Testimony of Brian J. Miller, M.D., M.B.A., M.P.H.

Assistant Professor of Medicine and Business (Courtesy)
The Johns Hopkins University School of Medicine
The Johns Hopkins Carey Business School

Nonresident Fellow
American Enterprise Institute

Before the

U.S. State Congress Joint Economic Committee

On

"Artificial Intelligence and Its Potential to Fuel Economic Growth and Improve Governance."

June 4, 2024

Chairman Heinrich, Vice Chairman Schweikert, and distinguished members of the Joint Economic Committee:

My name is Brian Miller, and I practice hospital medicine at the Johns Hopkins Hospital. As an academic health policy analyst, I serve as an Assistant Professor of Medicine and Business (Courtesy) at the Johns Hopkins University School of Medicine and as a Nonresident Fellow at the American Enterprise Institute. My research focuses on how we can build a more competitive and vibrant health sector to make healthcare more efficient, flexible, and personalized for patients. This perspective is based upon my prior regulatory experience at four federal regulatory agencies. Through my current 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 or the Johns Hopkins Health System, the American Enterprise Institute, or the Medicare Payment Advisory Commission.

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

1. Improving the clinical efficiency of care delivery through labor productivity growth
2. Driving administrative efficiency for delivery systems and insurers
3. Policies to promote the development of new science and new innovation

1. Improving the clinical efficiency of care delivery through labor productivity growth

Over the past 60 years, innovation has driven changes in clinical practice, with the life sciences industry developing over 1,200 new drugs.[1] Today, there are over 20,000 prescriptions drugs approved for marketing, 400 licensed biologic products, and 6,500 FDA-regulated medical device product categories[2] offering patients a variety of benefits including reduced mortality, morbidity, and improved functional status or quality of life. While retail prescription drug spending represents just 9% of national health expenditures,[3] it has driven massive transformations in care for patients and reduced morbidity and mortality. In contrast, the 51% of health care spending representing care delivered in hospitals and clinics largely remains a vast plain yet to be significantly transformed by operational and technological innovation.

It is this arena that automation and artificial intelligence (AI) offers the most promise to transform care. Through a combination of monopoly,[4] legal barriers to competition such as Stark Law,[5] and regulatory policy, current models of care delivery that are ill-suited to patients' needs and clinical efficiency have become encased in policy concrete. Economic measures lend further credence to the challenges of this policy story, with labor productivity in private community hospitals remaining on average flat or negative since at least as far back as 2000.[6] Other economic research suggests that health care suffers from Baumol's cost disease,[7] wherein the sector's wages rise despite a lack of productivity growth due to rising wages in other sectors with high productivity growth, driving rising health care delivery costs without consequential gains for consumer-patients.

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

[2] FDA at a Glance. U.S. Food & Drug Administration. October 2019. https://www.fda.gov/media/131874/download

[3] National Health Expenditures 2022 Highlights. Centers for Medicare & Medicaid Services. Dec 13, 2023. https://www.cms.gov/newsroom/fact-sheets/national-health-expenditures-2022-highlights

[4] Testimony of Brian J. Miller, M.D., M.B.A., M.P.H. Before the U.S. Senate Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights on "Antitrust Applied: Hospital Consolidation Concerns and Solutions." May 19, 2021. https://www.judiciary.senate.gov/imo/media/doc/Brian%20J%20Miller%20Senate%20Judiciary%20testimony%20for%2005%2019%202021.pdf

[5] Miller BJ, Ehrenfeld JM, Wu AW. Competition or Conflict of Interest—Stark Choices. *JAMA Health Forum*. 2021;2(2):e210150. doi:10.1001/jamahealthforum.2021.0150

[6] Private Community Hospitals Labor Productivity. U.S. Bureau of Labor Statistics. https://www.bls.gov/productivity/highlights/hospitals-labor-productivity.htm

[7] Bates LJ, Santerre RE. Does the U.S. health care sector suffer from Baumol's cost disease? Evidence from the 50 states. *J Health Econ*. 2013;32(2):386-391. doi:10.1016/j.jhealeco.2012.12.003

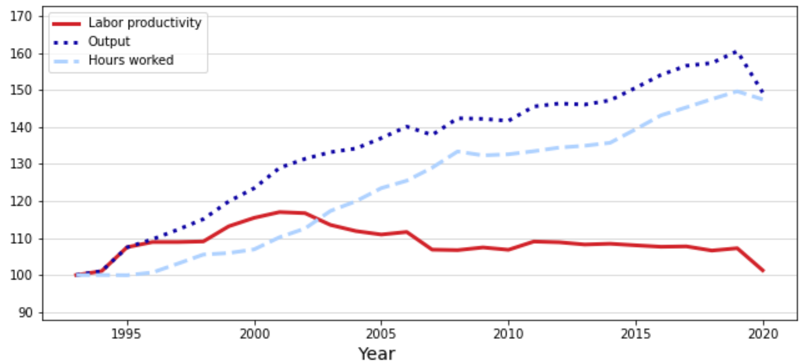

Figure 1: Labor productivity for private community hospitals (Index, 1993 = 100)[8]

