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Subcommittee on Competition Policy, Antitrust, and Consumer Rights

On

"Antitrust Applied: Hospital Consolidation Concerns and Solutions."

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Chairwoman Klobuchar, Ranking Member Lee, and distinguished members of the Subcommittee on Competition Policy, Antitrust, and Consumer Rights:

My name is Brian Miller and I practice hospital medicine at the Johns Hopkins Hospital. As an academic health policy researcher, I serve as an Assistant Professor of Medicine and Business (Courtesy) at the Johns Hopkins University School of Medicine and the Johns Hopkins Carey Business School. My research focuses on healthcare competition and payment policy and is based upon my prior regulatory experience at the Federal Trade Commission, Federal Communications Commission, U.S. Food and Drug Administration, and the Centers for Medicare and Medicaid Services. Through my role as a faculty member, I regularly engage with regulators, policymakers, and businesses in search of solutions to help create a better healthcare system for all.

In my testimony today, I will focus on three areas:

1. The harms of hospital consolidation
2. Combatting consolidation through competition policy
3. Promoting market entry through reform of anti-competitive laws

1. The Harms of Hospital Consolidation

Healthcare market consolidation has long been a focus of competition policy, and today's hearing explores the story of hospital and care delivery consolidation. Hospital care comprised 31% of annual health spending or $1.192 trillion in 2019.[1] With 90% of metropolitan statistical areas representing highly concentrated hospital markets,[2] as defined by a Herfindahl-Hirschman index (HHI) greater than 2,500,[3] hospital consolidation remains a focus of both study and action for policymakers, regulators, and competition authorities. The harms of hospital consolidation are many and well-documented, affecting consumers of all types, including patients, physicians, and payers, the latter group including health plans, employers, and governments. Harms include both traditional economic considerations such as higher prices in addition to non-price efficiency losses such as quality of care decrements.

It is well-documented that consolidation leads to higher prices for healthcare services.[4] Patients experience these higher costs in a variety of ways, including higher cost-sharing payments and higher health insurance premiums[5,6] reflecting rising hospital prices. Other losses are more difficult to quantify albeit are very real: research by Beaulieu and colleagues[7] has demonstrated a lack of quality benefits from hospital mergers, in addition to decrements in patient experience.

Physicians also experience losses from a lack of operational control, as clinical practice shifts from an "owner-operator" model to scaled enterprises, with those making decisions about how care is delivered positioned an increasing distance from the exam room. According to the National Academy of Medicine's report on physician

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[1] Marin AB, Hartman M, Lassman D, et al. National Health Care Spending In 2019: Steady Growth For The Fourth Consecutive Year. *Health Affairs*. 2021;1:14-24. doi: 10.1377/hlthaff.2020.02022

[2] Fulton BD. Health Care Market Concentration Trends In the United States: Evidence And Policy Response. *Health Affairs* 2017;36(9):1530-1538. doi: 10.1377/hlthaff.2017.0556

[3] U.S. Department of Justice and Federal Trade Commission. Horizontal Merger Guidelines. August 19, 2010. Pg19. https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf

[4] Cooper Z, Craig SV, Gaynor M, Van Reenen J. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *Quarterly Journal of Economics* 2019;134(1):51-107. doi: 10.1093/qje/qjy020

[5] Boozary AS, Feyman Y, Reinhard UE, Jha AK. "The Association Between Hospital Concentration And Insurance Premiums in the ACA Marketplaces." *Health Affairs* 2019;4:668-674. doi: 10.1377/hlthaff.2018.05491

[6] Trish EE, Herring BJ. How Do Health Insurer Market Concentration and Bargaining Power with Hospitals Affect Health insurance Premiums? *J Health Econ* 2015;42:104-11. doi: 10.1016/j.jhealeco.2015.03.009

[7] Beaulieu ND, Dafny LS, Landon BE, Dalton JB, Kuye I, McWilliams JM. Changes in Quality of Care after Hospital Mergers and Acquisitions. *N Engl J Med.* 2020 Jan 2;382(1):51-59. doi: 10.1056/NEJMsa1901383.

burnout,[8] this loss of control over the practice environment is a significant contributing factor to the nationwide epidemic of physician burnout.

Payers, employers, state governments, and the federal government experience harms too in the form of greater costs for purchased health benefits, and respond to rising premiums by increasing consumer cost sharing,[9] suppressing wage growth,[10,11] narrowing care networks,[12] or–if possible–decreasing plan benefits.

