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On

"Burdensome Red Tape: Overregulation in Health Care and the Impact on Small Business."

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Chairwoman Van Duyne, Ranking Member Mfume, and distinguished members of the Subcommittee on Oversight, Investigations, and Regulations:

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. My research focuses on how we can build a more competitive and vibrant health sector to make healthcare more flexible and personalized for patients. This perspective is based upon my prior regulatory experience at the Federal Trade Commission, Federal Communications Commission, U.S. Food & Drug Administration, and the Centers for Medicare & 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. Today I am here in my personal capacity, and the views expressed are my own and do not necessarily reflect those of the Johns Hopkins University, the American Enterprise Institute, or the Medicare Payment Advisory Commission.

In my testimony today, I will focus on:

- 1. The increasing regulatory burden on health care providers
- 2. The important role of small providers in the health care system
- 3. Consolidation within the health care system and what we can do about it

1. The increasing regulatory burden on health care providers

To be a clinician in 2023 in America is an existential challenge. While a desire to heal and be present for the most challenging portion of our patients' lives is a driving force, as is the desire to achieve technical mastery of a trade, overregulation and the overreach of the administrative state has subsumed these positive drivers. Over two-thirds of physicians exhibit symptoms of burnout,¹ a problem well-acknowledged to raise costs.² This is no surprise and is multi-factorial, driven by increasing administrative burdens, declining Medicare reimbursement relative to the hospital industry, and the expected consequence of physicians spending less time with their patients. Time-motion studies of medical residents demonstrate that medicine residents spend 12% of their day in patient rooms.³ Over 15 years ago, the typical primary care physician to complete all of the chronic, acute, and preventive care required, the average workday would be 26.7 hours, inclusive of documentation.⁵

The rise of Donabedian quality measurement in the 1960s spread to the practice medicine after the Institute of Medicine's 2000 *To Err is Human* report⁶ highlighted the large number of deaths due to medical error, frequently cited as the third leading cause of death domestically.⁷ Unsurprisingly and with the best of intentions, the health policy community responded by proposing to measure quality, both through process measures (are clinicians and health systems doing what we want them to do?) and outcome measures.

The following two decades noted a proliferation of quality reporting programs, including those addressing physician practices. Ironically, quality metric product markets are themselves consolidated, with a handful of stakeholders securing large government contracts. The Yale Center for Outcomes Research and Evaluation received over one-

¹ Shanafelt TD, West CP, Dyrbye LN, et al. Changes in Burnout and Satisfaction With Work-Life Integration in Physicians During the First 2 Years of the COVID-19 Pandemic. *Mayo Clin Proc.* Dec 2022;97(12):2248-2258. doi:10.1016/j.mayocp.2022.09.002

² Han S, Shanafelt TD, Sinsky CA, et al. Estimating the Attributable Cost of Physician Burnout in the United States. *Annals of internal medicine*. Jun 4 2019;170(11):784-790. doi:10.7326/m18-1422

³ Rosen MA, Bertram AK, Tung M, Desai SV, Garibaldi BT. Use of a Real-Time Locating System to Assess Internal Medicine Resident Location and Movement in the Hospital. *JAMA network open*. Jun 1 2022;5(6):e2215885. doi:10.1001/jamanetworkopen.2022.15885 ⁴ Tai-Seale M, McGuire TG, Zhang W. Time allocation in primary care office visits. Health Serv Res. 2007 Oct;42(5):1871-94. doi:

^{10.1111/}j.1475-6773.2006.00689.x.

⁵ Porter, J., Boyd, C., Skandari, M.R. *et al.* Revisiting the Time Needed to Provide Adult Primary Care. *J GEN INTERN MED* **38**, 147–155 (2023). https://doi.org/10.1007/s11606-022-07707-x

⁶ Institute of Medicine (US) Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000.

⁷ Makary M A, Daniel M. Medical error-the third leading cause of death in the US BMJ 2016; 353 :i2139 doi:10.1136/bmj.i2139

quarter of a billion dollars since 2008, out of over \$1.3 billion spent on measurement development by CMS.⁸ Across the economy, evidence shows that market concentration results in higher costs and lower quality. Thus, while generating quality metrics that raise operational costs for health care delivery, the Centers for Medicare & Medicaid Services (CMS) is also purchasing technical services in a concentrated market, likely at above market prices. Quality metric construction also remains a primarily academic measure, with few venues to practicing physicians to voice questions or concerns.