The absence of labor productivity growth has created a politically challenging combination of unsustainable spending–totaling $4.5 trillion[9] and growing at an average rate of 4.7% annually[10] – coupled with a growing need for and gap in the skilled labor supply. As care delivery outputs increase without any improvement in labor productivity, the care delivery sector has an ever insatiable appetite for more workers. In a system subject to time lags, financing challenges,[11,12] and varying degrees of state-based occupational regulation[13,14] of the health professions,[15,16,17,18,19] it is no surprise that there are shortages across a wide range of skilled trades, with a projected shortage of 78,610 registered nurses (by 2025),[20] 68,020 primary care physicians (by 2036),[21] and 21,150 adult psychiatrists (by 2030)[22] within the next decade just to name a few, all worsened by the recent COVID-19 pandemic amongst other factors driving burnout.[23,24,25] With Medicare and Medicaid expenditures in 2022 growing at 5.9% and 9.6% year over year

---

[8] Private Community Hospitals Labor Productivity. U.S. Bureau of Labor Statistics. https://www.bls.gov/productivity/highlights/hospitals-labor-productivity.htm

[9] NHE Fact Sheet. Centers for Medicare & Medicaid Services. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.

[10] Average Annual Percent Growth in Health Care Expenditures per Capita by State of Residence. Kaiser Family Foundation. August 2022. https://www.kff.org/other/state-indicator/avg-annual-growth-per-capita/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[11] Underwood, Bonamici, Horsford Introduce Legislation to Expand Access to Clinical Opportunities for Graduate Nursing Students. Press Release. Office of United States Representative Suzanne Bonamici, 1st District of Oregon. May 25, 2023. https://bonamici.house.gov/media/press-releases/underwood-bonamici-horsford-introduce-legislation-expand-access-clinical

[12] Porat-Dahlerbruch J, Aiken LH, Todd B, et al. Policy Evaluation Of The Affordable Care Act Graduate Nurse Education Demonstration. *Health Aff (Millwood)*. 2022;41(1):86-95. doi:10.1377/hlthaff.2021.01328

[13] Cox C & Foster S. *The Costs and Benefits of Occupational Regulation*. Federal Trade Commission. 1990. https://www.ftc.gov/system/files/documents/reports/costs-benefits-occupational-regulation/cox_foster_-_occupational_licensing.pdf

[14] Prepared Statement of The Federal Trade Commission on Competition and Occupational licensure Before the Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law, United States House of Representatives. September 12, 2017. https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_2017_vote.pdf

[15] Selected Advocacy Relating to Occupational Licensing. Federal Trade Commission. https://www.ftc.gov/policy/advocacy-research/advocacy/economic-liberty/selected-advocacy-relating-occupational-licensing

[16] Timmons EJ, Hockenberry JM, & Durrance CP. More Battles among Licensed Occupations: Estimating the Effects of Scope of Practice and Direct Access on the Chiropractic, Physical Therapist, and Physician Labor Market. *Mercatus Center*. September 28, 2016. https://www.mercatus.org/research/research-papers/more-battles-among-licensed-occupations

[17] Timmons EJ & Wei P. Resolving Roadblocks to Activating Additional Physicians. *Mercatus Center*. May 7, 2020. https://www.mercatus.org/research/policy-briefs/resolving-roadblocks-activating-additional-physicians

[18] Graboyes R & Feldstein M. For Greater Healthcare Access, License Physicians Like Pilots. *Mercatus Center*. September 9, 2021. https://www.mercatus.org/research/policy-briefs/greater-healthcare-access-license-physicians-pilots

[19] Scope-of-Practice Laws. *Mercatus Center*. March 22, 2017. https://www.mercatus.org/research/policy-briefs/scope-practice-laws

[20] Nurse Workforce Projections, 2020-2035. Health Resources & Services Administration. November 2022. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/Nursing-Workforce-Projections-Factsheet.pdf

[21] State of the Primary Care Workforce, 2023. Health Resources & Services Administration. November 2023. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/state-of-primary-care-workforce-2023.pdf

[22] Behavioral Health Workforce Projections, 2016-2030: Psychiatrists (Adult), Child and Adolescent Psychiatrists. Health Resources & Services Administration. https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/psychiatrists-2018.pdf

[23] Martin B, Kaminski-Ozturk N, O'Hara C, Smiley R. Examining the Impact of the COVID-19 Pandemic on Burnout and Stress Among U.S. Nurses. *J Nurs Regul*. 2023;14(1):4-12. doi:10.1016/S2155-8256(23)00063-7

[24] 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*. 2022;97(12):2248-2258. doi:10.1016/j.mayocp.2022.09.002

[25] Fact Sheet: Nursing Shortage. American Association of Colleges of Nursing. October 2022. https://www.aacnnursing.org/Portals/0/PDFs/Fact-Sheets/Nursing-Shortage-Factsheet.pdf

respectively and comprising 15% and 13% respectively of the federal budget,[26] crowding out discretionary spending, and industry stakeholders suggesting that we subsidize our way out of labor shortages[27,28] now is the time to think differently.