Another significant harm of hospital consolidation is frequently lost amongst the cascade of the aforementioned concerns: a loss of innovation. Competition is the lifeblood that powers our vibrant economy, driving both incremental and disruptive innovation. Broader economic indicators support a story of hospital consolidation, with labor productivity in hospitals remaining nearly flat over the past twenty years, even with periods of negative labor productivity growth – or year over year decreases in productivity[13] (see **Figure 1** in **Appendix**).

What does this mean for patients and physicians and how does this compare to other health sectors such as the life sciences? The pharmaceutical and medical device industries have produced a plethora of innovation with over 1,200 new molecular entities approved since 1950[14,15] and new disruptive technologies such as cardiac catheterization, angioplasty, and stenting, which revolutionized how we treat heart attack patients in the 1980s and 1990s. In contrast, much of the "daily activities" that we complete as clinicians and experience as patients in hospital and ambulatory care settings have not changed.

Many claim–and reasonably so–that some of this is due to regulatory barriers. But there are many examples where operations do not change as the organizations experience little to no competitive pressure. A simple example is the patient with heart failure, wherein fluid builds up and sometimes we have to hospitalize patients due to worsening symptoms (e.g. weight gain and shortness of breath with a subsequent need for supplemental oxygen) in order to remove fluid in the hospital with intravenous diuretics. Some patients are aware of their decline and undergo a planned admission, while many others are unaware until they are *in extremis* in their local emergency room, and are subsequently admitted to the hospital. Diuretics are prescribed by physicians and administered by nurses to the patient one to three times daily. Nurses manually record a patient's fluid intake, while a technician records the patient's urine output–the net of these numbers represents the patient's "progress" (or lack thereof) for the day. This is a manual process, and these data are then entered into a computer three to six times daily. In the setting of the intensive care unit, this can occur every one to two hours. This is just one of the many manual, labor-intensive processes that has not changed in over fifty years.

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[8] National Academy of Medicine. Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being. See Cht6, Pg101 https://www.nap.edu/catalog/25521/taking-action-against-clinician-burnout-a-systems-approach-to-professional

[9] "The average single coverage annual deductible among covered workers with a deductible has increased 25% over the last five years and 79% over the last ten years." See: 2020 Employer Health Benefits Survey. *Kaiser Family Foundation* October 8, 2020. https://www.kff.org/report-section/ehbs-2020-summary-of-findings/

[10] Baicker K, Chandra A. The Labor Market Effects of Rising Health Insurance Premiums. *Journal of Labor Economics* 2006;24(3). doi: 10.1086/505049

[11] Arnold, Daniel and Christopher M. Whaley, Who Pays for Health Care Costs? The Effects of Health Care Prices on Wages. Santa Monica, CA: RAND Corporation, 2020. https://www.rand.org/pubs/working_papers/WRA621-2.html

[12] Polsky D, Cidav Z, Swanson A. Marketplace Plans With Narrow Physician Networks Feature Lower Monthly Premiums Than Plans With Larger Networks. *Health Affairs* 2016;35(10):1842-1848. doi: 10.1377/hlthaff.2016.0693

[13] Bureau of Labor Statistics. A Closer Look: Private Community Hospitals. 2013. https://www.bls.gov/lpc/hospitals_2013.htm See Appendix for Figure 1

[14] Munos, B. Lessons from 60 years of pharmaceutical innovation. *Nat Rev Drug Discov* 8, 959–968 (2009). https://doi.org/10.1038/nrd2961

[15] More recent data suggest a still robust innovation rate, with and as recently as 2010-2018 as many as 41 new drugs and 12 new biologics annually. Darrow JJ, Avorn J, Kesselheim AS. FDA Approval and Regulation of Pharmaceuticals, 1983-2018. *JAMA*. 2020;323(2):164–176. doi:10.1001/jama.2019.20288

While 90% of metropolitan areas[16] are considered highly concentrated by U.S. Department of Justice Guidelines, even moderately concentrated marketplaces can be a challenge for consumers and economic measures do not tell the entire story of healthcare delivery consolidation. I use my own experience here as an example. My mother is 70 years old and is unlucky in that she is both a widow and suffers from advanced Alzheimer's that is progressing rapidly. Some days she cannot walk, is incontinent, has to be spoon fed, and does not recognize me. My sister and I have attempted to respect her wish to her remain in her home with minimal medical intervention.

Recently she developed a urinary tract infection, became confused, and fell at home. Weakened, my mother was bedbound unless carried around the house by my uncle. A short antibiotic course was ineffective and rather than hospitalize her or take her to urgent care, my sister and I reasoned, as clinicians ourselves, that her primary care physician may wish to try one more oral antibiotic or otherwise make her comfortable. It took five phone calls during regular business hours on the part of my sister, a hospital pharmacist, and myself, a practicing physician, to reach a covering physician to get her the antibiotic prescription that she needed.