The direct return for taxpayers is unclear. International markets present a cautionary tale, with the United Kingdom's National Health Service implementing a pay for performance program tying performance on process and outcomesbased quality metrics to financial bonuses for primary care physicians. A subsequent study on spirometry performance within the chronic obstructive pulmonary disease (COPD) quality domain demonstrated that practices performed spirometry in accordance with accepted standards 31% of the time and 12% of results did not event support the diagnosis of COPD.⁹

Costs are very clear. Physician practice metric reporting costs an estimated \$15.4 billion annually, 2.6 hours per week of physician time is spent on metric reporting, while office staff spend 12.5 hours weekly.¹⁰ What is not mention is that this is all time that is no longer spent on patient care – clinic visits, phone calls, and urgent care. CMS now has 2,266 quality metrics in its measures inventory,¹¹ some of which like the hospital readmissions reduction program may, ironically, even increase mortality.¹² It is thus no mystery that the cost of running a clinical practice is increasing.

While the Trump Administration's "Meaningful Measures Initiative" created a cascade of measures, titrated down into goals, objectives, families, and individual measures and the Biden Administration's "Universal Foundation" of quality metrics¹³ attempt to address this problem, neither separate nor together are they sufficient.

The inherent problem yet to be acknowledged is that quality metrics – like every animal, plant, or corporation – must have a lifecycle. Quality metrics "top out" and must be retired, others cease to change clinical operations, and still others are eventually found to be harmful.

⁸ Castellucci M. CMS, Yale New Haven Health on hot seat over design of quality measures. Accessed 4/1/2023,

https://www.modernhealthcare.com/article/20190119/NEWS/190119904/cms-yale-new-haven-health-on-hot-seat-over-design-of-qualitymeasures

⁹ Strong M, South G, Carlisle R. The UK Quality and Outcomes Framework pay-for-performance scheme and spirometry: rewarding quality or just quantity? A cross-sectional study in Rotherham, UK. *BMC Health Serv Res.* Jun 28 2009;9:108. doi:10.1186/1472-6963-9-108

¹⁰ Casalino LP, Gans D, Weber R, et al. US Physician Practices Spend More Than \$15.4 Billion Annually To Report Quality Measures. *Health Affairs*. 2016/03/01 2016;35(3):401-406. doi:10.1377/hlthaff.2015.1258

¹¹ Wadhera RK, Figueroa JF, Joynt Maddox KE, Rosenbaum LS, Kazi DS, Yeh RW. Quality Measure Development and Associated Spending by the Centers for Medicare & Medicaid Services. *Jama*. Apr 28 2020;323(16):1614-1616. doi:10.1001/jama.2020.1816

¹² Wadhera RK, Joynt Maddox KE, Wasfy JH, Haneuse S, Shen C, Yeh RW. Association of the Hospital Readmissions Reduction Program With Mortality Among Medicare Beneficiaries Hospitalized for Heart Failure, Acute Myocardial Infarction, and Pneumonia. *Jama*. Dec 25 2018;320(24):2542-2552. doi:10.1001/jama.2018.19232

¹³ Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS — The Universal Foundation. *New England Journal of Medicine*. 2023;doi:10.1056/NEJMp2215539

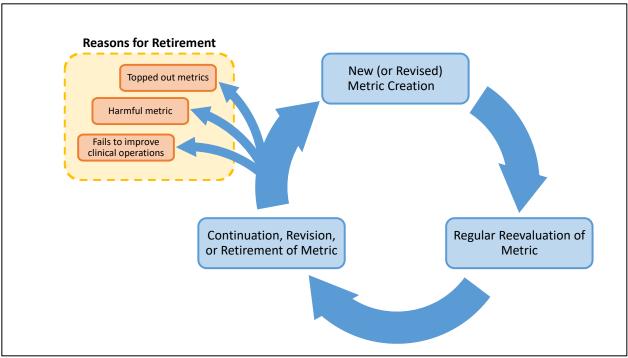


Figure 1: Quality Measure Lifecycle

Policymakers should require a cap on the number of metrics for CMS programs, require regular review and assessment of a minimum share of quality metrics (e.g. 10% annually), and a process for bottom-up quality metric innovation from practicing physicians. Further, policymakers should require that CMS contract with a minimum of three organizations for quality measure development, so as to avoid market concentration.