Various policy experts including the Congressional Budget Office have enumerated policy options to promote either separately or simultaneously[29,30] cutting spending[31] and increasing taxes[32] as a way out of our health care cost problem. Spending cuts invariably cut someone's revenue, a politically fraught exercise with large incumbent hospital[33] and physician lobbies,[34] while taxes reduce profits of individuals and businesses, both large and small, thereby discouraging investment.[35,36,37] Yet, a tax and spend approach does not address the inherent labor productivity problem and leaves Baumol's cost disease unsolved.

Instead, automation and AI offer us the opportunity to use our existing human capital more efficiently and treat Baumol's cost disease.[38] AI can be defined amongst multiple frames of reference, including system type, types of intelligence, or mechanism of learning:

System Type	Types of Intelligence	Learning
Reactive	Artificial Narrow Intelligence	Reinforcement Learning
Limited Memory	Artificial General Intelligence	Unsupervised Learning
Theory of Mind	Artificial Super Intelligence	Supervised Learning
Self-Aware AI		Deep Learning
		Machine Learning
		Artificial Intelligence

Figure 2: Definitional framings for AI[39,40]

[26] NHE Fact Sheet. Centers for Medicare & Medicaid Services. 2022. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[27] AAMC Statement on Senate Reintroduction of GME Expansion Bill. Press Release. Association of American Medical Colleges. April 27, 2023. https://www.aamc.org/news/press-releases/aamc-statement-senate-reintroduction-gme-expansion-bill
[28] AAMC-Supported Letter Calls for Increased CHGME Funding. Press Release. Association of American Medical Colleges. May 24, 2024. https://www.aamc.org/advocacy-policy/washington-highlights/aamc-supported-letter-calls-increased-chgme-funding
[29] Ten Options to Secure the Medicare Trust Fund. Committee for Responsible Federal Budget. June 16, 2022. https://www.crfb.org/blogs/ten-options-secure-medicare-trust-fund
[30] Options for Reducing the Deficit, 2023 to 2032--Volume I: Larger Reductions. Congressional Budget Office. December 7, 2022. https://www.cbo.gov/publication/58164
[31] Williams D, Grabert LM, Miller BJ, Rambur B, & Wilensky GR. Reducing Hospital Costs Without Hurting Patients. *Health Affairs Forefront*. October 20, 2023. DOI: 10.1377/forefront.20231018.935344
[32] Mermin GB, Garrett B, Hunter L, & Steuerle CE. Options for Increasing Medicare Revenues. Tax Policy Center. February 1, 2023. https://www.taxpolicycenter.org/publications/options-increasing-medicare-revenues/full
[33] Pollack R. Setting the Record Straight: Washington Post Editorial on Site-neutral Deeply Flawed and Poorly-timed. American Hospital Association. March 15, 2024. https://www.aha.org/news/blog/2024-03-15-setting-record-straight-washington-post-editorial-site-neutral-deeply-flawed-and-poorly-timed
[34] Joszt L. AMA Continues Call for Medicare Payment System Fix During Interim Meeting. *American Journal of Managed Care*. November 20, 2023https://www.ajmc.com/view/ama-continues-call-for-medicare-payment-system-fix-during-interim-meeting
[35] McBride W. What Is the Evidence on Taxes and Growth?. Tax Foundation. December 18, 2012. https://taxfoundation.org/research/all/federal/what-evidence-taxes-and-growth/
[36] Agostini, C. A. (2007). The Impact of State Corporate Taxes on FDI Location. *Public Finance Review*, 35(3), 335-360. https://doi.org/10.1177/1091142106292491
[37] Mukherjee A, Singh M, Žaldokas A. Do corporate taxes hinder innovation? *Journal of Financial Economics*. 2017/04/01/ 2017;124(1):195-221. doi:https://doi.org/10.1016/j.jfineco.2017.01.004
[38] Pande V. Solving Baumol's Cost Disease, in Healthcare. *Andreessen Horowitz*. December 14, 2020. https://a16z.com/solving-baumols-cost-disease-in-healthcare/
[39] Panch T, Szolovits P, Atun R. Artificial intelligence, machine learning and health systems. *J Glob Health*. 2018;8(2):020303. doi:10.7189/jogh.08.020303
[40] Laviola E. What Types of AI Are Being Used in Healthcare?. *HealthTech*. July 11, 2023. https://healthtechmagazine.net/article/2023/07/types-ai-in-healthcare-perfcon

While the exact boundaries of the definitions of AI can be debated, the principle behind it–automation–can serve to transform care delivery and improve labor productivity. AI has three primary categories of application in health care: 1) automation of the mundane (administrative tasks), 2) augmentation of human-driven clinical practice, and 3) automation of elements of clinical practice.[41] This section will address the potential of the latter two categories of use to improve labor productivity by both automating tasks and simultaneously up-scoping the activities of clinical professionals.

