep't of Just., Antitrust Div., Justice Department Welcomes Passage of The Competitive Health Insurance Reform Act of 2020 (Jan. 13, 2021), https://www.justice.gov/archives/opa/pr/justice-department-welcomes-passage-competitive-health-insurance-reform-act-2020.