Documents for the Record – 01/31/2024 HE Hearing

Majority:

- January 30, 2024 Letter from the American Association of Nurse Anesthesiology
- January 30, 2024 Letter from the American Society of Health-System Pharmacists
- January 30, 2024 Letter from the Federation of American Hospitals
- January 31, 2024 Letter from the HR Policy Association & American Health Policy Institute
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American Association of
NURSE ANESTHESIOLOGY

Written Statement for the Record by:

Dru Riddle, PhD, DNP, CRNA, FAAN
President
American Association of Nurse Anesthesiology

House Committee on Energy & Commerce
Subcommittee on Health hearing
"Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers"

2125 Rayburn House Office Building
Washington, DC 20515

January 31, 2024

Introduction

Chairman Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, thank you for the opportunity to offer this statement for the record. The American Association of Nurse Anesthesiology (AANA) is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, representing more than 61,000 CRNAs and student nurse anesthetists. CRNAs are advanced practice registered nurses (APRNs) and are the sole anesthesia providers in nearly all rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

We applaud the House Energy & Commerce Subcommittee on Health for its leadership in holding this hearing on "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers." This hearing highlights an important discussion of the need to rein in healthcare costs and make the system more affordable for everyone.

There is no doubt there are many factors that contribute to the ongoing growing costs of healthcare within the United States. Any attempt to lower costs and improve the efficiency of healthcare delivery will require across-the-board solutions and input from all stakeholders. We must address issues from education, to practice barriers, to competition within the healthcare market.

Unfortunately, over the last few years, a series of events and conditions have significantly and negatively impacted the healthcare workforce. Burnout and stress have led scores of healthcare practitioners to leave the healthcare workforce early, leading to workforce shortages that impact patients across the country.[1] There is also an impending anesthesia labor shortage, which is expected to continue to 2027.[2] Continued cuts to the Physician Fee Schedule, which have drastically affected anesthesia reimbursement, impeding access to care particularly in rural and underserved areas where CRNAs are the primary providers of anesthesia.[3,4] The decision by the Centers for Medicare & Medicaid Services (CMS) to end numerous waivers that were put in place for three years during the public health emergency (PHE) renewed unnecessary restrictions to care that proved extraneous, inefficient, and costly to patients.[5]

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[1] "A Worrisome Drop In The Number Of Young Nurses", Health Affairs Forefront, April 13, 2022. DOI: 10.1377/forefront.20220412.311784

[2] Negrusa et al 2021., Anesthesia Services: A Workforce Model and Projections of Demand and Supply. Nursing Economic$, 39(6), 275–284.

[3] Pollack, Rick. "Proposed Medicare Cuts Jeopardize Access to Care for Patients and Communities." The Hill. 07/02/23. https://thehill.com/opinion/congress-blog/4078385-proposed-medicare-cuts-jeopardize-access-to-care-for-patients-and-communities/

[4] Liao, C.J., Quraishi, J.A., & Jordan, L.M. (2015). Geographical Imbalance of Anesthesia Providers and its Impact On the Uninsured and Vulnerable Populations. Nursing economic$, 33 5, 263-70 .

[5] CMS. "CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency." https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf

The need to address increasing healthcare costs is critical. AANA strongly believes that any successful effort to rein in costs will require a multitude of solutions to address various factors at play in the healthcare market, and a willingness to challenge the status quo in our healthcare system.

Addressing Workforce Inefficiency and Increasing Competition

While it is increasingly urgent to take steps to address the demand for more healthcare workers, any effort to expand the pipeline will necessarily take time before producing results. In the meantime, Congress must take steps to more efficiently utilize the current healthcare workforce to broaden access, increase competition, and drive down costs for consumers and facilities. Removing unnecessary barriers to care for the current healthcare workforce will allow all providers to work to the top of their education and training.

Medicare's supervision requirement for CRNA services continues to be an unnecessary barrier to care that only drives up costs and impedes access to care. The Medicare requirement is more stringent than the laws of 43 states, which do not require supervision of CRNA services in their Nurse Practice Act, board of nursing regulations, medical practice acts, board of medicine rules, or their equivalent. As such, the Medicare supervision requirement is an unnecessary burden to care and cost driver in most states. Medicare's supervision requirement is the only known requirement that CMS has an opt-out option for and for which no other Medicare Part B provider is subject to, which proves that supervision regulations are an entirely unnecessary bureaucratic burden.

To date, 24 states have opted out of Medicare's supervision requirement for CRNA services, a growing trend in recent years of states seeking to remove these unnecessary barriers to patient care.[6] During the PHE, CMS waived the CRNA supervision requirement for three years, and during this time, there have been no documented cases of lapses in the quality of care.[7] In contrast, seven of the 24 states opted out during the PHE period and to date, no state that has opted out has reversed that decision. Multiple peer-reviewed studies have shown that supervision

[6] AANA. June 15, 2023. "Delaware Opts Out of Physician Supervision of CRNAs." PR Newswire. https://www.prnewswire.com/news-releases/delaware-opts-out-of-physician-supervision-of-crnas-301852470.html
[7] CMS. "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers." https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

of CRNAs does not improve patient outcomes.[8,9,10,11,12] **In light of all the evidence and the growing movement at the state level, we strongly urge Congress to permanently remove the supervision restriction within Medicare to more efficiently utilize the current anesthesia workforce.**

Data also shows that CRNAs working autonomously to deliver anesthesia is the single most cost-effective method of anesthesia delivery.[13] This requirement prevents facilities from using the anesthesia model that works best for them. Further, supervision results in unnecessary redundancies that increase costs to the system, especially in light of the fact that physician anesthesiologists are among the top ten highest paid physician specialties.[14]

Removing barriers to care is supported by a litany of outside organizations across the political spectrum that recognize the need to make reforms that put patients first and make healthcare delivery more efficient. H.R. 2713, the *Improving Care and Access to Nurses* (ICAN) *Act* would remove arbitrary supervision requirements for CRNAs in Medicare and address many outdated barriers to care for all APRNs. The legislation has bipartisan support, and is endorsed by the AARP, LeadingAge, Americans for Prosperity, National Association of Rural Health Clinics, National Rural Health Association, and the Progressive Policy Institute, as well as over 235 national, state, and local organizations. **We urge Congress to pass the ICAN Act and remove these unnecessary barriers to care, to immediately increase efficiency and lower costs for patients.**

Address Cuts to the Physician Fee Schedule

For the last few years, cuts to the Physician Fee Schedule (PFS) have hit the anesthesia conversion factor, continuing to lower the reimbursement for anesthesia services. This comes at a time when we have faced record high inflationary pressures. The most recent PFS, that went into effect on January 1, 2024, cuts reimbursement for anesthesia by 3.37%, a continuation of

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[8] Negrusa, Brighita PhD; Hogan, Paul F. MS; Warner, John T. PhD; Schroeder, Caryl H. BA; Pang, Bo MS. Scope of Practice Laws and Anesthesia Complications: No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications. Medical Care 54(10):p 913-920, October 2016. | DOI: 10.1097/MLR.0000000000000554

[9] Brian Dulisse and Jerry Cromwell. August 2010. No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians Health Affairs 2010 29:8, 1469-1475

[10] Needleman, J., & Minnick, A. F. (2009). Anesthesia provider model, hospital resources, and maternal outcomes. Health services research, 44(2 Pt 1), 464–482. https://doi.org/10.1111/j.1475-6773.2008.00919.x

[11] Simonson, Daniel C.; Ahern, Melissa M.; Hendryx, Michael S.. Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery: A Retrospective Analysis. Nursing Research 56(1):p 9-17, January 2007.

[12] Beissel D. E. (2016). Complication Rates for Fluoroscopic Guided Interlaminar Lumbar Epidural Steroid Injections Performed by Certified Registered Nurse Anesthetists in Diverse Practice Settings. *Journal for healthcare quality : official publication of the National Association for Healthcare Quality*, *38*(6), 344–352. https://doi.org/10.1111/jhq.12093

[13] The Lewin Group. May 2016. "Update of Cost Effectiveness of Anesthesia Providers." https://www.lewin.com/content/dam/Lewin/Resources/AANA-CEA-May2016.pdf

[14] Haeffele, Paige. April 14, 2023. "Average Physician Salary Across 29 Specialties, Ranked."

multiple prior years of cuts.[15] Decreased reimbursement, partnered with sky-high inflation, is putting pressure on providers and facilities that can make anesthesia less accessible and decrease competition within the anesthesia market.

The decrease in anesthesia reimbursement is particularly troublesome for rural and underserved populations and to the rural facilities that serve them. Without anesthesia services, hospitals and facilities are unable to offer critical services, including surgical and obstetrical care. Data from Chartis shows that 453 rural hospitals are at risk of closure, due to revenue drops and staffing issues.[16] If Congress does not address the ongoing cuts to anesthesia reimbursement in the PFS, and increase the pipeline, rural closures risk occurring, access will decrease, the market with consolidate, and costs will continue to rise. **It is critical that Congress eliminate the reimbursement cuts within the Physician Fee Schedule for 2024 and create a long-term solution to this problem.** AANA welcomes the opportunity to partner with the Committee on developing the contours of these solutions.

Conclusion

We appreciate the Subcommittee's attention to these important matters. Addressing the increasing cost of healthcare for patients and providers requires a multitude of solutions. Removing outdated and redundant barriers to care, expanding the pipeline for providers, and ensuring adequate reimbursement are all necessary steps to addressing healthcare costs. We look forward to continuing to work with the Subcommittee, the full Committee, and the entire Congress to enact common sense solutions that will put patients ahead of profits, make the healthcare workforce efficient and robust, and maintain the highest levels of safety.

Should you have any questions, please reach out to the AANA Federal Government Affairs team by contacting Matthew Thackston at mthackston@aana.com or Kristina Weger at kweger@aana.com.

[15] Coronis Health. November 13, 2023. "2024 Medicare Physician Fee Schedule: Impact on Anesthesia." https://www.coronishealth.com/blog/2024-medicare-physician-fee-schedule-impact-on-anesthesia/

[16] Chartis. 2023. "Rural Health Safety Net Under Renewed Pressure as Pandemic Fades." https://www.chartis.com/sites/default/files/documents/chartis_study_rural_health_safety_net_under_renewed_pressure_as_pandemic_fades.pdf

January 31, 2024

The Honorable Chairman Brett Guthrie
House Energy and Commerce Committee
Health Subcommittee
2434 Rayburn House Office Building
Washington, DC 20515

The Honorable Ranking Member Anna Eshoo
House Energy and Commerce Committee
Health Subcommittee
272 Cannon House Office Building Office Building
Washington, DC 20515

Re: January 31st Energy and Commerce, Health Subcommittee Hearing on Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers.

Dear Representatives Guthrie and Eshoo:

Thank you for holding this hearing on the growing cost of health care. The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies. Therefore, we want to highlight several areas that will save health care dollars, as well as proposals that may ultimately have a negative impact on patient care.