Augmentation of human-driven clinical practice can transform medical care. For example, intelligent warnings such as blind spot monitors, advanced driver assistance systems like Toyota Lane Change Assist, and automated safety systems like Mercedes PRE-SAFE ensure a safer driving experience. Current care delivery modalities are akin to a 747 with analog controls and no autopilot, with AI-driven technology (clinical decision support) and adaptive displays offering the potential to improve clinical practice in acute and critical safety settings for intensivists, anesthesiologists, nurses, and other providers to manage patients more effectively and efficiently while also addressing human factors concerns[42] such as information overload, situational awareness, and task management.[43]

In other clinical settings, automation and AI may improve the efficiency and accuracy of clinical practice, assisting clinicians in diagnostic tasks built upon pattern recognition, such as diagnosis based upon CT scans,[44] mammography interpretation,[45] melanoma diagnosis,[46] or review of pathology slides.[47] Other emerging areas include prognostication in cancer[48] and improving radiation treatment planning,[49] with AI-assisted care likely to become the standard of care in multiple areas. Much of this innovation occurs and will continue to evolve at the bedside as part of clinical practice, as front-line practitioners identify and begin to solve longstanding problems in conjunction with engineers and software developers.

Beyond augmentation, automation of elements of clinical practice can drive increased efficiency. With the time required to provide appropriate guideline-directed primary care estimated at a 26.7 hour workday,[50] it is clear that there is an opportunity to automate clinical tasks in order to better serve patients, improve labor productivity, and not harm the clinical workforce. Autonomous AI-driven care can support service delivery, from screening for diabetic retinopathy to point-of-care digital cytology[51] to interpretation of electroencephalograms[52] with some clinical use cases even revealing higher performance for machine learning when compared to humans.[53] All of these opportunities offer an ability for existing clinicians to devote more time to patient counseling, clinical coordination, procedures, and other tasks, unlocking productivity gains in health care delivery for the first time in decades.

---

[41] Spear J, Ehrenfeld JM, Miller BJ. Applications of Artificial Intelligence in Health Care Delivery. *J Med Syst*. 2023;47(1):121. Published 2023 Nov 17. doi:10.1007/s10916-023-02018-y

[42] Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: a study of human factors. *Anesthesiology*. 1978;49(6):399-406. doi:10.1097/00000542-197812000-00004

[43] Jones, C.P.L., Fawker-Corbett, J., Groom, P., Morton, B., Lister, C. and Mercer, S.J. (2018), Human factors in preventing complications in anaesthesia: a systematic review. *Anaesthesia*, 73: 12-24. https://doi.org/10.1111/anae.14136

[44] Ziegelmayer S, Reischl S, Havrda H, et al. Development and Validation of a Deep Learning Algorithm to Differentiate Colon Carcinoma From Acute Diverticulitis in Computed Tomography Images. *JAMA Netw Open*. 2023;6(1):e2253370. doi:10.1001/jamanetworkopen.2022.53370

[45] Lång K, Josefsson V, Larsson AM, et al. Artificial intelligence-supported screen reading versus standard double reading in the Mammography Screening with Artificial Intelligence trial (MASAI): a clinical safety analysis of a randomised, controlled, non-inferiority, single-blinded, screening accuracy study. *Lancet Oncol*. 2023;24(8):936-944. doi:10.1016/S1470-2045(23)00298-X

[46] Phillips M, Marsden H, Jaffe W, et al. Assessment of Accuracy of an Artificial Intelligence Algorithm to Detect Melanoma in Images of Skin Lesions. *JAMA Netw Open*. 2019;2(10):e1913436. doi:10.1001/jamanetworkopen.2019.13436

[47] Steiner DF, Nagpal K, Sayres R, et al. Evaluation of the Use of Combined Artificial Intelligence and Pathologist Assessment to Review and Grade Prostate Biopsies. *JAMA Netw Open*. 2020;3(11):e2023267. doi:10.1001/jamanetworkopen.2020.23267

[48] Torrente M, Sousa PA, Hernández R, et al. An Artificial Intelligence-Based Tool for Data Analysis and Prognosis in Cancer Patients: Results from the Clarify Study. *Cancers (Basel)*. 2022;14(16):4041. Published 2022 Aug 22. doi:10.3390/cancers14164041

[49] Kawamura M, Kamomae T, Yanagawa M, et al. Revolutionizing radiation therapy: the role of AI in clinical practice. *Journal of Radiation Research*. 2024;65(1):1–9. https://doi.org/10.1093/jrr/rrad090

[50] Porter J, Boyd C, Skandari MR, Laiteerapong N. Revisiting the Time Needed to Provide Adult Primary Care. *J Gen Intern Med*. 2023;38(1):147-155. doi:10.1007/s11606-022-07707-x