Quality reporting burdens are real and drive administrative activity. When I was an internal medicine resident, one of my colleagues was already planning their retirement by the second year of our three year residency.

2. The important role of small providers in the health care system

Many patients frequently seek care at large health systems, often for tertiary or quaternary care. I myself have trained in and recognize the value that many large health systems have in offering highly trained and specialized care.

To better illustrate the challenges of large health systems, I have included some statistics to illustrate their scale:

- 1. *Mayo Clinic Jacksonville*: 400 acre campus for outpatient and inpatient care, soon to undergo an expansion including a 179,000 square foot hotel.¹⁴
- 2. *Mayo Clinic Rochester*: "The five-block downtown Mayo campus is easily walkable, even in the winter, thanks to Mayo's extensive subway and skyway system."¹⁵
- 3. *Massachusetts General Hospital Yawkey Outpatient Center*: 380,000 square feet¹⁶ (does not include the larger hospital)
- 4. University of Minnesota Medical Center: 1,700 beds¹⁷

¹⁴ Kevin Punsky, "Mayo Clinic Invests in Major Hospital Expansion to Enhance Patient Experience," Mayo Clinic News Network, February 22, 2022, https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-invests-in-major-hospital-expansion-to-enhance-patient-experience/.

¹⁵ "Getting around Mayo Clinic in Rochester, Minnesota - Mayo Clinic," accessed July 18, 2023, https://www.mayoclinic.org/patient-visitorguide/minnesota/getting-around.

¹⁶ "Massachusetts General Hospital—Yawkey Center for Outpatient Care [Boston, MA] - HCD Magazine," HCD Magazine - Architecture & Interior Design Trends for Healthcare Facilities, August 31, 2007, https://healthcaredesignmagazine.com/architecture/massachusetts-general-hospital-yawkey-center-outpatient-care-boston-ma/.

¹⁷ "University of Minnesota Medical Center | University of Minnesota Health," accessed July 18, 2023, https://bettercaremn.umn.edu/universityminnesota-medical-center.

The medical school at which I trained at occupies several blocks of downtown Chicago, see the following map:



Figure 2: Map of Northwestern Medicine Downtown Chicago Campus¹⁸

What does this mean for consumers? Walking one quarter of a mile on the street between buildings and navigating a 23 story clinic building to make it to an appointment is neither convenient nor easy. Half of Medicare-Medicaid beneficiaries had one impairment in the activities of daily living (e.g. dressing, bathing, etc.),¹⁹ and many other populations of patients have significant functional impairments or, more simply, are just not feeling well.

This is not to say that large health systems do not have an important place in American health care, as they do. Rather that small physician groups may be more accessible, more conveniently located (akin to retail chains), and may be more able to customize clinical care itself and the *processes for the delivery of care*.

We should work to preserve this choice for patients.

¹⁸ "Living in Chicago," accessed July 18, 2023, https://www.feinberg.northwestern.edu/admissions/why-northwestern/chicago.html.

¹⁹ Maiss Mohamed et al., "A Profile of Medicare-Medicaid Enrollees (Dual Eligibles)," KFF (blog), January 31, 2023,

https://www.kff.org/medicare/issue-brief/a-profile-of-medicare-medicaid-enrollees-dual-eligibles/.

3. Consolidation within the health system

Consolidation of health care markets is a significant problem for patients, employers, and policymakers. Hospital care comprises around 31% of annual health spending, with physician care representing another 19%. Researchers note that over 90% of metropolitan statistical areas representing highly concentrated hospital markets.²⁰

The harms of hospital consolidation are well-documented, with consolidation leading to higher prices,²¹ borne by patients as higher cost-sharing payments and higher health insurance premiums.^{22,23} Patients also experience other losses: a lack of quality gains from hospital mergers and – unsurprisingly – decrements in patient experience.²⁴ Higher health care costs also hurt workers, as rising costs for health benefits can suppress wages or be transferred to workers in the form of higher premiums and cost sharing.²⁵