While in some ways I am understandably dissatisfied with this level of service, I mention this not to critique the delivery system that provides care to my mother. Rather it is to highlight the problem that she faces as a patient-consumer and that my sister and I face as her proxies: in the moderately concentrated market in which she lives, her current care ecosystem is her only option for integrated care delivery. This is precisely where the problem is: many patients like my mother have specific needs only met through mass-customized, integrated care delivery and do not have meaningful choice. This problem does not change whether the monopoly or market participant is government, non-profit, or for-profit–the ills of monopoly remain unchanged. I recognize my mother's many advantages–most do not have two clinicians as children, one of them a healthcare policy expert–and worry about other patients.

It is thus clear to many of differing perspectives that the hospital industry is gravely ill, suffering from the effects of consolidation and a lack of competition. As policy experts, we have a variety of tools in our black bag. Last month, testifying in front the House of Representatives on similar issues, colleagues highlighted multiple bipartisan reforms, including addressing Federal Trade Commission (FTC) jurisdictional issues over non-profits[17] along with the need for increased agency staff and funding.[18] At the end of his written testimony, Alden Abbott, a Senior Research Fellow at the Mercatus Center, alluded to how "major legal reforms unrelated to antitrust are key to improving the effectiveness of healthcare competition."[19] It is these sorts of bipartisan policy prescriptions that I wish to turn to, as this is where competition policy has historically struggled: combatting consolidation and encouraging market entry.

2. Combatting Consolidation through Competition Policy

Policymakers have multiple competition policy levers to address pre-existing consolidation, here I will focus on two of the largest levers available: payment site neutrality and Stark Law reforms.

Site-Neutral Payment

Site-neutral payment is a payment policy issue of longstanding bipartisan interest. What is it? Simply put, it means paying the same amount for the same service provided, regardless of where it is provided. While sensible,

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[16] Fulton BD. Health Care Market Concentration Trends In the United States: Evidence And Policy Response. *Health Affairs* 2017;36(9):1530-1538. doi: 10.1377/hlthaff.2017.0556

[17] *How Health Care Consolidation Is Contributing to Higher Prices and Spending, and Reforms That Could Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets: U.S. House of Representatives Committee on the Judiciary,* 107th Congress (2021) (Testimony of Leemore S. Dafny, Ph.D.). Pg12 https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-DafnyL-20210429.pdf

[18] *How Health Care Consolidation Is Contributing to Higher Prices and Spending, and Reforms That Could Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets: U.S. House of Representatives Committee on the Judiciary,* 107th Congress (2021) (Testimony of Alden Abbot) Pg1 https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-AbbottA-20210429.pdf

[19] T *How Health Care Consolidation Is Contributing to Higher Prices and Spending, and Reforms That Could Bolster Antitrust Enforcement and Preserve and Promote Competition in Health Care Markets: U.S. House of Representatives Committee on the Judiciary,* 107th Congress (2021) (Testimony of Alden Abbot) Pg5 https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-AbbottA-20210429.pdf

implementation is challenging due to the litany of payment systems under the Medicare Fee For Service program. This is best illustrated through a tangible example.

If a physician sees a new patient and has a 15 minute visit, the physician can bill Medicare under the physician fee schedule for an evaluation and management service. If a hospital purchases that same practice and designates the practice as a provider-based facility (either on campus or off campus, with the boundary at 250 yards and less than 35 miles, respectively),[20] the provider-based facility bills as a hospital outpatient department. Functionally, the hospital submits a claim, billing Medicare under the outpatient prospective payment system (OPPS),[21] in addition billing separately for the professional service component and receiving reduced reimbursement as a facility fee. Considering the 15 minute office visit, the physician fee schedule payment rate for calendar year 2017 (CY2017) was $109.46 for a new patient, while if delivered in a hospital outpatient setting the total would be $184.44, or $106.56 for the ambulatory payment classification (APC) under the OPPS and $77.88 for the facility fee.[22] This higher total reimbursement is beneficial for hospitals while simultaneously detrimental for patients, who experienced higher Part B coinsurance amounts due to larger bills for the same service.

Understandably, this payment policy loophole drove hospital acquisition of physician practices. Recognized as a problem by MedPAC[23] and the Office of Inspector General,[24,25] a partial fix was included as part of the Bipartisan Budget Act of 2015. The Act prohibited *new* off-campus provider-based hospital outpatient facilities from receiving higher payment[26] after January 1, 2017. Provider-based facilities had to continue to meet minimal requirements for clinical and financial integration.