[51] Holmström O, Linder N, Kaingu H, et al. Point-of-Care Digital Cytology With Artificial Intelligence for Cervical Cancer Screening in a Resource-Limited Setting. *JAMA Netw Open*. 2021;4(3):e211740. doi:10.1001/jamanetworkopen.2021.1740

[52] Tveit J, Aurlien H, Plis S, et al. Automated Interpretation of Clinical Electroencephalograms Using Artificial Intelligence. *JAMA Neurol*. Published online June 20, 2023. doi:10.1001/jamaneurol.2023.1645

[53] Mercan E, Mehta S, Bartlett J, Shapiro LG, Weaver DL, Elmore JG. Assessment of Machine Learning of Breast Pathology Structures for Automated Differentiation of Breast Cancer and High-Risk Proliferative Lesions. *JAMA Netw Open*. 2019;2(8):e198777. doi:10.1001/jamanetworkopen.2019.8777

Augmentation and automation may also occur in the home or real-world setting to facilitate consumer-driven care, as technology can augment traditional patient-clinician relationships promoting self-management and independence. For example, a closed-loop system consists of insulin pump tied with a continuous glucose monitor with dosing driven by algorithms, tested first in small groups[54] and in broader populations[55] including young children[56] with improved blood glucose control. While a simple example, many chronic conditions such as diabetes, atrial fibrillation, hypertension, and other diseases offer the potential for patient-driven treatment assisted by automation and AI in conjunction with the use of wearables expanding access while reducing the real-life burden on patients of managing disease. Given well-documented care gaps and consequential personal and societal costs for millions of Americans with obesity, diabetes,[57] hypertension,[58] and other conditions due to an inadequate labor supply, maldistribution of clinicians, and inefficient delivery system, the need for scalable, low-cost personalized solutions that operate at a time and in a setting most convenient for patients is critical

2. Driving administrative efficiency for delivery systems and insurers

Automation and AI also offer the opportunity to improve labor productivity through automation of the mundane or administrative tasks. With over half of physicians suffering from burnout[59] frequently driven by administrative tasks and burnout driving quality losses,[60,61] improving labor productivity is both a pragmatic economic and moral imperative. Recent research demonstrates that clinical workers spend a significant fraction of their time on administrative tasks: the average primary care physician spends over 6 hours daily writing note, hospital nurses on medical-surgical units spend 35.3 of their time on documentation as compared to 19.3% on patient care activities,[62] while internal medicine residents spend 13% of their day in face-to-face contact. Agencies such as the Agency for Healthcare Research and Quality have funded successful descriptive research in this arena for over 20 years,[63] providing a clearly measured imperative for action.

Many day-to-day administrative tasks can be automated through AI such as diagnostic coding and billing and charting, freeing up clinical staff inclusive of nurses and physicians to spend more time counseling and directly interacting with patients. For example, companies such as Nuance, DeepScribe, Nabla, and Suki are working on early attempts to use ambient AI to automate clinical notetaking. Eventually clinicians will review, edit and then sign AI-generated notes as opposed to spending time during and between patient encounters to document visits. With over 70,000 ICD-10 diagnosis codes to support billing, AI could save time and reduce physician cognitive burden while simultaneously improving billing and diagnosis coding accuracy (the latter of which would prevent fraud, waste, and abuse in risk-adjusted capitated health benefit programs).

AI can also be prudently deployed to address concerns regarding innumerable challenges and administrative burdens of prior authorizations for both clinicians and health plans. With the average physician reporting filing out 37 prior

---

[54] Brown S, Raghinaru D, Emory E, Kovatchev B. First Look at Control-IQ: A New-Generation Automated Insulin Delivery System. *Diabetes Care*. 2018;41(12):2634-2636. doi:10.2337/dc18-1249

[55] Brown SA, Kovatchev BP, Raghinaru D, et al. Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes. *N Engl J Med*. 2019;381(18):1707-1717. doi:10.1056/NEJMoa1907863

[56] Wadwa RP, Reed ZW, Buckingham BA, et al. Trial of Hybrid Closed-Loop Control in Young Children with Type 1 Diabetes. *N Engl J Med*. 2023;388(11):991-1001. doi:10.1056/NEJMoa2210834

[57] Najafipour H, Farjami M, Sanjari M, Amirzadeh R, Shadkam Farokhi M, Mirzazadeh A. Prevalence and Incidence Rate of Diabetes, Pre-diabetes, Uncontrolled Diabetes, and Their Predictors in the Adult Population in Southeastern Iran: Findings From KERCADR Study. *Front Public Health*. 2021;9:611652. Published 2021 Nov 1. doi:10.3389/fpubh.2021.611652

[58] Centers for Disease Control and Prevention (CDC). Vital signs: awareness and treatment of uncontrolled hypertension among adults--United States, 2003-2010. *MMWR Morb Mortal Wkly Rep*. 2012;61:703-709.