Proposals the Will Save Health Care Dollars:

Fully Utilizing Pharmacists as Providers: In its 2019 Interim Healthcare Study, the North Dakota Insurance Department notes that medication nonadherence and the related hospital admissions and emergency department visits are significant health care cost drivers.[1] Clinical pharmacists collaborate with physicians, nurses, and other healthcare professionals to provide safe and effective medication use and improve patient health outcomes while reducing workload burdens on other clinical staff.[2] Pharmacists are also a critical source of preventive care, such as vaccines and tests, in rural and underserved areas, helping patients avoid costly conditions like flu, RSV, and COVID-19. If pharmacists are recognized as Medicare providers, they would play a significant role in reducing these costs. We recommend swift action, such as the adoption of H.R. 1770, the Equitable Community Access for Pharmacists Services, that will provide these timely and reliable health care services provided by pharmacists.

Expanding Access to Biologics: Barriers to accessing biosimilars are raising health care costs. Despite a determination by the Food and Drug Administration (FDA) that a biosimilar has "no clinically meaningful differences" between the biological product and the reference product in terms of the safety, purity, and potency of the product. To be determined interchangeable, redundant switching studies must be performed, in which the clinical impact of switching between a reference product and the biosimilar are reviewed. These studies can delay a biosimilar coming to market and frustrate pharmacists' ability to substitute a biosimilar for a more costly reference drug, despite the determination that it is a safe and effective version of the medication.

[1] 20210108 ND Legislative Management Interim Healthcare Study-FINAL.pdf

[2] McFarland, MS, Nelson J, Ourth H, Groppi J and Morreale A. Optimizing the primary care clinical pharmacy specialist: Increasing patient access and quality of care within the Veterans Health Administration. J Am Coll Clin Pharm. 2020;3:494-50; Funk, K., Pestka, D., McClurg, M., Carroll, J., Sorensen, T. Primary Care Providers Believe That Comprehensive Medication Management Improves Their Work-Life. Journal of American Board of Family Medicine. 2019; 32(4): 462-473. doi: 10.3122/ jabfm.2019.04.180376.

We recommend elimination of the requirement for switching studies, making a biosimilar interchangeable with its reference product upon approval by the FDA. This will allow pharmacists to dispense these safe and effective products to patients for much less than their reference products.

Reining In Fees: Pharmacy fees have increased dramatically over the last few years, adding gratuitous costs to health care. According to data released by the Centers for Medicare and Medicaid Services (CMS), "performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 170 percent per year between 2012 and 2020 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates"[3] These fees were originally created to incentivize quality. However, they have become arbitrary in nature and purpose and quite extensive. For instance, many times the quality metric a pharmacy fee is based on is irrelevant to the setting and medical condition a drug is used to treat. Pharmacy fees are also usually unknown until a drug is dispensed and the claim adjudicated. Until recently, these fees were enforced retroactively, placing pharmacists in financial peril. While the retroactive collection of fees is expected to terminate based on CMS's recent ruling, vague administrative fees and unclear performance measures may not be impacted.[4] We recommend no administrative, prescription, quality, performance, or other care-related fees should be collected retroactively, but clearly outlined at the point of sale. We also recommend individual or group plans, and their PBMs, should be prohibited from enforcing pharmacy fees except when the quality measure on which a fee based is directly relates to the condition a patient is being treated and is appropriate for the setting in which the patient is being treated in. Lastly, we recommend any performance-related fee must be clearly outlined in scope and magnitude within the contract with a pharmacy, allowing pharmacies to properly forecast budgeting and understand expectations.

Proposal that will Negatively Impact Patients Care:

Site Neutrality: Site neutrality provisions would reimburse hospital outpatient departments that administer drugs to critically ill patients by lowering rates to the same level as physician and free-standing facilities. This would negatively impact patient care because hospitals are required to provide these services under specific standards which are intended to protect patient care (see chart below). We recommend Congress reject site neutrality proposals for drug administration that would negatively impact hospitals' ability to meet Joint Commission and USP requirements that protect patient care.

ASHP thanks you for holding this hearing and looks forward to working with you on these and other proposals to save health care dollars. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists

[3] Federal Register / Vol. 87, No. 89 / Monday, May 9, 2022 / Rules and Regulations; page 27834).
[4] *Id.*

REJECT SITE-NEUTRAL PAYMENT FOR LOWER STANDARDS OF INFUSION CARE

Infusion sites do not provide equivalent care. Hospital payment rates must be sufficient to support the higher standard of care that Centers for Medicare & Medicaid Services and other regulators require hospitals to meet for drug administration.

Site-neutral payment should apply only to infusion sites that meet the same rigorous standards for safe drug preparation, safe administration, care coordination, and oversight requirements as hospitals do.

	REQUIREMENTS	HOSPITAL	PHYSICIAN OFFICE	FREE-STANDING SITE
SAFE PREPARATION	Clean room with positive air pressure to prevent microbial contamination	✓	✗	✗
	Environmental sampling to ensure sterile conditions	✓	✗	✗
	Drug preparation supervised by a licensed pharmacist	✓	✗	✗
	Employee protections from exposure to hazardous drugs	✓	✗	✗
	Drug Supply Chain Security Act rules prevent use of counterfeit or mishandled drugs	✓	✗	✗
SAFE ADMINISTRATION	Drug barcoding and EHR integration reduce administration errors	✓	✗	✗
	Hospital pharmacist confirms safe dosing and checks for drug-drug interactions	✓	✗	✗
	On-site physician for prompt response to adverse reactions	✓	✓	✗
CARE COORDINATION	On-site pharmacy prevents delays accessing medication	✓	✗	✗
	On-site pharmacy can modify dosing on day of infusion based on therapeutic needs	✓	✗	✗
	Provides care for the most complex patients	✓	✗	✗
	Provides access to care 24 hours per day	✓	✗	✗
	Provides care to uninsured and underinsured patients	✓	✗	✗
SAFETY OVERSIGHT	Food and Drug Administration, state boards of pharmacy, U.S. Pharmacopeia, and The Joint Commission	✓	✗	✗

Charles N. Kahn III
President and CEO

STATEMENT

of the

Federation of American Hospitals

to the

U.S. House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

Re: "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers."

Wednesday, January 31, 2024

The Federation of American Hospitals (FAH) submits the following Statement for the Record in advance of the House Energy and Commerce (E&C) Health Subcommittee's hearing entitled *Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers*.

The FAH is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH appreciates the Subcommittee's leadership in exploring what factors are causing cost increases for patients, the health care sector, and for federal health programs such as Medicare and Medicaid. The FAH believes that to meaningfully address cost concerns in the health care system a holistic approach is necessary, encompassing a broad array of stakeholders including, among others, health care providers, payors, insurers, pharmaceutical manufacturers, medical device makers, and regulators.

Within the health care sector, hospitals are leaders in controlling costs. According to a recent report by CMS on National Health Expenditures,[1] U.S. health care spending grew by 4.1% to reach $4.5 trillion in 2022. Despite this overall growth, Medicare spending growth on hospital services was at its lowest level in 17 years at 2.2%, well below other parts of the health care sector, including prescription drugs (8.4%) and nursing care facilities (5.6%). This is despite the fact that hospitals are an aggregator of costs across the system with many different inputs when it comes to patient care, including the high cost of prescription drugs, food, medical equipment, and other services. The data are clear that hospitals are doing our part to bend the cost-curve.

To help further the Committee's goal of lowering health care costs, the FAH offers the following recommendations:

1) Reduce Excess Payments in Medicare Advantage

At MedPAC's January 2024 meeting, analysts presented data showing that Medicare Advantage practices regarding coding intensity and favorable patient selection will result in $353 billion in excess payments this decade alone compared to what spending would have been in Traditional Medicare. These excess payments have been on a steady rise since 2021, from $51 billion to an estimated $88 billion in 2024. MedPAC has previously issued a number of recommendations to address the underlying causes of coding intensity. With respect to how plans engage in favorable enrollee selection, staff referenced various tools MA plans deploy such as limited networks and prior authorization that could disincentivize seniors in their decision whether to select an MA plan or remain in traditional Medicare. Curtailing both of these practices would greatly lower health care costs and generate significant savings extending Medicare Trust Fund solvency for many years.

2) Maintain the Current Ban on Self-Referral to Physician-Owned Hospitals (POH)

To help keep health care spending under control, it is imperative that Congress continue to reject efforts to weaken the existing ban on self-referral to POHs. Such arrangements are mired in conflicts of interest, and years of independent data show such arrangements result in over-utilization of Medicare services at significant cost to patients and the Medicare program. It is for this reason, among others, that the FAH strongly opposes *The Patient Access to Higher Quality Health Care Act of 2023* (H.R. 977) and similar legislative proposals such as draft legislation recently circulated by Rep. Burgess.

There is a substantial history of Congressional policy development and underlying research on the impact of self-referral to POHs. The empirical record is clear that the conflicts of interest inherent in these hospital ownership arrangements promote unfair competition and result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns. The standing policy includes more than a decade of work by Congress, involving numerous hearings, as well as analyses and findings by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), Government Accountability Office (GAO), and Medicare Payment Advisory Commission (MedPAC).

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[1] National Health Expenditures 2022 Highlights (cms.gov)

Recently released data from the health care consulting firm Dobson | DaVanzo reinforced those findings, showing that POHs:

- Cherry-pick patients by avoiding Medicaid beneficiaries and uninsured patients;
- Treat fewer medically complex cases;
- Enjoy patient care margins 15 times those of community hospitals;
- Provide fewer emergency services—an essential community benefit; and,
- Despite POH claims of higher quality, are penalized the maximum amount by CMS for unnecessary readmissions at five times the rate of community hospitals.[2]

CMS itself recently reimposed "program integrity restrictions" on POH expansion criteria to guard against "a significant risk of program or patient abuse," and to "protect the Medicare program and its beneficiaries from overutilization, patient steering, and cherry-picking."[3]

3) Reduce Burnout and Eliminate Gaps in Health Care Workforce

Hospitals are investing heavily in both training and patient care management innovation to improve the bandwidth of registered nurses and reduce nurse workload burden. By allowing nurses to reduce paperwork and non-clinical responsibilities through technology and process enhancements, nurses can spend time more efficiently caring for patients and reduce inefficient workload and therefore are less likely to experience burnout.

Medicare Advantage (MA) prior authorization processes, for example, cause increased workload and administrative burden for clinicians. Recent polling found that nearly nine in ten nurses reported insurer-required administrative burdens have negatively impacted patient clinical outcomes, and nearly three-fourths reported an increase in administrative tasks over the last five years.[4] Congress could put patients over paperwork by passing the *Improving Seniors Timely Access to Care Act* (H.R. 3173) to automate and streamline the prior authorization process.