Recognizing the persistent problems posed by the lack of payment site neutrality, the Trump administration attempted to correct the problem, including a degree of cuts to previously grandfathered off-campus facilities, proposing a reduced OPPS payment.[27,28] Policy experts noted this distinction,[29] and unsurprisingly the hospital industry sued. After a series of appeals, the hospital industry won initially in 2019.[30] CMS again attempted implementation of payment

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[20] 42 CFR § 413.65 - Requirements for a determination that a facility or an organization has provider-based status. https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:2.0.1.2.13#se42.2.413_165

[21] MedPAC. Payment Basics: Outpatient Hospital Services Payment System. 2020. http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_opd_final_sec.pdf

[22] See example in Centers for Medicare & Medicaid Services. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs *Federal Register* 2018. https://www.federalregister.gov/documents/2018/11/21/2018-24243/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center#p-1580

[23] MedPAC. Report to Congress: Medicare Payment Policy. 2020. http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf

[24] Office of Inspector General. Hospital Ownership of Physician Practices. 1999. Available at: https://oig.hhs.gov/oei/reports/oei-05-98-00110.pdf

[25] Office of Inspector General. CMS is Taking Steps to Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain. 2016. Available at: https://oig.hhs.gov/oei/reports/oei-04-12-00380.pdf

[26] H.R.1314 - Bipartisan Budget Act of 2015. Sec. 603. Treatment of Off-Campus Outpatient Departments of a Provider. 114th Congress (2015-2016). https://www.congress.gov/bill/114th-congress/house-bill/1314

[27] Centers for Medicare & Medicaid Services. "CMS Finalizes Rule that Encourages More Choices and Lower Costs for Seniors." 2018. https://www.cms.gov/newsroom/press-releases/cms-finalizes-rule-encourages-more-choices-and-lower-costs-seniors

[28] Centers for Medicare & Medicaid Services. Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 2018, Available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf

[29] Wilensky. "Medicare's Move Toward Site-Neutral Payment." Healthcare Financial Management Association. 2018. https://www.hfma.org/topics/hfm/2019/january/62678.html

[30] Minemyer P. Judge strikes down Trump administration's site-neutral payments. *Fierce* Healthcare September 17, 2019. https://www.fiercehealthcare.com/hospitals-health-systems/judge-strikes-down-trump-administration-s-site-neutral-payments-rule

site neutrality for calendar year 2020 payment rules, and the hospital industry sued again[31] and lost,[32] with CMS proposing implementation while the hospital industry has now appealed to the U.S. Supreme Court.[33]

The Committee for a Responsible Federal Budget estimated that full implementation of site neutral payment would save Medicare $217 to $279 billion over the next decade,[34] an estimate inclusive only of direct payment policy effects. Full implementation of site neutral payment would eliminate payment policy arbitrage as a rationale for hospitals' purchase of clinics. Given repeated industry-driven legal challenges to site neutral payment , Congress could save the Medicare program money and increase competition in ambulatory care markets by providing CMS with clear statutory authority for site neutral payment, rendering this debate null.

Stark Law Reforms

Rising Medicare program expenditures in the 1980s and a series of academic studies demonstrating increased utilization of physician-owned services prompted oversight and eventual regulation of these clinical operational practices. As is typical, the devil is in the details.

A 1992 study in *JAMA* by Jean Mitchell, Ph.D. and Elton Scott, Ph.D. of physician-owned, joint-venture freestanding physician therapy and rehabilitation facilities[35] found both shorter visits and a greater mean number of visits (16 v. 11) for physician-owned, joint-venture physical therapy sites as compared to non-joint-venture facilities. Unsurprisingly this pattern of practice was associated with higher revenue, noting that outcomes were not assessed so it is unclear what was most clinically appropriate. A 1990 study in the *New England Journal of Medicine* found a similarly concerning finding of increased utilization when primary care physicians completed in-office radiology services.[36]

From this place of valid concerns regarding budgetary sustainability of Medicare, inappropriate utilization or induced demand, and ethical concerns, a series of reforms were passed in both statue[37,38] and rulemaking[39,40,41] collectively known as Stark Law. In accordance with Stark Law, physicians are prohibited from making referrals for designated health services (DHS) to an entity in which they have a financial relationship and subsequently billing Medicare. What is considered a DHS is wide-ranging, including radiology and imaging services to home health services to durable medical equipment and supplies. While there are exceptions to Stark Law, including recent attempts to promote value-

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[31] Reuter E. Hospitals sue CMS again over site-neutral payments. *MedCity News* January 14, 2020. https://medcitynews.com/2020/01/hospitals-sue-cms-again-over-site-neutral-payments/