[59] 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*. 2022;97(12):2248-2258. doi:10.1016/j.mayocp.2022.09.002

[60] Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among American surgeons. *Ann Surg*. 2010;251(6):995-1000. doi:10.1097/SLA.0b013e3181bfdab3

[61] Khullar D. Burnout, Professionalism, and the Quality of US Health Care. *JAMA Health Forum*. 2023;4(3):e230024. doi:10.1001/jamahealthforum.2023.0024

[62] Hendrich A, Chow MP, Skierczynski BA, Lu Z. A 36-hospital time and motion study: how do medical-surgical nurses spend their time?. *Perm J*. 2008;12(3):25-34. doi:10.7812/tpp/08-021

[63] Physician Burnout. Agency for Healthcare Research and Quality. https://www.ahrq.gov/prevention/clinician/ahrq-works/burnout/index.html

authorization forms weekly,[64] the average oncology office having 6 full time staff to manage prior authorization,[65] while an internal survey of an academic dermatology department found that 6.6% of all visits generated a prior authorization.[66] With prior authorization long a topic of policy consternation resulting in the introduction of legislation to implement gold card programs[67] and CMS rulemaking,[68] AI and automation offer the potential to reduce clinician and patient burdens, improving productivity. For example, AI could automate data submission for clinicians, while for health plans at the first level of review where there are clear guidelines, algorithms could be utilized for *approval*. Eventually, frictions in the prior authorization process could be reduced through automation allowing near real-time adjudication during a clinical visit for the first layer of review, freeing up clinicians and health plan employees to focus on either patient care or more complex care management decisions.

Automation and AI can also drive efficiency and good governance for large public benefits programs such as Medicaid. Functions that are not inherently governmental functions can be undertaken by contractors instead of by governmental personnel, as defined by the Federal Activities Inventory Reform Act of 1998, the Office of Management and Budget Circular A-76, and the recent Office of Procurement Policy (OFPP) Policy Letter 11-01.[69] Agencies undertake 2 tests, specifically (1) the nature of function test (i.e. exercise of sovereign power is inherently governmental) and (2) exercise of discretion test. In the context of Medicaid, the procedural determination of Medicaid eligibility and redetermination are ripe for intervention.[70]

There is bipartisan frustration with Medicaid enrollment and eligibility determinations. Recent rules target administrative barriers to entry,[71] while others emphasize the role that eligibility plays in improper payments, where it accounts for account for 73.7% or >$61 billion 2022.[72] Regardless of one's perspective, these challenges highlight the need for process improvement. As part of the 2020 Families First Coronavirus Response Act, Congress increased the federal Medicaid matching funds by 6.2% if states implemented continuous Medicaid coverage for enrollees, with redetermination starting on April 1, 2023. With redetermination for over 20 million Americans ongoing,[73] both initial eligibility and redetermination offer an opportunity to deploy AI and automation, as eligibility is defined in statute leaving little discretion.

Other use cases such as a fraud detection, long a concern in both Medicare and Medicaid, with CMS noting that the improper payment rate in Fee For Service Medicare was 7.38% or $31.2 billion, contrasting with $16.6 billion or 6.01% in Part C.[74] Improving payment accuracy, eligibility, and redetermination all offer an opportunity to reduce fraud, waste and abuse while ensuring that Americans who need these programs can continue to benefit from them.

---

[64] Survey quantifies time burdens of prior authorization. American Medical Association. Published January 30, 2017. Accessed July 10, 2023. https://www.ama-assn.org/practice-management/prior-authorization/survey-quantifies-time-burdens-prior-authorizationc

[65] Lin NU, Bichkoff H, Hassett MJ. Increasing Burden of Prior Authorizations in the Delivery of Oncology Care in the United States. *J Oncol Pract*. 2018;14(9):525-528. doi:10.1200/JOP.18.00428

[66] Carlisle RP, Flint ND, Hopkins ZH, Eliason MJ, Duffin KC, Secrest AM. Administrative Burden and Costs of Prior Authorizations in a Dermatology Department. *JAMA Dermatol*. 2020;156(10):1074-1078. doi:10.1001/jamadermatol.2020.1852

[67] Congressmen Gonzalez and Burgess Re-Introduce Bipartisan Bill to Improve Care for Medicare Recipients. Press Release. Office of Congressman Vicente Gonzalez Representing the 34th District of Texas. August 2, 2023. https://gonzalez.house.gov/media/press-releases/congressmen-gonzalez-and-burgess-re-introduce-bipartisan-bill-improve-care

[68] CMS Interoperability and Prior Authorization Final Rule CMS-0057-F. Centers for Medicare & Medicaid Services. January 17. 2024. https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

[69] Definitions of "Inherently Governmental Function" in Federal Procurement Law and Guidance. Congressional Research Service. December 23, 2014. https://www.everycrsreport.com/files/20141223_R42325_ba76864808b1cfc5b92720461b225702a81ac71d.pdf

[70] Cho T, Miller BJ. Using artificial intelligence to improve administrative process in Medicaid. *Health Aff Sch*. 2024;2(2):qxae008. Published 2024 Jan 29. doi:10.1093/haschl/qxae008