Another avenue for cost containment is allowing new workers in the health care sector by opening pathways for legal immigration from foreign countries. The downstream impact of reduced net legal immigration in recent years due to both policy and pandemic factors has increased labor costs for struggling hospitals and created enormous gaps in "unskilled" employment areas. There are an estimated two million fewer working-age legal immigrants in the US than there would have been if pre-pandemic levels were maintained[5]. These factors push hospitals to turn to nurse staffing agencies who engage in concerning and potentially anticompetitive conduct including price gouging, as was widely reported throughout the

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[2] Dobson | DaVanzo Study. (2023). https://www.fah.org/wp-content/uploads/2023/03/2023 FactSheetwAppendixandCharts_POH-vs.-NonPOH-Only.pdf.
[3] Centers for Medicare and Medicaid Services. (2023). Proposed Inpatient Prospective Payment System and Policy Changes. Retrieved from https://www.govinfo.gov/content/pkg/FR-2023-05-01/pdf/2023-07389.pdf
[4] *Costs of Caring - The Financial Stability of America's Hospitals and Health Systems Is at Risk as the Costs of Caring Continue to Rise.* (2023, April). American Hospital Association. https://www.aha.org/costsofcaring
[5] Sasso, M. & Bloomberg News. (2023, February 24). Where are the Workers: Labor Market Millions Short Post-Pandemic. *Governing*. https://www.governing.com/work/where-are-the-workers-labor-market-millions-short-post-pandemic

COVID-19 pandemic.

Federal legislative action is essential to help hospitals maintain a strong workforce, including:

- *The Conrad State 30 and Physician Access Reauthorization Act* (H.R. 4942) to improve and extend the existing program that allows international physicians trained in America to remain in the country if they practice in underserved areas.
- *The Healthcare Workforce Resilience Act* to recapture 25,000 unused immigrant visas for nurses and 15,000 unused immigrant visas for physicians that Congress has previously authorized and allocate those visas to international physicians and nurses.

In addition to immigration reform solutions, other actions include eliminating State Department bureaucratic delays and inefficiencies in immigration to allow foreign-trained qualified physicians and nurses to come to the US to fill vacancies unfilled by US workers.

4) Medical Liability Reform

Medical liability reform should be a critical component of any effort to reduce costs in health care. Billions of dollars are spent annually on defensive medicine to mitigate the risk of liability. The high costs associated with the current medical liability system harm hospitals and physicians, as well as patients and their communities. In December 2016, the Congressional Budget Office (CBO) scored comprehensive medical liability reforms (e.g., capping awards for noneconomic damages at $250,000 and punitive damages either at $500,000 or at twice the value of awards for economic damages, whichever is greater) as reducing the federal deficit by $62 billion.

These costs often force providers and physicians to move from states with high insurance costs or stop providing services that may expose them to a greater risk of litigation. This adversely impacts patients' access to important health care services. To help make health care more affordable and efficient, the current medical liability system must be reformed.

5) Encourage Responsible Use of Artificial Intelligence (AI) Tools to Improve Health Care

The responsible use of AI technology can both improve health care outcomes and address long-standing systemic issues that lead to increased cost in health care delivery.

For example, the administrative burden on health care providers and clinicians has been a significant impediment to improving efficiency in health care delivery. Physicians and nurses often spend between 30-50 percent of their time on documentation, payer authorization processes, and other administrative processes. Generative AI, in particular, is capable of becoming a tool to assist in documentation, searching for and summarizing patient information, generating communication (e.g., with payers) and supporting communication with patients and families. These use cases are lower risk (i.e., they do not rely on the AI to directly answer clinical questions or support diagnosis or treatment) but high value in the form of returning time

to the care teams so they can focus on patients, critical decision making, and improving the quality of care delivered.

As Congress considers approaches for regulating AI, we urge you to recognize that the health care sector has an existing set of risk management frameworks. Any AI regulatory requirements that conflict with existing risk management processes will slow down progress in realizing the benefits of technology and could inadvertently result in less effective risk management of complex health care systems and organizations.

Congress should consider an AI framework that is risk-based and focuses on processes to ensure algorithms are transparent, auditable, ethical, fair, non-biased, and safe – as this would provide health care stakeholders with the necessary information for responsible use similar to the *Health Insurance Portability and Accountability Act* (HIPAA). Unleashing this technology would undoubtedly result in a more cost-efficient health care system.

Thank you for taking our comments into consideration as you consider solutions to reduce health care spending. If you have any questions or would like to discuss these comments further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

STATEMENT FOR THE RECORD BY
HR POLICY ASSOCIATION AND THE AMERICAN HEALTH POLICY INSTITUTE
TO THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

"HEALTH CARE SPENDING IN THE UNITED STATES: UNSUSTAINABLE FOR PATIENTS, EMPLOYERS, AND TAXPAYERS"

JANUARY 31, 2024

The HR Policy Association (Association) and the American Health Policy Institute (Institute) appreciate the Committee holding this important hearing titled "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers." This issue is critically important for employers as rising costs directly impact the ability of employees and their families to access and receive affordable, high-quality health care.

The Association is the leading organization representing chief human resource officers of over 390 of the largest employers in the United States. Collectively, their companies provide health care coverage to over 20 million employees and dependents in the United States. The Institute, a part of the Association, examines the challenges employers face in providing health care to their employees and recommends policy solutions to promote affordable, high-quality, employer-based health care. The Institute serves to provide thought leadership grounded in the practical experience of America's largest employers.

More than half of Americans receive coverage via an employer: about 54.5 percent of U.S. residents—or 179.8 million people.[1] Large employers are committed to maintaining employer-sponsored health insurance (ESI) as an essential benefit for employees. However, employers and employees are facing serious affordability challenges that threaten the viability of this system if they are not addressed. One in four workers feel that they cannot afford their health care needs without causing financial hardship.[2]

The Association applauds Congress for passage of the Lower Costs, More Transparency Act which would enable employers to better manage their health care costs by increasing PBM and hospital price transparency. The opaque nature of the health care system has limited the ability of employers to manage their health care costs and this legislation is a step in the right direction in creating a more robust, competitive, and accountable health care industry.

[1] Census Bureau. https://www.census.gov/content/dam/Census/library/publications/2023/demo/p60-281.pdf
[2] Commonwealth: https://www.axios.com/2023/10/26/health-care-unaffordable-insurance

Without transparency legislation, employers, and the employees and dependents they cover, are often in the dark about the prices of health care services until after the service has been received. However, data alone will not transform the health care market. Those in the health care industry must commit to not only providing complete datasets but providing consumer-friendly datasets. The Association recognizes the increase in administrative burdens that reporting requirements may pose. Congress should work to ensure the administrative burdens are not so high that those in the health care industry work to avoid these transparency requirements or other reforms.

* * *

The HR Policy Association and the American Health Policy Institute welcome any opportunity to provide input and speak in further detail about improving the ability of employers to provide high-quality, affordable health care benefits to their employees and dependents. We commend the Committee for acting on the unsustainable increases in health care spending and believe the data provided through the Lower Costs, More Transparency Act will only better inform future legislation.

Sincerely,

Margaret Faso
Executive Director, American Health Policy Institute
Senior Director, Public Policy, HR Policy Association

AMERICAN ACADEMY OF FAMILY PHYSICIANS

January 31, 2024

The Honorable Brett Guthrie
Chairman
House Energy and Commerce Committee,
Health Subcommittee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
House Energy and Commerce Committee,
Health Subcommittee
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Guthrie and Ranking Member Eshoo:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 129,600 family physicians and medical students across the country, I write to thank the Subcommittee for its focus on addressing the high costs of health care in this country with today's hearing titled "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers." As the nation's only medical specialty group dedicated solely to primary care, the AAFP sincerely appreciates the Subcommittee's focus on this important issue and the forum to provide feedback.

Family physicians are uniquely trained to care for patients across the lifespan, regardless of gender, age, or type of problem, be it biological, behavioral, or social. They serve as a trusted first contact for health concerns with training to address most routine health care needs. The foundation of family medicine is primary care, defined as the provision of integrated, accessible health care services by physicians and their health care teams who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. **Primary care is person-centered, team-based, community-aligned, and designed to achieve better health, better care, and lower costs.**

Primary care is the only health care component where an increased supply is associated with better population health, more equitable outcomes, as well as lower mortality rates, leading the National Academies of Sciences, Engineering, and Medicine (NASEM) to call it a common good.[i] An increase of one primary care physician per 10,000 people is associated with an average mortality reduction of 5.3%, or 49 fewer deaths per 100,000 per year.[ii] Evidence clearly demonstrates that improving access to longitudinal, coordinated primary care reduces costs, improves utilization of recommended preventive care, and reduces hospitalizations. Yet the United States has continuously underinvested in primary care, which only accounts for a mere five to seven percent of total health care spending in the country.[iii]

The AAFP's Robert Graham Center, in collaboration with the Milbank Memorial Fund and the Physicians Foundation, released the nation's first primary care scorecard last year and found that primary care's share of the overall U.S. health care spend decreased from 6.2% in 2013 to 4.6% in 2020. This underinvestment in prevention and primary care is evidenced by U.S. health outcomes, with Organization for Economic Co-operation and Development (OECD) data indicating that we have

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higher rates of obesity, diabetes, and heart disease, and a larger share of the population with multiple chronic conditions.[iv]

Our existing federal policy and regulatory framework fails to recognize and promote the true value of primary care. As it stands now, we financially reward individual health care transactions and financially penalize long-term relationships between a patient and primary care team. **Decades of systemic underinvestment in primary care and prevention, coupled with overwhelming administrative burden, have led to poorer population health and a greater emphasis on rescue medical care, which is directly contributing to our nation's exorbitant health care spending**. It is with this in mind that the AAFP offers the following feedback on opportunities for federal policymakers to meaningfully invest in primary care to reduce health care expenditures while improving patients' access to care and outcomes.

Appropriately Paying for Primary Care

High quality, comprehensive primary care, by design, is intended to reduce health care spending and improve patient outcomes. **Therefore, Congress should advance and support efforts to meaningfully promote and bolster access to comprehensive, continuous, patient-centered primary care, including for Medicare beneficiaries.**

Unfortunately, fee-for-service (FFS), the dominant model of physician payment, fails to support primary care by consistently underinvesting in primary care services. Primary care spending lags in the U.S. compared to most other high-income countries.[v] Across payers, including both public and private insurance, primary care spending in the United States amounts to approximately five to eight percent of health spending across all payers, with an even lower percentage in Medicare, compared to approximately 14 percent of all health spending in most high-income nations. Nations with greater investment in primary care report better patient outcomes and lower health care costs.[vi] [vii] [viii]

The piecemeal approach FFS takes to financing primary care undermines and undervalues the whole-person approach integral to primary care. Across payers, physicians must document several unique screening codes, vaccine administration, other preventive services and counseling codes, an office visit, care management codes, integrated behavioral health codes, and several other services to justify payment for typical, comprehensive primary care, even though these services are all foundational parts of primary care.