To add insult to the injury, 58% of hospitals are tax-exempt institutions, an exemption conservative estimated at \$27.6 billion.²⁶ Many have large boards driving weak oversight, with some noting challenges with spending and accountability at IRS-designated charitable institutions in highly concentrated markets with UPMC operating a corporate jet for executives and business development as far back as 2008,²⁷ while Atrium health noted 380 flights on private jets from 2008 - 2012 for executives and 29 flights on private jets for its health system CEO.²⁸ Still, the others note that the Mayo Clinic decorated its lobby with 13 Dale Chihuly glass sculptures weighing 6,000 pounds and comprised of 1,375 pieces of glass.²⁹

It is in this environment that policymakers rightly express concern about market concentration, noting that hospitals have successfully lobbied to prevent physician-owned and -operated enterprises from competing with them, through the ban on physician-owned hospitals and Stark Law, which functionally prohibits physician ownership and operations of integrated care delivery in a small business setting.³⁰ Repealing the ban on physician-owned hospitals has the potential to expand access,³¹ lower costs, and improve quality.³²

Consolidation is a vexing problem, with Congress' foot historically – accidentally – on the accelerator. The lack of site neutral payment – wherein payers pay the same amount for a service regardless of where it is performed – has also driven clinic – hospital consolidation. The nonpartisan 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,³³ noting that full implementation of site neutral payment would eliminate payment policy arbitrage as a rationale for hospitals' purchase of clinics.

²⁵ "Health Insurance Costs Are Squeezing Workers and Employers," Center for American Progress (blog), November 29, 2022,

https://www.americanprogress.org/article/health-insurance-costs-are-squeezing-workers-and-employers/.

https://www.healthleadersmedia.com/strategy/upmc-sees-jet-key-tool-quest-global-reach.

doi:10.1001/jamahealthforum.2021.0150

²⁰ 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

²¹ 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 ²² 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

²³ 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

²⁴ 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.

²⁶ Jamie Godwin, Scott Hulver Published: Mar 14, and 2023, "The Estimated Value of Tax Exemption for Nonprofit Hospitals Was About \$28 Billion in 2020," KFF (blog), March 14, 2023, https://www.kff.org/health-costs/issue-brief/the-estimated-value-of-tax-exemption-for-nonprofithospitals-was-about-28-billion-in-2020/.

²⁷ HealthLeaders, "UPMC Sees Jet as a Key Tool in Quest for Global Reach," accessed July 18, 2023,

^{28 &}quot;Carolina Health System Interview with Charlotte Observer," accessed July 18, 2023, https://atriumhealth.org/documents/news/chs-interviewwith-charlotte-observer.pdf.

^{29 &}quot;Glass Chandeliers by Dale Chihuly," Mayo Clinic Proceedings 76, no. 11 (November 1, 2001): 1176, https://doi.org/10.4065/76.11.1176. ³⁰ Miller BJ, Ehrenfeld JM, Wu AW. Competition or Conflict of Interest—Stark Choices. JAMA Health Forum. 2021;2(2):e210150.

³¹ Miller BJ, Moffit RE, Ficke J, Marine J, Ehrenfeld JM. "Reversing Hospital Consolidation: The Promise of Physician-Owned Hospitals." Health Affairs Forefront April 12, 2021.

³² Cho T, Meshnick AB, Ehrenfeld JM, Miller BJ. "Cost and Quality of Care in Physician-Owned Hospitals: A Systematic Review." Mercatus *Center at George Mason University* Arlington, Virginia. September 7, 2021. ³³ 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

4. Conclusions: together we can fix these problems

Health policy is at a turning point – government intervention to solve problems begets more government intervention. Increasing regulatory barriers and administrative complexity raise barriers to entry, crushing small businesses and raising the cost of services for purchasers. In order to preserve the vital role for small practices, policymakers should direct CMS to cap the number of quality metrics and create a quality metric lifecycle, with onboarding, off-ramps, and routine metric performance evaluation. CMS should be required to contract with a minimum of 3 measurement development organizations, and create a direct channel for bottom up innovation from practicing physicians. Finally, policymakers should expand access and lower costs by repealing the ban on physician-owned hospitals, considering reforms to Stark Law, and implement site neutral payment.