[71] Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes Final Rule Fact Sheet. Centers for Medicare & Medicaid Services. March 27, 2024. https://www.cms.gov/newsroom/fact-sheets/streamlining-medicaid-childrens-health-insurance-program-and-basic-health-program-application

[72] 2022 Medicaid & CHIP Supplemental Improper Payment Data. Centers for Medicare & Medicaid Services. November 2022. https://www.cms.gov/files/document/2022-medicaid-chip-supplemental-improper-payment-data.pdf-0

[73] Medicaid Enrollment and Unwinding Tracker. Kaiser Family Foundation. May 23, 2024. https://www.kff.org/report-section/medicaid-enrollment-and-unwinding-tracker-national-federal-unwinding-and-enrollment-data/

[74] Fiscal Year 2023 Improper Payments Fact Sheet. Centers for Medicare & Medicaid Services. November 15, 2023. https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2023-improper-payments-fact-sheet

3. **Policies to promote the development of new science and new innovation**

Policymakers have multiple policy options to promote the use of automation and AI to drive productivity gains in health care delivery. First, policymakers should look to facilitate bottom-up innovation from clinicians and engineers by both streamlining and strengthening FDA oversight. Within FDA product review centers AI can be deployed to undertake basal first layer analysis of clinical trial data, both speeding upon pharmaceutical product and medical device review while allowing FDA staff to undertake more complex analytical questions. Policymakers should consider requiring the FDA to hold public workshops, integrate innovators' and entrepreneurs' feedback, and subsequently issue a strategic plan delineating steps (e.g. guidance, NPRM) to operationalize key regulatory principles in FDA discussion papers on distributed manufacturing and point-of-care manufacturing of drugs (which could reduce product costs for consumers),[75] AI in drug manufacturing,[76] AI in drug and biological products,[77] and uses of AI in medical product centers.[78] In order to both facilitate innovation, the FDA should also delineate areas of device and drug development where applications of AI do not require oversight or necessitate minimal oversight, in accordance with the FDA's own stated principles of risk-based regulation and least burdensome principles.[79]

Recognizing that liability concerns may present barriers to adoption, the FDA should work with entrepreneurs, physicians, patients, and engineers to explore the potential of performance-based regulation for software-driven medical devices and pure software as a medical device. Voluntary alternative pathways[80] in addition to (not in place of) traditional 510(k) and premarket approval (PMA pathways) for FDA approval would strengthen and provide FDA oversight flexibility for a rapidly evolving marketplace. Recognizing that AI and software exist on a rapid cycle improvement model as opposed to discrete innovation in traditional devices, performance-based regulation would promote pragmatic innovation emerging from the exam room and hospitals.

Clinical evidence of safety and efficacy could be generated in a variety of ways, such as meeting technical consensus standards derived from standards development organizations, testing in an accredited third party lab, substantial equivalence, modeling simulations, and other mechanisms. As a first step, policymakers could require the FDA to convene stakeholders and undertake a public workshop to explore best practices in performance-based regulation for medical software. Doing so would build on prior work to adapt the risk-based device regulatory framework such as the predetermined change control software,[81] software as a medical device (SaMD),[82] and precertification program.[83] These actions would facilitate rapid cycle innovation, promoting both stacked incremental innovation and revolutionary innovation.

Recognizing the problems with excessive centralization of standards, clinical evidence of safety and efficacy should be driven by scientific and clinical appropriateness coupled with innovator preferences, and not be tied to any single third party standards organization. The Government Accountability Office (GAO) has long highlighted the problems with standards and certification monopolies, with a 2004 GAO report[84] highlighting challenges with the Joint Commission's certification process to ensure that hospitals meet the Medicare Conditions of Participation, resulting in Congress revoking the Joint Commission's certification monopoly in 2008 as part of the Medicare Improvements

---

[75] Distributed Manufacturing and Point-of-Care Manufacturing of Drugs. U.S. Food & Drug Administration. October 2022. https://www.fda.gov/media/162157/download?attachment

[76] Artificial Intelligence in Drug Manufacturing. U.S. Food & Drug Administration. 2023. https://www.fda.gov/media/165743/download?attachment

[77] Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products. U.S. Food & Drug Administration. https://www.fda.gov/media/167973/download

[78] Artificial Intelligence & Medical Products: How CBER, CDER, CDRH, and OCP are Working Together. U.S. Food & Drug Administration. March 2024. https://www.fda.gov/media/177030/download

[79] The Least Burdensome Provisions: Concept and Principles. U.S. Food & Drug Administration. February 5, 2019. https://www.fda.gov/media/73188/download

[80] Cho T, Gowda V, Schulzrinne H, Miller BJ. Integrated Devices: A New Regulatory Pathway to Promote Revolutionary Innovation. *Milbank Q*. January 22, 2024. doi:10.1111/1468-0009.12692

[81] Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions. U.S. Food & Drug Administration. April 3, 2023. https://www.fda.gov/media/166704/download

[82] Software as a Medical Device (SAMD): Clinical Evaluation. U.S. Food & Drug Administration. December 8, 2017. https://www.fda.gov/media/100714/download

[83] Digital Health Software Precertification (Pre-Cert) Pilot Program. U.S. Food & Drug Administration. September 26, 2022. https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program

[84] CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals. U.S. Government Accountability Office. July 2024. https://www.gao.gov/assets/gao-04-850.pdf

for Patients and Providers Act of 2008. The FDA would benefit from additional Congressional oversight to ensure that a single standards development organization does not control AI product development.