For these reasons, the AAFP has long advocated to accelerate the transition to value-based care using alternative payment models (APMs) that provide prospective, population-based payments to support the provision of comprehensive, longitudinal primary care. As detailed in our comments on the Calendar Year 2024 Medicare Physician Fee Schedule (MPFS), we strongly believe that well-designed APMs provide primary care a path out of the under-valued and overly burdensome FFS primary care payment system that exists today, and in turn will better enable the Medicare program to meet the needs of its growing and aging beneficiary population.

While FFS is not the future the AAFP envisions for primary care, it is the present. Federal policymakers must ensure the current FFS system appropriately and sustainably compensates physicians to make more meaningful progress toward the future – one that rewards quality of care over volume of services. Specifically, **the Academy strongly urges Congress to consider legislative solutions, including reforms to the Medicare Access and CHIP Reauthorization Act (MACRA), and support positive policy changes that would address unsustainable FFS**

payment rates for physicians, promote patients' access to continuous, comprehensive primary care, improve health outcomes, and reduce federal health care spending.

This is why the AAFP, alongside 36 other organizations representing clinicians, patient advocates, and other health care stakeholders, applauded the Centers for Medicare and Medicaid Services (CMS) for finalizing their proposal to implement the add-on code known as G2211. As of January 1, 2024, G2211 is being billed alongside codes for office/outpatient evaluation and management (E/M) visits to better recognize the time, intensity, and practice expenses needed to meaningfully establish relationships with patients and address most of their health care needs with consistency and continuity.

Sustained continuity of care has been shown to improve quality and reduce health care spending by improving uptake of preventive services, increasing adherence to care plans for patients with chronic conditions such as diabetes, and decreasing hospitalizations and emergency department use overall.[ix] This add-on code is a needed investment in strengthening patient-clinician relationships by supporting clinicians' ability to foster longitudinal relationships, address unmet social needs, and coordinate patient care across the team. Evidence indicates increasing payments for these types of services reduce patient appointment wait times and supports the provision of services that improve patient health and can reduce costs.[x] [xi] [xii] The Academy greatly appreciates Congress allowing G2211 to be implemented. This is an incremental but meaningful step toward bolstering access to all the services that Medicare beneficiaries need and appropriately paying for the complex care that primary care physicians provide each and every day, with the likelihood to yield long-term health care savings.

However, **an across-the-board cut of 3.37% to Medicare payment for all services provided by physicians also went into effect on January 1, 2024**. This cut is undermining positive policy changes intended to promote investment in primary care and hamstringing CMS' ability to appropriately pay for all the services a patient needs**.** The AAFP, alongside the entire physician community, urges the Subcommittee and the rest of Congress to provide physicians with immediate relief from the full cut. **If Congress fails to act in a timely manner, patients across the country will further struggle to access care.** They are likely to face increased health care costs as they may be unable to see a clinician before their condition(s) are exacerbated or they will be forced to seek care in a more expensive setting, like the emergency department.

The Subcommittee and Congress must also act to address statutory budget-neutrality requirements and the lack of an annual inflationary update to physician payment, which together continue to hurt physician practices, slow the adoption of value-based payment models, accelerate consolidation, and jeopardize patients' access to care – all while increasing federal health care spending. In June 2023, the Academy submitted robust recommendations to the Subcommittee on ways to reform MACRA to address challenges affecting our members and their patients. We applaud the Committee for recently advancing the *Physician Fee Schedule Update and Improvements Act* (H.R. 6545) which would, among other things, provide relief from the zero-sum budget neutrality requirements by increasing the budget neutrality threshold and requiring timely updates to the direct costs used to calculate practice expense Relative Value Units (RVUs). The AAFP urges the Subcommittee to expeditiously consider additional, meaningful reforms to MACRA and Medicare physician payment.

Reimagining Graduate Medical Education

The U.S. faces a critical family physician workforce shortage, compounded by misalignment of resources in medical education, which has led to disparate access to care for patients nationwide. Though the current system excels at educating skilled physicians and physician researchers, **the primary care physician shortage prevents the U.S. from taking advantage of the better outcomes and lower per capita costs associated with robust primary care systems in other countries.**

Evidence indicates that physicians typically practice within 100 miles of their residency program[xiii], meaning that the current distribution of trainees in large academic hospitals also leads to physician shortages in medically underserved and rural areas. These shortages result in access barriers and disparities in health outcomes for patients living in rural and underserved communities.

The Academy encourages Congress to consider ways to reimagine our country's GME system so that it better supports and invests in primary care, including an expansion of training in community-based settings. This will bolster our primary care workforce for the future and allow us to realize the true value of primary care for generations to come, including significant cost savings and improved patient outcomes as we shift toward a system that prioritizes health care, rather than sick care.

The AAFP supports consistent funding for GME for family medicine to ensure that new residency slots are allocated to address rural and urban imbalances, reduce physician shortages, and focus on medically underserved areas, including funding for programs such as the Teaching Health Center GME (THCMGE) program.

The THCGME program has a proven track record of achieving its legislative mandate to train the next generation of primary care physicians. Since its inception in 2010, the program has trained more than 2,027 primary care physicians and dentists in community-based settings, 61% of whom are family physicians. THCGME graduates are more likely to continue practicing primary care and serving in medically underserved communities than those in traditional Medicare GME-supported programs.

The program's reauthorization has been extended to March 8, 2024 with the recently passed short-term continuing resolution. While the Academy continues to call on Congress to pass the *Doctors of Community (DOC) Act* (H.R. 2569) to provide permanent funding for and expansion of the program, we have also expressed strong support for the bipartisan *Lower Costs, More Transparency Act* (H.R. 5378) and applaud the House for passing this important legislation. The bill includes a seven-year reauthorization of the program and historic funding levels. Without stable federal funding, most THCs would be unlikely to maintain residency recruitment and enrollment, threatening the initial program investments and even the viability of the program itself.

Moreover, Congress should take additional steps to address disparate access to care in rural and other medically underserved areas. Merely expanding the existing Medicare GME system will not fix the shortage and maldistribution of physicians. **Any expansion of Medicare GME slots should be targeted specifically toward hospitals and programs in areas and specialties of need, including by considering which ones have a proven track record of training physicians who ultimately practice in physician shortage areas.**

One barrier to creating a more equitable and effective Medicare GME program is the lack of transparency in how funds are used. **Medicare is the largest single payer of GME, spending**

about $16 billion annually, but it does not assess how those funds are ultimately used or whether they actually address physician shortages.[xiv] CMS has indicated their authority is limited to making payment to hospitals for the costs of running approved GME residency programs. Congress should pass legislation granting the Secretary of the Department of Health and Human Services (HHS) and other relevant agencies authority to collect and analyze data on how (or if) Medicare GME positions are aligned with national workforce needs and publish an annual report.

Addressing Misaligned Incentives that Increase Health Care Costs

Site of service payment differentials also contribute to increased health care spending despite no demonstrated differences in the quality of patient care and outcomes. Currently, hospitals are directly rewarded financially for acquiring physician practices, freestanding ambulatory surgical centers, and other lower cost care settings. Medicare allows hospitals to charge a facility fee for providing outpatient services that can be safely performed in the ambulatory setting. Unfortunately, there is little evidence that these additional payments are reinvested in the acquired physician practice, many of which are primary care practices. Thus, the hospital increases its revenue by acquiring physician practices and beneficiaries are forced to pay higher coinsurance.[xv]

Medicare's increased payments for services performed in HOPDs does not just impact the Medicare program and beneficiaries, however. Private health plans generally use Medicare's payment system as a basis for how much they pay physicians and hospitals, meaning that this influences and directs spending and resources among commercial plans and patients. Therefore, **adopting comprehensive site neutral payment policies in Medicare would have significant impacts in saving money across the health care sector**, with one study estimating that it would lead to $471 billion in savings over the next 10 years.[xvi]

In terms of direct patient costs, Medicare patients collectively would save about $67 billion on Part B premiums and $67 billion on cost-sharing. Premiums for private health insurance plans would be about $107 billion lower over that period, which would amount to a reduction in aggregate premiums of 0.75%. Privately insured patients would also save about $18 billion on cost-sharing due to lower payment rates.[xvii]

The AAFP has long supported the advancement of thoughtful site neutral payment policies that would establish payment parity across care settings with careful consideration as to not unintentionally accelerate consolidation. We have called for an expansion of payment parity to all on-campus and off-campus hospital-based departments, as well as other facilities. We support reducing payment differences between sites of service since it enables patients to make more informed healthcare decisions by making costs more transparent and would reduce patient cost-sharing. As such, site neutral payment encourages patient choice based on quality rather than cost.

As noted previously, the AAFP has strongly supported the *Lower Costs, More Transparency Act* (H.R. 5378), which bipartisan leaders of the Energy and Commerce Committee have championed. We appreciate that it ensures payment for physician drug administration services will be the same in an off-campus hospital outpatient department (HOPD) as in a physician's office. We have urged Congress to swiftly pass this measure, while also continuing to advocate for additional action to build upon and advance more substantial site neutral payment policies.

The Academy also appreciates that the *Lower Costs, More Transparency Act* seeks to codify and increase compliance with existing hospital and insurer price transparency requirements, as well as to advance billing transparency by requiring off-campus HOPDs to use distinct National Provider

Identifiers (NPI). Improving transparency ultimately provides policymakers, researchers, and other stakeholders with a better understanding of the factors that are accelerating consolidation and increasing health care costs, and will better prepare them to respond and implement meaningful solutions.

Implementing Prior Authorization Reform

Medicare Advantage (MA) and Medicaid managed care organizations (MCOs) that use utilization management processes, such as prior authorization, frequently describe them as a cost-control mechanism. However, **repeated evidence has shown that many MCOs use prior authorization inappropriately, causing care delays and worsening patient outcomes and satisfaction**. A 2022 report from the HHS Office of Inspector General (OIG) confirmed that MA plans sometimes deny prior authorization and payment requests that meet Medicare coverage rules by using clinical criteria not in Medicare coverage rules and requesting unnecessary documentation, as well as making errors.

In addition to enrollees in MA plans, enrollees in other health plans needing care for their own chronic illness,[xviii] their children's chronic illness,[xix] and rare diseases[xx] have experienced barriers to care from prior authorization requirements. In 2022, California-based L.A. Care, which administers Medicaid and other types of coverage, failed to address a backlog of more than 9,000 prior authorization requests and more than 67,000 complaints or appeals.[xxi] Meanwhile, an OIG report published in July 2023 found that Medicaid MCOs denied one out of every eight prior authorization requests in 2019, yet minimal data collection on and oversight of these practices is being done by state Medicaid agencies.[xxii]

In an American Medical Association (AMA) survey of physicians, 94 percent reported that prior authorization delays access to care, while 80 percent reported that it led to patients abandoning their treatment and 33 percent reported that it had led to a serious adverse event for their patient. Additionally, **86 percent of surveyed physicians reported that prior authorization sometimes, always, or often leads to higher overall utilization of health care resources, such as additional office visits, emergency department visits, or hospitalizations**.

