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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 categories2 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.

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The absence of labor productivity growth has created a politically challenging combination of unsustainable spending—totaling $4.5 trillion—and growing at an average rate of 4.7% annually—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, and varying degrees of state-based occupational regulation of the health professions, 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, 68,020 primary care physicians by 2036, and 21,150 adult psychiatrists by 2030 within the next decade just to name a few, all worsened by the recent COVID-19 pandemic amongst other factors driving burnout. With Medicare and Medicaid expenditures growing at 5.9% and 9.6% year over year, the total challenging combination of unsustainable spending—totaling $4.5 trillion—and growing at an average rate of 4.7% annually—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, and varying degrees of state-based occupational regulation of the health professions, 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, 68,020 primary care physicians by 2036, and 21,150 adult psychiatrists by 2030 within the next decade just to name a few, all worsened by the recent COVID-19 pandemic amongst other factors driving burnout. With Medicare and Medicaid expenditures growing at 5.9% and 9.6% year over year.
respectively and comprising 15% and 13% respectively of the federal budget, crowding out discretionary spending, and industry stakeholders suggesting that we subsidize our way out of labor shortages 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 cutting spending and increasing taxes 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 and physician lobbies, while taxes reduce profits of individuals and businesses, both large and small, thereby discouraging investment. 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. AI can be defined amongst multiple frames of reference, including system type, types of intelligence, or mechanism of learning:

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<th>System Type</th>
<th>Types of Intelligence</th>
<th>Learning</th>
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<tr>
<td>Reactive</td>
<td>Artificial Narrow Intelligence</td>
<td>Reinforcement Learning</td>
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<tr>
<td>Limited Memory</td>
<td>Artificial General Intelligence</td>
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<td>Theory of Mind</td>
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<td>Self-Aware AI</td>
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<td>Artificial Intelligence</td>
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Figure 2: Definitional framings for AI

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 concerns42 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 cancer48 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 frontline 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 cytology51 to interpretation of electroencephalograms52 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.

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 an insulin pump tied with a continuous glucose monitor with dosing driven by algorithms, tested first in small groups and in broader populations including young children 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, hypertension, 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 frequently driven by administrative tasks and burnout driving quality losses, 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, 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, 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

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authorization forms weekly, the average oncology office having 6 full time staff to manage prior authorization, while an internal survey of an academic dermatology department found that 6.6% of all visits generated a prior authorization. With prior authorization long a topic of policy consternation resulting in the introduction of legislation to implement gold card programs and CMS rulemaking, 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. 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.

There is bipartisan frustration with Medicaid enrollment and eligibility determinations. Recent rules target administrative barriers to entry, while others emphasize the role that eligibility plays in improper payments, where it accounts for account for 73.7% or >$61 billion 2022. 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, 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. 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.

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
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),55 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 pathways80 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 report84 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

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,\(^\text{85}\) 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,\(^\text{86}\) telehealth has finally begun to become a routine part of care, a change unfortunately forced by a global pandemic.\(^\text{87}\)

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\(^\text{88}\) to a median wait time of 51 days to see a nephrologist at a hospital in North Carolina\(^\text{89}\) 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](https://www.finance.senate.gov/imo/media/doc/02082024_mello_testimony.pdf)


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.