Finally, and most importantly, payment policy must deploy automation and AI-driven care to promote competition and lower costs. CMS should not create additional standards for AI tied to Medicare Conditions of Participation,[85] noting that product liability, medical malpractice, state hospital licensing, and finally existing conditions of participation require a lengthy list of quality and safety management programs, which already encompass and address many of the risks of the deployment of software and AI products. Further regulations tied to conditions of participation would restrict access to AI innovation and undermine the FDA's role as a science-based product regulator, thus depriving patients and clinicians of meaningful and tangible productivity improvements.

Instead, policymakers should work to shape the Medicare program to pay for new technology by driving competition. Ideally beneficiaries will be able to choose by which modality to safely and conveniently access care:

1. Audio only
2. Audio/video
3. Audio/video with a remote, technology-assisted exam
4. Automated/AI-driven service either remote or in-person
5. Technology-augmented in-person, human capital-driven medical service
6. Human-driven, in-person service

While Medicare Advantage–the managed care version of Medicare–has the flexibility to cover additional services, policymakers must ensure that beneficiaries in fee for service (FFS) Medicare have equal access to innovative technologies that expand access and lower cost.

Recent history reminds us of the challenges of avoiding innovation, where concerns about induced demand and fraud, waste, and abuse collectively prevented us from meaningfully covering and paying for telehealth for over 20 years. With the Medicare Payment Advisory Commission denoting that over 5 million Medicare beneficiaries using telehealth in 2022 and practitioners developing specialization,[86] telehealth has finally begun to become a routine part of care, a change unfortunately forced by a global pandemic.[87]

Policymakers should avoid repeating this mistake and promote tiered payment for automated/AI-driven service. For example, a modifier that serves as a multiplier could be added to the physician fee schedule in order to reflect resource intensity, varying with the service in question (e.g. 0.1 for audio-only service, 0.5 for automated/AI-driven service, and 1.0 for human-driven, in-person service). This would promote competition between software developers, physicians, and health systems to find the most patient-centric and efficient way to deliver services.

4. Conclusions

Both patients and clinicians are tired of inefficient and expensive care delivery and administration. Statistics enumerate this story well, with the median Emergency Department wait time of 330 minutes in the District of Columbia[88] to a median wait time of 51 days to see a nephrologist at a hospital in North Carolina[89] to 25 years without labor productivity growth. There is more than enough room to use automation and AI to drive efficiency gains.

Together we can deploy AI And automation to cure Baumol's cost disease–a chronic condition that is killing our economy–in healthcare. Policymakers should ensure that regulatory policy facilitates the use of automation and AI, encouraging bottom up innovation from the exam room to ensure that innovation has a chance to augment and automate elements of clinical practice. AI can also improve administrative efficiency reducing waste through

[85] Facilitating Responsible Governance of Healthcare AI Tools: Testimony presented to the U.S. Senate Committee on Finance, February 8, 2024. https://www.finance.senate.gov/imo/media/doc/02082024_mello_testimony.pdf

[86] O'Donnell B & Tabor L. Telehealth in Medicare: Status Report. MedPAC. April 11, 2024. https://www.medpac.gov/wp-content/uploads/2023/10/Telehealth-April-2024-SEC.pdf

[87] Lee JS, Bhatt A, Pollack LM, et al. Telehealth use during the early COVID-19 public health emergency and subsequent health care costs and utilization. *Health Aff Sch*. 2024;2(1):qxae001. doi:10.1093/haschl/qxae001

[88] Bean M. ED visit times, by state. *Becker's Hospital Review*. February 1, 2024. https://www.beckershospitalreview.com/rankings-and-ratings/ed-visit-times-by-state.html

[89] Schettini P, Shah KP, O'Leary CP, et al. Keeping care connected: e-Consultation program improves access to nephrology care. *Journal of Telemedicine and Telecare*. 2019;25(3):142-150. doi:10.1177/1357633X17748350

simplifying prior authorization for patients and physicians or addressing Medicaid improper payments. The FDA can facilitate innovation, while avoiding the ills of standards monopolies and the government placing its finger on the scales of competition. Policymakers can also empower CMS to pay for automation, promoting service delivery innovation and competition. By promoting instead of fearing innovation and facilitating mechanisms to pay for safe and effective rapid cycle innovation, together we can improve our care delivery system.