The AAFP has strongly supported Congressional efforts to streamline and implement prior authorization reporting requirements as a means to address some of the unrelenting administrative burden physicians are subject to and ensure better patient access to care. This includes endorsing the bipartisan *Improving Seniors' Timely Access to Care Act* that passed the House last Congress and would require implementation of an electric prior authorization program in MA, as well requiring MA plans to provide real-time decisions.

We applaud CMS' recent steps to proactively implement many of the provisions of this legislation through recently finalized rulemaking. However, Congressional action is still greatly needed to codify these requirements. **Congress should also consider requiring data collection and greater oversight by state Medicaid agencies on the use of prior authorization by Medicaid managed care plans**.

Promoting Utilization of Cost-Effective Interventions

As Benjamin Franklin said, "an ounce of prevention is worth a pound of cure." And prevention is an integral part of primary care. Every day, family physicians provide routine and lifesaving preventive health measures and interventions, such as immunizations, screenings for cancer or heart disease, and tobacco cessation counseling. To promote equitable utilization of cost-effective preventive care,

the AAFP believes that all health plans should provide first-dollar coverage for low-cost, high-value, evidence-based services such as recommended vaccines, screenings, and preventive medications.

Vaccines are one of the safest and most cost-effective public health technologies we have. Current adult vaccination coverage yields an estimated 65 million averted disease cases and $185 billion in averted case costs over a 30-year period.[xxiii] The COVID-19 pandemic was a real-time demonstration of the invaluable role that vaccines play in saving lives, when they are affordable and accessible. Yet each year, the United States spends $27 billion on four vaccine-preventable illnesses in adults over the age of 50: flu, pertussis, pneumococcal (pneumonia), and shingles.[xxiv]

This is in part due to remaining barriers that prevent many individuals from being able to readily access and receive all recommended vaccines in their physician's office. Medicare currently splits vaccine coverage between Part B (outpatient care) and Part D (prescription drug coverage). New vaccines, such as respiratory syncytial virus (RSV), are only covered under Medicare Part D, which was designed for pharmacies to submit claims and makes it particularly challenging for primary care physicians to deliver recommended vaccines in their office.

Approximately 8.5 million Medicare enrollees have Part B but not Part D coverage, leaving them without affordable access to Part D vaccines.[xxv] For those with Part D coverage, physicians can give patients a bill to submit to their Part D plan for reimbursement, but this forces patients to pay a potentially high out-of-pocket cost upfront, which creates barriers to access. There is an online clearinghouse that allows physicians to check Part D coverage and electronically submit an out-of-network Part D claim, but physicians must pay for this service by sharing a portion of their payment. Because of these barriers to administering the vaccine in-office, physicians can recommend or prescribe a Part D-only vaccine to a patient, who must then identify and secure a separate appointment at an in-network pharmacy on order to be vaccinated.

Legislative action is needed to ensure that physicians can easily provide all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines to Medicare beneficiaries. **The Academy urges Congress to pass legislation to require Medicare Part B coverage of all recommended vaccines, allowing beneficiaries to more readily access vaccines from their usual source of care and improving our nation's uptake of one of the most cost-effective public health measures.**

Reducing improper payments in federal health care programs

Overvaluation of global surgical codes: Under the MPFS, surgical services are billed and paid for using global codes that are valued to include most parts of a surgical episode of care. Depending on the service, some include preoperative appointments, the surgery itself, and various types of postoperative care. MACRA required CMS to collect data on how best to value global packages and to reassess every four years the continued need for this data collection.

As MACRA required, CMS began data collection in 2017, making 2023 the seventh year of data collection. As CMS' contractor, RAND, has reported, the data clearly show that the reported number of visits does not match what's expected based on the assumptions underlying the valuation of the 10 and 90-day global procedures. For example, only four percent of postoperative visits assumed in 10-day global surgical codes are provided.[xxvi] Thus, CMS continues to be concerned that its current valuations of the global packages reflect certain E/M visits that are not typically furnished in the global period. **In other words, there is strong evidence suggesting that the current RVUs for global**

packages are inaccurate in terms of the number and level of postprocedural visits involved and who is providing them when they do occur.

The zero-sum, budget-neutral nature of the fee schedule ensures any overvaluation of one part, such as the 10 and 90-day global packages, undervalues the remainder of the fee schedule, including primary care. The continued potential overvaluing of the 10 and 90- day global packages contributes to the MPFS' underinvestment in primary care. The AAFP believes the global period for all surgical services should be zero days. All surgical services with a longer global period, such as 10 or 90 days, should have their global period reduced to zero days and be revalued accordingly. Use of a zero-day global period facilitates more accurate valuation of surgical services.

In their most recent report, RAND outlined an alternative methodology for valuing the global surgical packages and estimated that it would result in more than $2.5 billion being returned to the Medicare conversion factor.[xxvii] **The AAFP has and will continue to encourage CMS and Congress to address the apparent overvaluation of these surgical packages given the negative impact of these overpayments on primary care and other non-surgical services under the MPFS.**

Overpayments to Medicare Advantage (MA) plans: CMS makes monthly payments to private payers who serve as MA organizations administering Medicare benefits to beneficiaries who enroll in their MA plan. The payment amounts are partially determined according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.

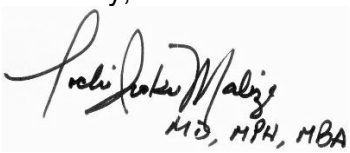
The AAFP recognizes that risk adjustments are important for ensuring payments to MA organizations accurately reflect patient complexity and support equitable access to coverage and care for patients. However, a growing body of evidence suggests that some MA organizations may be overly focused on recording health conditions that increase risk scores and therefore increase their monthly payments without a corresponding level of care documented for enrollees.[xxviii] [xxix] For example, plans have reported diagnosis codes that are not fully supported by patients' medical records, an indication that patients aren't receiving related or indicated care.[xxx]

This month, **the Medicare Payment Advisory Commission released new findings that project the federal government will overpay MA plans by $88 billion in 2024**.[xxxi] The AAFP is strongly supportive of comprehensive and accurate documentation of all patient's diagnoses and advises members that all coding should comply with the ICD-10-CM coding guidelines. If reports of overpayment are accurate, the AAFP is concerned that significant funding that could support broader, more equitable access to high-quality primary care is being diverted with no benefit to MA enrollees. **Congress could consider advancing policies to address incentives that create unintended consequences and ensure that payments to MA organizations contracted to administer benefits are benefitting MA enrollees with the delivery of high value services, including comprehensive, continuous primary care that can help to reduce health care expenditures in the long run.**

Additional guardrails should be considered to prevent MA organizations from failing to invest in and support the provision of high-quality primary care. Primary care practices continue to struggle with inadequate physician payment rates, staffing shortages, and overwhelming administrative burden. Additional payment cuts, costly system updates, and other downstream effects of these changes could further destabilize the primary care practices Medicare beneficiaries depend on.

Thank you for the opportunity to offer these recommendations. The AAFP looks forward to continuing to work with you to advance policies that ensure all Americans have access to quality affordable health care. Should you have any questions, please contact Natalie Williams, Senior Manager of Legislative Affairs at nwilliams2@aafp.org.

Sincerely,



Tochi Iroku-Malize, MD, MPH, MBA, FAAFP
Board Chair, American Academy of Family Physicians

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January 31, 2024

The Honorable Brett Guthrie
Chairman
Energy and Commerce Committee
Subcommittee on Health
Washington, D.C. 20515

The Honorable Anna Eshoo
Ranking Member
Energy and Commerce Committee
Subcommittee on Health
Washington, D.C. 20515

RE: Hearing, "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers"

Dear Chairman Guthrie and Ranking Member Eshoo:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments in advance of your hearing, "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers."

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC offers the following solutions to modernize the nation's healthcare system to both improve patient outcomes and reduce spending.

Transition to Patient-Centered, Value-Based Care

HLC believes Congress should further explore value-based care as a long-term way to improve patient outcomes while reducing costs by using dollars more efficiently. A value-based care system will improve healthcare quality and outcomes for patients. The shift to value-based care will require numerous changes in the way our healthcare system is structured and operates. This shift will enable consistent and efficient data collection, as well as communication among healthcare providers which will allow for better utilization of the healthcare workforce.

We urge Congress to enact H.R. 5013, the "Value in Health Care Act," bipartisan legislation that makes several important reforms to build on the successes of alternative payment models (APMs) and improve health equity and access to care. The bill extends the five percent advanced APM incentives and gives the Centers for Medicare & Medicaid Services authority to adjust APM qualifying thresholds so that the current one-size-fits-all approach does not serve as a disincentive to including rural, underserved, primary care or specialty practices in APMs. To allow more clinicians to continue the transition to value, the bill establishes a voluntary track for accountable care organizations in the Medicare Shared Savings Program to take on higher

levels of risk and provides technical assistance for clinicians new to APMs. The bill also removes revenue-based distinctions that disadvantage rural and safety net providers and improves financial benchmarks so that APM participants are not penalized for their own success.

Make CMMI More Effective

After over a decade of projecting that the models initiated by the Center for Medicare and Medicaid Innovation (CMMI) would reduce Medicare spending, the Congressional Budget Office (CBO) issued a recent report estimating that in its first decade of operation, CMMI's efforts had actually elevated federal spending by $5.4 billion between 2011 and 2020. Cost savings alone should not be the only factor to consider when evaluating the effectiveness and potential of CMMI. Two important takeaways from this report can enhance CMMI's work and lead to more successes moving forward.

First, we have already witnessed that CMMI can have its greatest impact in helping to transition the healthcare system from its traditional fee-for-service orientation to a value-based framework. Continuing this progress will lead to greater cost-efficiency within the system, while attaining positive patient outcomes, enhancing equity, and without undermining healthcare quality. In the years to come, this is where CMMI should focus the lion's share of its work, developing sustainable models that will achieve meaningful savings through patient-centered coordinated care and that have bipartisan support.

Second, it is critical to get health provider participation in innovative payment and delivery models. CBO also notes that CMMI "might achieve larger net budgetary savings in its second decade by drawing on the lessons from past models when designing new ones." We must ensure that providers' incentives to participate in the models are not outweighed by burdens of operating under the model. When new models create onerous burdens on those organizations that might otherwise want to engage, the result is lack of participation. As CBO pointed out in its report, there have been instances in which CMMI models have created inconsistent and even contradictory mandates for providers to follow, creating unnecessary paperwork and expense. Listening to health providers, being responsive to their concerns and ideas, and incentivizing them to participate in new demonstration projects is critical in CMMI's second decade. Mandatory participation models may seem the best approach for success (although MedPAC has noted some of the limitations and lack of evidence) but creating cost-effective voluntary models that are appealing to providers and their patients will yield more lasting results.