[32] American Hospital Ass'n v. Azar, No. 20-5193 (D.C. Cir. 2020) https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf

[33] American Hospital Association v. Becerra, No. 20-1113 (U.S. Supreme Court. 2021) https://www.aha.org/system/files/media/file/2021/02/AHA-Petition-2-10-Final.pdf

[34] Committee for a Responsible Federal Budget. Equalizing Medicare Payments Regardless of Site-of-Care. (2021). https://www.crfb.org/papers/equalizing-medicare-payments-regardless-site-care

[35] Mitchell JM, Scott E. Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics. *JAMA*. 1992;268(15):2055–2059. doi:10.1001/jama.1992.03490150107033

[36] Hillman BJ, Joseph CA, Mabry MR, Sunshine JH, Kennedy SD, Noether M. Frequency and costs of diagnostic imaging in office practice--a comparison of self-referring and radiologist-referring physicians. *N Engl J Med*. 1990 Dec 6;323(23):1604-8. doi: 10.1056/NEJM199012063232306.

[37] H.R.3299 - Omnibus Budget Reconciliation Act of 1989. 101st Congress (1989-1990).

[38] H.R.2264 - Omnibus Budget Reconciliation Act of 1993. 103rd Congress (1993-1994).

[39] Health Care Financing Administration. Medicare Program: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships. *Federal Register* 2001;66(3):856-965. https://www.govinfo.gov/content/pkg/FR-2001-01-04/pdf/01-4.pdf

[40] Centers for Medicare & Medicaid Services. Medicare Program: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II). *Federal Register* 2004:69(59):16054-16146. https://www.govinfo.gov/content/pkg/FR-2004-03-26/pdf/04-6668.pdf

[41] Centers for Medicare & Medicaid Services. Medicare Program: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III). *Federal Register* 2007;72(171):51012-51099. https://www.govinfo.gov/content/pkg/FR-2007-09-05/pdf/07-4252.pdf

based care,[42] implementation remains challenging, with the most recent value-based care rulemakings on Stark and Anti-Kickback Law enumerated at 191[43] and 212 pages, respectively.[44] Regulatory costs and understanding remains well outside the operating purview of small and mid-sized businesses such as private practices, mid-sized health systems, and many rural facilities.

The world in which Stark Law was passed and today's healthcare landscape are very different. The 1980s marked the peak of fee for service (FFS) medicine, soon followed by the rise of managed care. Today, 39% the Medicare program enrollment is in Medicare Advantage, a risk-adjusted capitated public-private program.[45] Nearly 76% of Medicaid enrollees take part in managed care programs,[46] with 46% of Medicaid spending channeled through risk-adjusted capitation paid to a Medicaid managed care organization.[47] Other markets are making the transition to capitated models at varying speeds. Incentives within a capitated model are very different, as the health plan or integrated delivery system loses money from fraud, waste, and abuse–including inappropriate utilization or induced demand.

Even outside of capitated payment models, FFS medicine today is very different, as with technology payers have new tools to survey for and prevent inappropriate use, including utilization review, prior authorization, and automatic pre-payment claims editing. Furthermore, benefit design can be adjusted in some settings to use market forces to control for inappropriate utilization or induced demand, including bundling, first introduced as part of the part of the prospective payment system based upon the diagnosis-related group (DRG) for Medicare hospitalizations[48] or the application of per diem rates for services such as home care.[49]

Yet Stark Law persists in a changed world. What function does it now serve? In applying a competition policy framework, one must also examine the harms of Stark Law. At the time Stark Law and self-referral were debated as policy questions, experts raised concerns regarding rigidity of the law, quality of care, and the downsides of limiting physician agency.[50] Unfortunately, some of these harms have come to pass.

Patients, many of whom experience challenges with both health[51] and health insurance literacy,[52] depend upon both health systems and their physicians to make decisions about their health, goals, and efficient and effective use of healthcare products and services. Limiting shared decision-making for either corporations or physicians transfers these

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[42] Centers for Medicare & Medicaid Services. Modernizing and Clarifying the Physician Self-Referral Regulations Final Rule (CMS-1720-F). November 20, 2020. https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f

[43] Centers for Medicare & Medicaid Services. Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations. *Federal Register* 2020;85(232):77492-77682. https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf

[44] Centers for Medicare & Medicaid Services. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. *Federal Register* 2020;85(232):77684-77895. https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf

[45] Freed M, Damico A, Neuman T. A Dozen Facts About Medicare Advantage in 2020. *Kaiser Family Foundation* 2020. Available at: https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/

[46] Medicaid Enrollment in Managed Care by Plan Type. *Kaiser Family Foundation* 2018. https://www.kff.org/medicaid/state-indicator/enrollment-by-medicaid-mc-plan-type/

[47]Total Medicaid MCO Spending. *Kaiser Family Foundation* 2019. https://www.kff.org/other/state-indicator/total-medicaid-mco-spending/

[48] Iglehart JK. Medicare begins prospective payment of hospitals. *N Engl J Med*. 1983 Jun 9;308(23):1428-32. doi: 10.1056/NEJM198306093082331. PMID: 6405277.