Providers with more value-based care arrangements fared better financially during the pandemic than those relying on fee-for-service volume-based arrangements. Legislation that helps focus CMMI's mission on driving toward value-based care should be considered as a way to improve CMMI's success as opposed to tying its hands.

Incorporate Preventive Health Savings into CBO's Modeling Approach

Improving access to preventive health services and factoring these investments into budget scoring are critical elements to reducing healthcare spending and improving patient health outcomes. Chronic diseases are responsible for 7 of 10 deaths among Americans each year, and they account for 90 percent of the $4.1 trillion our nation spends annually on medical care.[1]

We urge Congress to pass H.R. 766, the "Preventive Health Savings Act," which will allow Congress to more easily request CBO estimates of preventive health initiatives beyond the ten-year scoring window in order to capture potential long-term health savings in federal programs. Research has demonstrated that certain expenditures for preventive health interventions

[1] Health and Economic Costs of Chronic Diseases, Centers for Disease Control and Prevention (October 2023), https://www.cdc.gov/chronicdisease/about/costs/index.htm.

generate savings when considered in the long term, but those cost savings may not be apparent when assessing only the first ten years—those in the "scoring" window. This legislation will allow Congress to see the full savings of enacting prevention-focused policy measures and is an important step to addressing the chronic disease epidemic.

Make Telehealth and Acute Hospital Care at Home Waivers Permanent

Over the past several years, we have seen the value of telehealth in healthcare delivery, especially for vulnerable populations. HLC commends Congress for extending telehealth waivers through the end of 2024 and recommends building upon this foundation by removing the existing prohibitions under Section 1834(m) of the Social Security Act that prevents patients from receiving telehealth services where they are located. Limiting telehealth services to originating sites reduces patients' ability to receive important care in a setting they prefer. These care options recognize the infrastructure challenges many rural communities face and ensure these patients are not left behind in future care innovations. In considering these additional modes of care delivery, we encourage Congress to make certain that patients are not unduly burdened by additional hurdles to receive telehealth.

We also commend Congress for extending the Acute Hospital Care at Home waiver program that allows patients to receive acute care in the home. These tools have shown the ability to deliver high quality and lower cost care where the patient resides. We encourage Congress to make this waiver and the telehealth waiver permanent.

Modernize the Physician Self-Referral (Stark) Law and the Anti-Kickback Statute (AKS)

We encourage Congress to grant the Secretary of Health and Human Services greater authority to create new safe harbors and exceptions to existing AKS and Stark policies. The landscape of the healthcare sector is rapidly changing, and the impact of certain regulations is rarely predicted with complete accuracy. Additional flexibilities would recognize the significant challenges required to make effective revisions to the Stark Law or the AKS.

While it is important to ensure that financial relationships are only for the purpose of improving care, providers have struggled to comply with the Stark Law, given its imposition of a strict liability framework for all violations. Violations of the AKS are an intent-driven analysis, and we support Congress taking steps to harmonize the standard for violations to ensure providers who unintentionally violate the Stark Law are not unduly punished.

HLC applauds the broad approach to safe harbors that was ultimately adopted in the Office of the Inspector General (OIG) 2021 final rule, particularly the focus on connecting and ensuring all patients receive high quality care. However, we believe too much guidance has made them too difficult to abide by and largely ineffective. We have specific concerns with those measures taken to ensure equal access to services – while they are intended to prohibit discriminatory practices, in reality, restricting value-based entities from making different offerings based upon patient insurance type prohibits gifting targeted services to areas of greater need.

We also recommend lifting barriers currently in place and allowing all relevant stakeholders to fully participate in value-based arrangements without threat of legal repercussions. The AKS expressly excludes pharmaceutical and medical device manufacturers as well as laboratories from substantially all the newly created safe harbors in the 2021 final rule.[2] The exclusion of these stakeholders fails to recognize the extensive information sharing and individual care assistance they provide within the value-based ecosystem. Pharmaceutical and medical device

[2] Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment, Office of the Inspector General, U.S. Department of Health and Human Services (November 20, 2020), https://oig.hhs.gov/reports-and-publications/federal-register-notices/Ineligible-Entities-Chart.pdf.

manufacturers regularly work with providers in collecting data and assisting in tailored treatment plans so a patient can receive optimal care.[3] Additionally, a medical device manufacturer has the capability to work with a payer to streamline monitoring services of patients suffering chronic conditions – using their already in use devices to watch for any diagnostic changes. This collaboration requires extensive involvement with the manufacturer, payers, providers and patients.[4] Unfortunately, participating in any collaboration becomes unnecessarily risky without the safe harbors applying to manufacturers.

Measurable improvements to care coordination require significant interactions among patients, providers, and all other stakeholders. OIG's approach in determining which and how entities may participate in safe harbors fails to consider innovative ways that stakeholders can contribute to the care delivery process by applying new payment methods that encourage value-based arrangements.

Protect, Improve, and Invest in Medicare Advantage

We urge Congress to protect and invest in Medicare Advantage (MA), a popular program that a majority of seniors choose for their care and has been shown to reduce utilization and costs without sacrificing quality. Congress needs to ensure the incentives in MA support a robust healthcare delivery system that is patient-centered.

MA now serves over half (51 percent) of the Medicare-eligible population.[5] A recent Avalere Health analysis compared utilization, spending, and quality outcomes between MA and Medicare FFS beneficiaries with chronic conditions. MA beneficiaries had lower utilization rates of high-cost services such as inpatient stays and ER visits, and, regardless of condition, MA beneficiaries spent less overall on healthcare. The analysis found quality outcomes to be similar. Additionally, MA serves a higher proportion of beneficiaries with clinical and social risk factors as well a much higher percentage of beneficiaries who identify as a racial or ethnic minority (28.1 percent in MA vs. 12.8 percent in FFS).[6]

Realign Incentives for Efforts to Address Fraud, Waste, and Abuse

Fraud, waste, and abuse (FWA) are estimated to account for up to 10 percent of costs for health plans, and efforts to combat fraud and wasteful spending play a crucial role in ensuring that healthcare resources are directed towards actual patient care.[7] We believe Congress can make significant strides in reducing medical spending and improving patient care by recharacterizing FWA mitigation efforts costs as part of quality improvement rather than administrative functions.This reclassification would incentivize organizations to engage more actively in fraud prevention and waste reduction, ultimately leading to a more efficient, cost-effective, and patient-centered healthcare system.

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[3] Impact of Value-Based Care on the Medical Device Industry: Three Takeaways from the Case for Transformation, Ropes & Gray (September 7, 2017), https://www.ropesgray.com/en/newsroom/alerts/2017/09/Impact-of-Value-Based-Health-Care-Medical-Device-Industry-Three-Takeaways.

[4] Fred Donovan, Medical Technology Focuses on Patient Engagement, Care Coordination, HIT Infrastructure (June 24, 2019), https://hitinfrastructure.com/news/medical-technology-focuses-on-patient-engagement-care-coordination.

[5] Medicare Advantage in 2023: Enrollment Update and Key Trends, Kaiser Family Foundation ((August 2023), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/.

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[7] US Department of Justice, Health Care Fraud (January 21, 2020), https://www.justice.gov/archives/jm/criminal-resource-manual-976-health-care-fraud-generally

HLC and its member organizations stand ready to work with you to invest in innovative programs to improve patient outcomes while also reducing medical spending. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

Maria Ghazal
President and CEO

THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

STATEMENT FOR THE RECORD BY

THE ERISA INDUSTRY COMMITTEE (ERIC)

TO THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

"HEALTH CARE SPENDING IN THE UNITED STATES: UNSUSTAINABLE FOR PATIENTS, EMPLOYERS, AND TAXPAYERS"

January 31, 2024

Chairman Guthrie, Ranking Member Eshoo, and Members of the subcommittee, thank you for the opportunity to submit a statement for the record on behalf of The ERISA Industry Committee (ERIC) for the hearing entitled "*Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers*." We appreciate the subcommittee's interest in how the unsustainable rise of health care costs impacts employer benefits and employees' health, and look forward to working with you to find solutions that will make quality health care more affordable and accessible.

ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state, city, and Congressional district.

ERIC member companies offer comprehensive health coverage for employees, their families and retirees through self-insured plans governed by the Employee Retirement Income Security Act of 1974 (ERISA). They do so to attract and retain employees, to be competitive for human capital, to improve health and productivity, and to provide peace of mind. Large employers, like ERIC member companies, roll up their sleeves to improve how health care is delivered in communities across the country. They do this by developing value-driven and coordinated care programs, implementing employee wellness programs, providing transparency tools, and a myriad of other innovations that improve quality, reduce costs, and drive value for working families.

Below, we highlight the topline policy proposals ERIC urges you to consider to address the rising costs of health care for employees, their families, retirees, and employers. More than 179 million Americans receive health insurance from their employers, and employers can and should be important partners to help forge affordability solutions. ERIC looks forward to working with you on the following policy proposals identified by our member companies as key to this shared goal.

I. Transparency and Accountability Reforms

ERIC member companies believe transparency is integral both to reduce health care costs and improve quality of care. Health care costs for employers continue to rise at an unsustainable rate. To help mitigate these costs, Congress should significantly strengthen transparency in the health care system, thus giving rise to better care for patients, more competition, greater value, and improved quality and safety.

ERIC applauds the passage of the "*Lower Costs, More Transparency Act"* (LCMT, H.R. 5378) as an important step in addressing the need for greater health care transparency. Too many hospitals are still failing to meaningfully comply with the U.S. Department of Health and Human Services (HHS) regulations requiring them to make public standard charges, including negotiated rates. Notably, the legislation would enshrine in statute the requirement that hospitals publicly post the negotiated price for health care items and services in a machine-readable format and increase compliance with and enforcement of this requirement. And LCMT brings price transparency to other health care facilities that were left out of the transparency regulations. In addition, the legislation strengthens group health plan transparency in coverage requirements and makes important changes to facilitate better access by plan sponsors to much needed data.

While these policies are significant and necessary, we urge Members of Congress to continue to push forward on additional reforms to ensure optimal transparency. The more accurate, complete, accessible, and up-to-date the data is when shared with employer-sponsored health plans, the more plan sponsors may do to ensure not only their own compliance with current law and regulations, but also continued access to affordable, quality health care for the millions of workers who receive health coverage through employer-sponsored insurance. If Congress wants employers to be active purchasers who make changes and advocate on behalf of employees throughout the plan year, then employers need information about costs throughout the plan year – not just in an end-of-the-year summary.

Additionally, ERIC applauds the LCMT Act's pharmacy manager benefit (PBM) data reporting requirements, which are a positive step forward. However, commonsense accountability reforms that would hold PBMs accountable to fair market practices when partnering with employers are critical. PBM transparency, as with transparency across all health care stakeholders, remains one component of the goal to lower costs and ensure access to affordable, quality care. However, PBM transparency alone will not be enough to address the issues employers face in ensuring that people covered by employer-sponsored plans are truly receiving the best care at the best price. To that end, ERIC remains strongly supportive of the PBM accountability reforms contained in the "*Pharmacy Benefit Manager Reform Act"* (S. 1339) and supports additional policies to reorient the PBM industry away from deriving revenues via drug price arbitrage, and instead to delivering value for plans and patients.

II. Provider Consolidation and Unfair Pricing Practices

Health care provider market consolidation continues to rise, including mass purchase of provider practices by hospital systems. With such widescale consolidation comes great market power to demand higher prices. ERIC member companies are seeing the impact of this through enhanced pressures regarding provider contracting, as well as varying payment rates across sites of care for the same service performed by a provider.

There is no case for a laissez-faire approach to such egregious market failures. Immediate intervention is needed to preserve free markets in health care as they continue to spiral out of control leading to affordability concerns for employers and their workforce. The subcommittee should consider three ways it can help further the goal of discouraging consolidation and unfair pricing. This would include applying site-neutral policies in full across payment settings, requiring honest billing by providers to appropriately reflect services provided at the point of care, and fostering fairness in contracting practices.

A. Site Neutral Payments

By expanding site-neutral payment policies, Congress can remove a powerful incentive for hospitals to purchase physician practices in order to collect higher rates from rebranded off-campus hospital outpatient departments (HOPDs). We strongly support Section 203 of the LCMT Act, which ensures that Medicare rates for physician-administered drugs in off-campus HOPDs are the same as in physician offices. However, comprehensive site-neutral payment reforms are essential, and we urge Congress to take additional action to enact comprehensive site-neutral payment reform to additional services and facilities. Positive changes like this in the Medicare program provide a critical stepping stone to enable private payers to enact similar policies.

B. Improved Billing Requirements

Provider consolidation has also given rise to unethical medical billing practices. The subcommittee should support, and Congress should enact legislation that will stop hospitals from reclassifying a doctor's office they own as a hospital setting in order to charge more money ("*Facilitating Accountability in Reimbursement (FAIR) Act"* (H.R. 3417) and "*Site-based Invoicing and Transparency Enhancement (SITE) Act"* (S. 1869)). We support the "honest billing" provisions included in Section 204 of the LCMT Act that are applicable to Medicare payments as an initial step towards mitigating these distorted practices. However, we strongly urge Congress to expressly extend such honest billing requirements to the commercial market. Requiring transparency of sites of care in medical bills is in no way a violation of free market principles, and indeed is exactly the kind of regulation needed to preserve free markets.

Congress should also direct the Government Accountability Office (GAO) to investigate billing by medical providers, to determine whether fraudulent billing is common. ERIC member companies have reported a significant increase in "up-coding," wherein providers bill for more difficult or lucrative services or procedures, as well as instances of providers who are more junior, yet bill at higher rates by subsuming their charges under the auspices of a more senior provider (which would have severe consequences in other realms, such as the legal profession). Based on the findings of GAO, Congress should consider legislation to further discourage these harmful and inappropriate billing practices to protect patients from high health care costs.

Patients also need to receive timely hospital bills for their health care services. Timely bills are a key step in preventing surprise billing, which Congress aimed to end starting in 2022. We encourage the subcommittee to revisit a policy requiring hospitals to issue medical bills to patients within 30 days of a patient's discharge. This provision has been scored and previously vetted by the committee and could be picked back up immediately.

C. Fairness in Contracting

Health care providers are using market power to demand unethical and deeply unfair contractual terms, which reduce the quality and safety of care while increasing costs for patients. We encourage the subcommittee to promote competition and reduce network consolidation by crafting legislation that would allow:

- Discounts or incentives for enrollees who choose high-quality and low-cost providers;
- Insurers and employers to contract with hospitals and providers for their patients, without requirements to enter additional contracts with other affiliated providers or hospitals;

- Health insurance issuers to negotiate their own rates with other providers who are not a party to the contract of the provider involved; and

- Hospitals and issuers to freely negotiate prices, without requirements to pay higher amounts for items or services than other issuers have agreed to.

III. Innovation in Patient Safety

Preventable medical errors are one of the leading causes of death in the United States. The Energy and Commerce Committee has been at the forefront of congressional work towards preventing and reducing medical errors for the past two decades, evidenced by its leadership in enacting the *Patient Safety and Quality Improvement Act of 2005* (PSQIA). Despite the importance of this statute and the many years of work to address the issue, patient safety remains a significant issue and one for which additional steps are needed to complement PSQIA.

Specifically, more can and should be done so that current technology can be applied to the health care system to reduce preventable adverse events in the future. ERIC supports bipartisan proposals that are targeted to bring real change to these concerns.

A. *Creation of a National Patient Safety Board*

Patient safety reportable events have not decreased since 1999. Most policies related to reducing preventable medical errors have been focused on the actions of frontline workers, but the reliance on individuals is part of why efforts to sustain, spread, or standardize progress have been unsuccessful. Meanwhile, other industries have seen dramatic improvements in safety. The aviation industry has had a stellar safety record thanks to the work of the Commercial Aviation Safety Team (CAST) and the National Transportation Safety Board (NTSB), which together have been improving and promoting transportation safety in the United States for more than 25 years.

An independent federal board housed within the Department of Health and Human Services -- the National Patient Safety Board (NPSB) -- would model the efforts of CAST and NTSB within health care. The NPSB, with its nonpunitive, multidisciplinary Research and Development Team, would complement existing agencies in monitoring and anticipating patient safety events with modern tools such as machine learning, predictive analytics, and artificial intelligence. It would provide expertise to study the causes of errors and create recommendations and solutions to prevent future harm. By serving as a central repository for these patient safety solutions, NPSB will leverage existing systems to bring key learnings into practice. The NPSB would guarantee a data-driven, scalable approach to preventing and reducing patient safety events in health care settings. No other government agency, including the Agency for Healthcare Research and Quality (AHRQ), is undertaking the work that NPSB would do. ERIC urges Congress to advance legislation to establish the NPSB and appropriate the necessary funding to save patient lives.

B. *Serious Reportable Events or "Never Events"*

The National Quality Forum (NQF) created a set of serious, preventable, and harmful clinical events that occur throughout different clinical settings so that health professionals could assess, measure, and report performance. This list includes events such as wrong-site surgeries, malfunctioning devices, medication errors, and more – each of which is 100 percent preventable with proper safeguards and processes in place. These events happen to patients in employer-sponsored health plans and those in government programs such as Medicare, but are handled quite differently depending on a patient's insurance.

Currently, for patients with employer-sponsored insurance who experience one of these "never events," the plan will not compensate providers or permit providers to bill the patient or the plan for services related to the serious reportable event. ERIC encourages Congress to improve patient safety by aligning Medicare patient safety standards with the private sector, by updating the current Medicare "no-pay list" policy established under the *Deficit Reduction Act* (Public Law 109-171) to cover all NQF serious reportable events, and to mirror the Leapfrog Group's hospital safety metrics and "never events" policy.

IV. Bipartisan Action Needed on Prescription Drug Competition

The subcommittee should consider taking action to address the gaming of Food and Drug Administration (FDA) rules, which continue to have an ill effect on the availability of and competition among prescription drugs. Many of the current problems in the prescription drug market are a result of failure by various parties to abide by the standards established by the 1984 *Drug Price Competition and Patent Term Restoration Act* (Public Law 98-417), usually referred to as the *Hatch Waxman Act*. The law strikes a balance wherein innovator companies are rewarded with market monopolies, for a limited duration of time, and then must face competition from generic products. Various strategies are now used to delay or escape entirely from that competition, and the result has been unconscionable prices and costs to plan sponsors and patients. ERIC supports policies to address drug shortages, increase competition and address market failures, including but not limited to:

- Enacting policies to promote an affordable and competitive market for biosimilars, including eliminating barriers to substitution such as the "interchangeability" designation;
- Ending the abuse of the drug patent system reflected in such practices as "product hopping", "ancillary product patents" (which occur because a lack of FDA coordination with the U.S. Patent and Trademark Office), and "patient thickets," among others.
- Stopping abuse of FDA "citizen petitions";
- Preventing the blocking of generic competition (and other forms of patent trolling);
- Addressing issues related to so-called "international free-riding" wherein Americans pay vastly higher drug costs than other wealthy, industrialized nations;
- Eradicating sovereign immunity schemes;
- Addressing unsustainable downward pricing pressure in the generic essential medicines market that leads to shortage;
- Preventing unconscionable markup of prescription drug costs at hospitals, and ending abuse in the 340(b) drug program;
- Implementing stop-gap policies until international prices are properly calibrated, for example, proposals to allow certain medication to be reimported or purchased from overseas pharmacies that are registered with and regulated by the FDA; and
- Investigating and addressing false or misleading information, discouraging anti-competitive behaviors, and increasing progress to get products to market.

V. Telehealth

ERIC member companies are pioneers in offering robust telehealth benefits. Telehealth enables individuals to obtain the care they need, when and where they need it, affordably and conveniently. Telehealth visits are generally less expensive than in-person visits and significantly less expensive than urgent care or emergency room visits. Telehealth visits allow individuals who may not have a primary care provider and are experiencing medical symptoms an affordable alternative to an otherwise unnecessary emergency room visit. Access to telehealth benefits saves individuals significant money and reduces the cost to the plan, which ultimately lowers health insurance premiums.

Telehealth benefits reduce the need to leave home or work and risk infection at a physician's office, provide a solution for individuals with limited mobility or access to transportation, and have the potential to address provider shortages, especially related to mental health, and improve choice, competition, and reduce costs in health care.

ERIC's member companies continue to innovate in their benefit designs to reflect telehealth improvements – held back only by various federal and state government barriers. This includes overly restrictive provider licensing, unnecessary barriers such as banning store-and-forward communications, or specific technology requirements. Additionally, ERIC member companies are interested in offering telehealth to certain sectors of their workforce who currently cannot be offered these services. We encourage Congress to pass the "*Telehealth Benefit Expansion for Workers Act of 2023*" (H.R. 824). This bill would allow employers to offer standalone telehealth benefits to millions of individuals who are not enrolled on the employer's full medical plan, such as part-time workers, interns, seasonal workers, persons on a waiting period, and others, by removing barriers presented under current law, such as the *Affordable Care Act* (ACA).