[49] MedPAC. Payment Basics: Home Health Care Services Payment System. 2015. http://www.medpac.gov/docs/default-source/payment-basics/home-health-care-services-payment-system-15.pdf

[50] Morreim EH. Conflicts of Interest: Profits and Problems in Physician Referrals. *JAMA*. 1989;262(3):390–394. doi:10.1001/jama.1989.03430030078038

[51] Kutner M, Greenberg E, Jin Y, et al. The Health Literacy of America's Adults Results From the 2003 National Assessment of Adult Literacy. *U.S. Department of Education* 2006.

[52] Norton M, Hamel L, & Brodie M. Assessing Americans' Familiarity with Health Insurance Terms and Concepts. *Kaiser Family Foundation*. (2014). https://www.kff.org/health-reform/poll-finding/assessing-americans-familiarity-with-health-insurance-terms-and-concepts/

burdens onto patients, ironically on those least equipped to deal with it i.e. those with the greatest medical and socioeconomic burdens. It could be the 90 year-old cancer patient with newly diagnosed pancreatic cancer who is looking for a surgical oncologist and radiation oncologist who together will "take a chance on me but not prolong my life if things go poorly" while also providing wraparound social support and home care services. Or perhaps it is the morbidly obese heart failure patient with a bad back and knees, barely able to walk and dependent upon Social Security Disability Income, Medicare, and Medicaid who wants to get the "most bang for my buck at the physical therapist" having previously been disabled and bedridden in a skilled nursing facility. These are the patients to whom Stark Law transfers the burdens of care navigation: those who already have the greatest burdens to bear.

Finally, Stark Law presupposes that corporations are less self-interested parties than physicians. In many cases, corporations mandate or otherwise enforce corporate self-referral upon physicians, scrutinizing and scoring providers on the basis of "within system" versus external referrals. Yet this very activity can be part of the key to offering integrated care delivery, as organizations can coordinate and systematize care for complex patients, and with recent changes in payment policy, better integrate remote telehealth and in-person services across specialties and care sites. When physician-owned and -operated organizations attempt to construct integrated care delivery, they face prohibitions imposed through Stark Law, while corporations face regulatory oversight. Regulation, not prohibition, is the appropriate mechanism for combating waste, fraud, and abuse.

Faced with high compliance costs, many physician organizations choose not to compete in these markets, or alternatively merge with hospital organizations, furthering consolidation in the pursuit of integrated care delivery. Lost competition hurts patients through higher prices, quality decrements, and innovation losses when a need for regulation is replaced with a ban on competition for a single market participant. Policymakers can address this by re-examining Stark Law, repealing outdated provisions, and placing physician and corporate enterprises on an equal footing.

3. Promoting market entry through reform of anti-competitive laws

Physician-owned hospitals (POHs) represent a powerful lever through which policymakers can promote market entry.[53] Currently, new POHs are statutorily excluded from participation in the Medicare program, a policy with both a long history and recent legislative efforts aimed at its repeal in 2017[54] and 2019.[55]

Physician-Owned Hospitals

In an effort to improve clinical operations and drive both improved patient experience and medical quality, physicians pooled their capital and opened hospitals beginning in the 1980s. Concerns rapidly emerged, including accusations of POHs "cherry picking" healthy patients leaving community hospitals with sicker patients, adverse selection against Medicare and Medicaid patients, skimping on charity or uncompensated care, and favoring of commercial payers among other concerns. Both academic and government-sponsored reports revealed complexity in this marketplace not entirely consistent with these claims. For example, a 2003 Government Accountability Office (GAO) study found that surgical-specialty POHs served fewer Medicaid patients while cardiac hospitals served–unsurprisingly given the natural history of cardiac disease–more Medicare patients than did general hospitals.[56] It is worth noting here that the GAO compared physician specialty hospitals to corporate or non-profit *general* hospitals.

Claims regarding charity care are to be viewed with similar skepticism: CMS staff research found that while a small sample of cardiac and orthopedic surgical specialty hospitals provided less uncompensated care that their non-profit competitors, when tax payments were considered the total aggregate community benefit was larger, representing 3.74% of revenue for cardiac POHs, 7.23% of revenue for orthopedic POHs, and 0.87% of revenue for non-profit

[53] Miller BJ, Moffit RE, Ficke J, Marine J, Ehrenfeld J. Reversing Hospital Consolidation: The Promise of Physician-Owned Hospitals. *Health Affairs Blog* April 12, 2021. doi: 10.1377/hblog20210408.980640

[54] H.R.1156 - Patient Access to Higher Quality Health Care Act of 2017. 115th Congress (2017-2018). https://www.congress.gov/bill/115th-congress/house-bill/1156

[55] H.R.3062 - Patient Access to Higher Quality Health Care Act of 2019. 116th Congress (2019-2020). https://www.congress.gov/bill/116th-congress/house-bill/3062

[56] Government Accountability Office. Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served. (2003). https://www.gao.gov/assets/gao-03-683r.pdf

community hospitals.[57] Finally, lost in the policy discussion of the time was that POHs are a market split equally between community hospitals and specialty surgical hospitals, the latter of which is comprised of three primary sub-markets cardiac, orthopedic, and general surgical hospitals.[58]

Based upon this litany of concerns, policymakers implemented an 18-month moratorium in 2003 and eventually a ban on new POHs (and existing POHs from expanding) from participating in the Medicare program by closing the "whole hospital exception,"[59] functionally prohibiting new POHs from entering the marketplace. POHs could apply to CMS for an exception, either as a high Medicaid facility or an applicable hospital as defined by other criteria related to local population and bed supply, a market entry barrier that hospitals with other ownership structures do not face. Executed as part of 2010 Patient Protection and Affordable Care Act (ACA),[60] a ban on a single market participant is inconsistent with the goals of the ACA, which aimed to expand insurance coverage, undertake a series of insurance reforms, and support quality improvement efforts. Economic consequences are real, with significant market forecloses in 2010 as over 75 new hospitals either planned or under development were prematurely terminated, representing nearly $2.5 billion in economic losses at the time of the law's passage in 2010.[61] One can only imagine the consequences of a now lost decade of hospital construction and potential innovation in clinician-driven care delivery.

Even if we take at face value the hospital industry's concerns that POHs are cherry-picking healthier patients–a claim on which the evidence is mixed–this is a problem best addressed by payment policy. Payers, public and private, can modify payment rates in order to adjust for differential patient acuity and complexity. CMS did just that in response to concerns regarding overpayment of specialty hospitals, and in 2007 updated the inpatient prospective payment system (IPPS) in order to better account for complicating conditions and case mix index.[62]

The law now serves a different purpose: functioning as an anti-competitive ban on market entry for a single market participant for what many would agree were problems of regulation and payment policy. Flagged as a competition policy issue in the White House Report on Choice and Competition in healthcare markets,[63] Congress can rectify the anti-competitive effects of Section 6001 by repealing it. Finally, concerns about this marketplace can and should be addressed by policymakers and regulators, ensuring that regulatory solutions are used for regulatory problems.

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[57] See table 6.1 from
Centers for Medicare & Medicaid Services. (2005). Study of Physician-Owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pg. 58. Available at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/RTC-StudyofPhysOwnedSpecHosp.pdf

[58] Blumenthal DM, Orav EJ, Jena AB, Dudzinski DM, Le ST, Jha AK. Access, quality, and costs of care at physician owned hospitals in the United States: observational study. *BMJ*. 2015 Sep 2;351:h4466. doi: 10.1136/bmj.h4466. PMID: 26333819; PMCID: PMC4558297.

[59] Previously Stark Law provided a safe harbor entitled the "whole hospital exception," wherein a physician could refer Medicare or Medicaid patients to a hospital where the physician had a financial interest if the physician was authorized to perform services at the hospital and had a financial interest in the entire hospital. See: Cole CM. Physician-Owned Hospitals and Self-Referral. *AMA Journal of Ethics* 2013;15(2):150-155.

[60] H.R.3590 - Patient Protection and Affordable Care Act. Sec. 6001. Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals. 111th Congress (2009-2010). https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Section_6001_of_the_ACA.pdf

[61] Impact of Implementation of Section 6001. *Physician Hospitals of America* 2011. https://cdn.ymaws.com/www.physicianhospitals.org/resource/resmgr/docs/Economic_Impact_of_Section_6.pdf

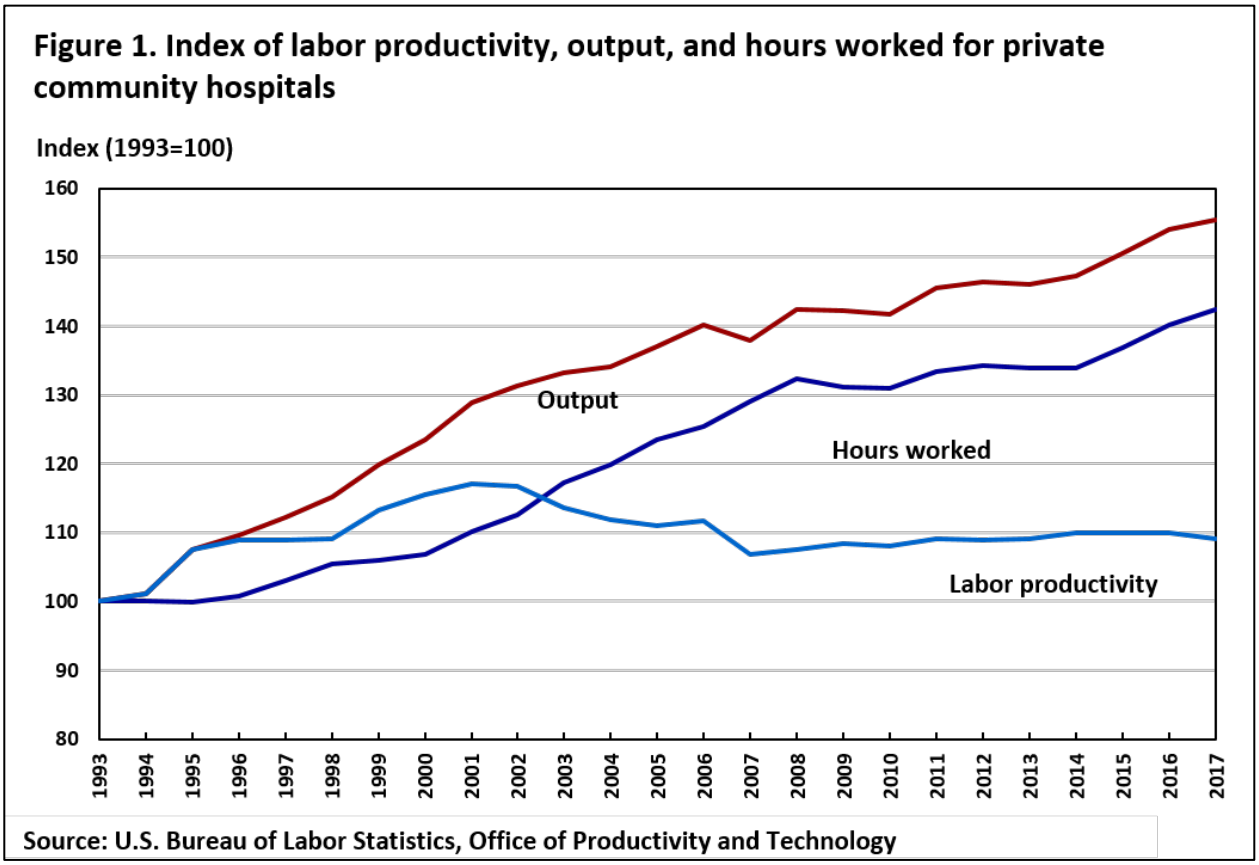
[62] Center for Medicare & Medicaid Services. Improving Medicare's Hospital Inpatient Prospective Payment System to Better Recognize the Costs of Care. 2007. https://www.cms.gov/newsroom/fact-sheets/improving-medicares-hospital-inpatient-prospective-payment-system-better-recognize-costs-care

[63] US Dept. of HHS, US Dept. of the Treasury, US Dept. of Labor. Reforming America's Healthcare System Through Choice and Competition. 2018. Pg.74. https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf

4. Conclusions

One of the great joys of competition policy is that it is uniquely bipartisan: everyone is trying to get to the same place, just with different ideas of how best to get there. Every patient deserves choice in how, when, and where they receive their care. Payment policy choices such as the maintenance of differential payment for the same service delivered at different care sites drive hospital-physician practice consolidation, and should be rectified through the full implementation of site neutral payment. While implemented with the best of intentions, now archaic legal barriers like Stark Law and the ban on new physician-own hospitals participating in the Medicare program now serve to favor one market participant through exclusion of another, preventing meaningful competition between corporate- and physician-owned and operated delivery systems. Congress can correct these ills and help make healthcare markets more functional.

Appendix



Source: Figure 1 from "A Closer Look: Private Community Hospitals" *Bureau of Labor Statistics.* https://www.bls.gov/lpc/hospitals_2013.htm