Impediments to provider licensing seriously impact telehealth coverage offered to employees from state to state. For example, primary care is largely available to employees in every state, but offering behavioral health and mental health services to patients in each state is a challenge because there are not enough licensed providers in many states. Everyone's telehealth care access is limited based on state rules and what can be covered through the medical plan or Employee Assistance Program (EAP). ERIC urges the subcommittee to advance policies that would allow qualified mental health providers to practice across state lines to improve access to patient care for patients with employer-sponsored insurance. Congress should facilitate reciprocity of state-provided licenses. ERIC believes that all patients and providers can benefit from state licensing reciprocity for licensed and certified practitioners or professionals (those that treat physical and mental health conditions) in all states, and for all types of services, especially to link patients with providers of their choice. While there are different possible paths forward such as national reciprocity, a national license, or one comprehensive interstate compact with financial incentives for states, employers urge Congress to work through this challenge and come to consensus on a solution that will benefit all patients.

Conclusion

Thank you for this opportunity to share our views. ERIC is committed to helping forge solutions that result in improved health care access, affordability, quality, transparency, and safety for all Americans. We are confident that our policy recommendations can provide meaningful changes to our health care system. We look forward to working with the subcommittee to further help in policy development and enact legislation.

Written Testimony

Submitted to Subcommittee on Health Energy and Commerce

On behalf of the National Association of Free and Charitable Clinics

Nicole Lamoureux, CEO and President

January 31, 2024

On behalf of the NAFC Board of Directors, our patients, and the 1,400 Free and Charitable Clinics and Pharmacies in the United States, thank you for the opportunity to submit this written testimony about the "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers" hearing to the Subcommittee on Health.

The Unsustainable Nature of Health Care Spending:

The current trajectory of healthcare spending in our country is economically unsustainable and ethically unacceptable. As we discuss the financial burdens placed on patients, employers, and taxpayers, it is imperative to shed light on the plight of the millions of uninsured and underinsured individuals who bear the heaviest brunt of these escalating costs. With 27 million uninsured Americans, the cost of health care remains a tremendous burden, disproportionately affecting those without access to affordable insurance options.

The Role of Free and Charitable Clinics and Pharmacies:

Amidst this crisis, the invaluable contribution of Free and Charitable Clinics and Pharmacies cannot be overstated. These organizations serve as beacons of hope for the most vulnerable members of our society, providing access to essential healthcare services without federal

government financial support. With over 1,400 such clinics and pharmacies nationwide, a volunteer and staff workforce of over 200,000 provides affordable access to health care to 1.7 million people annually. These organizations not only represent a lifeline for millions of uninsured and underinsured individuals, but they also provide vital medical care that would otherwise be out of reach. For every dollar that is donated to Free or Charitable Clinics or Pharmacies, seven dollars in services are provided.

Data and Insights:

The data from these grassroots healthcare nonprofit organizations is astounding:

- In 2022 alone, these organizations provided care to 1.7 million patients through 5.8 million patient visits.
- Shockingly, 85% of these patients were uninsured, underscoring the dire need for accessible and affordable healthcare options.
- Of the patients served, 59% were members of racial/ethnic minorities, highlighting the critical role these clinics play in addressing health disparities.
- Additionally, 52% of patients were employed, emphasizing the widespread impact of healthcare costs on the workforce.
- Notably, 41% of patients served were Caucasian, while 33% were Hispanic and 14% were Black, reflecting the diversity of the population benefiting from these services.
- 69% of clinics/pharmacies have an operating budget of $500,000 or less.
- 35% of locations are in rural areas, 49% in urban areas and 33% are in suburban areas

Addressing the Challenges of Health Care Spending:

We urge this esteemed committee to recognize the indispensable role of Free and Charitable Clinics and Pharmacies in mitigating the adverse effects of unsustainable healthcare spending. Furthermore, we call upon Congress to take concrete steps to support and bolster these vital healthcare providers. Specifically, we recommend granting these clinics automatic HPSA (Health Professional Shortage Area) and MUA (Medically Underserved Area) designations, akin to Federally Qualified Health Centers, to facilitate loan repayment for healthcare providers and address workforce shortages in underserved communities. Additionally, we urge the Committee to include Free and Charitable Clinics and Pharmacies in testimony opportunities and meetings for further information and education on how this country can scale cost-saving measures that are utilized at these organizations.

Conclusion:

In conclusion, the unsustainable nature of health care spending in the United States demands urgent attention and decisive action. By recognizing and supporting the invaluable contributions of Free and Charitable Clinics and Pharmacies, we can take meaningful strides towards achieving equitable access to healthcare for all Americans. Cost-saving measures in this country will be achieved when Congress recognizes that America's safety net extends beyond government-recognized agencies. It's crucial to understand that the 27 million uninsured patients in this country often resort to emergency rooms for basic healthcare needs, driving up costs for everyone. By working with nonprofits and grassroots organizations on the ground, not only can we foster innovation in healthcare, but we can also address the root causes of rising healthcare costs. Providing care to the uninsured and those who serve them is essential for tackling the underlying issues of healthcare affordability and accessibility. It is time for Congress to think

outside the box of the current healthcare paradigm and take bold steps to enact the change needed for equitable, affordable, accessible healthcare.

better solutions
for healthcare

January 31, 2024

Chair Cathy McMorris Rodgers (R-WA)
Ranking Member Frank Pallone, Jr. (D-NJ)

Dear Chair Rodgers and Ranking Member Pallone:

Thank you for prioritizing market-based solutions to address the affordability crisis impacting American workers and their employees.

Better Solutions for Healthcare, a national coalition representing a broad range of employers and consumers, strongly supports provisions of the FAIR Act (H.R. 3417) included in the bipartisan Lower Costs, More Transparency Act (H.R. 5378) – which received a strong 320 – 71 House floor vote December 11, 2023. Better Solutions has been working to advance legislation harmonizing billing practices in off-campus hospital outpatient facilities, ending hospital systems' "dishonest billing" practices, and shining more light on hospital prices.

We commend the work of the three House committees with healthcare jurisdiction for their pragmatic efforts to produce a joint proposal to lower costs and increase transparency in the healthcare system. This bill includes policies to increase price transparency from hospitals, promote honest billing, and address the practice of hospitals charging enormous mark-ups and facility fees based on the site of care. And we urge the Senate to follow your leadership.

According to a recent study, hospital outpatient departments' (HOPDs) prices are substantially higher – as much as five times more expensive – than care performed in an ambulatory surgery center (ASC) or office setting. This comes at a time when over 100 million Americans are struggling with medical debt and corporate hospital systems continue to consolidate at an alarming rate.

Enacting legislation harmonizing billing practices between on- and off-campus corporate hospital facilities will benefit patients and lower healthcare costs.

Better Solutions is a coalition of leading business and healthcare organizations, including national employer groups, American Benefits Council, National Alliance for Healthcare Purchaser Coalitions, and the Public Sector HealthCare Roundtable, as well as hundreds of local and state business leaders. Our coalition's mission is to educate the public about the role corporate hospital systems play in driving up the cost of healthcare and ways to lower the prices Americans pay for care.

Too many corporate hospital systems have engaged in dishonest billing practices for too long, and patients and employers have been paying the price. It is clear there is now bipartisan consensus that we must put an end to these alarming price mark-ups. The high cost of hospital care is a threat to families and taxpayers alike, and we commend these lawmakers for advancing meaningful reform to help lower the cost of healthcare in America.

We thank the committee for their continued bipartisan leadership and urge the Senate to follow the pragmatic leadership of the House by advancing policies to make the healthcare system better for patients, employers, and taxpayers.

Sincerely,
Connie Partoyan
Executive Director

The Alliance to Fight for Health Care

Advancing employer-provided coverage

Submission for the record

House Committee on Energy & Commerce
Subcommittee on Health
Hearing: "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers"
January 31, 2024

The **Alliance to Fight for Health Care** thanks the Subcommittee for holding the hearing, "Health Care Spending in the United States: Unsustainable for Patients, Employers, and Taxpayers," to discuss rising health care costs and bipartisan solutions, such as the House-passed Lower Costs, More Transparency Act.

The **Alliance to Fight for Health Care** is a broad-based coalition comprised of businesses, patient advocates, employer organizations, unions, health care companies, consumer groups, and other stakeholders that support employer-provided health coverage. Together, we are working to ensure that employer-provided coverage remains an available and affordable option for working Americans and their families by **lowering the cost of health care services and increasing transparency and innovation.**

Employers, unions, patient advocates and other Alliance members want Congress to address policies that, first and foremost, are driving up costs for patients. A recent American Cancer Society Cancer Action Network study found that certain cancer treatment services provided in hospital outpatient departments (HOPDs) were **reimbursed at a rate that was three times higher** than services provided in a physician office setting, while some services were reimbursed at a **rate of more than five to six times** higher when provided in HOPDs. The study estimated a hypothetical patient receiving cancer treatments over the course of a year would have experienced a **$1,500 reduction in out-of-pocket costs** over the course of a year if site-neutral payment had been implemented and that **Medicare Part B spending would have been $7,750 less**.

In addition, a new study released by the Leukemia & Lymphoma Society (LLS) found that certain treatment services across eight disease groups were **reimbursed at a rate that was 1.5 to four times higher** when provided in an HOPD setting compared with a freestanding physician office setting. As a result, the study found a **Medicare patient with multiple myeloma could save an average of $303.48 in out-of-pocket costs** per year if site-neutral payments were expanded, while a **patient with commercial insurance could save $665.10 on average.**

That is why the Alliance is grateful for this Committee's leadership in addressing this important topic and supports proposals included in the Lower Costs, More Transparency Act that aim to:

- **Protect patients from paying hospital prices for doctors' office visits**; and
- **Ensure fair billing practices for care provided by off-campus HOPDs**.

The Alliance to Fight for Health Care

Advancing employer-provided coverage

Policy: Protect patients from paying hospital prices for doctors' office visits

The Alliance supports lowering the cost of health care services through policy proposals such as site-neutral payment reform. Current Medicare and private health insurance payment policies pay more for certain services provided in off-campus HOPDs. According to the Medicare Payment Advisory Commission (MedPAC), this disparity is incentivizing health care consolidation and higher health care costs. It also makes it harder for smaller, independent physician practices to compete. As shown in an AMA survey, fewer than half of physicians now work in physician-owned practices, a trend that has sharply risen since 2012.

We strongly support Section 203 of the Lower Costs, More Transparency Act, which aligns Medicare payments for physician-administered drugs in off-campus HOPDs and freestanding physician offices, and we urge Congress to work on a bicameral basis to complete this important work. As noted above, this policy serves as an important first step toward protecting patients from paying hospital-level prices for outpatient care provided outside of the hospital and for removing financial incentives driving consolidation among health care providers.

We urge Congress to build on this progress and consider additional site-neutral payment reforms. MedPAC, in its June 2022 report, estimated expanding site-neutral payment policies in Medicare could generate $6.6 billion in annual savings for Medicare and taxpayers and lower cost-sharing for Medicare beneficiaries by $1.7 billion. These policies can all be designed to protect vulnerable rural or safety-net hospitals, while protecting patients from climbing costs and the other ramifications of consolidation. There is significant support for site-neutral payment reform. A Morning Consult poll found 86% of insured adults, across political parties, believe health care costs should remain the same regardless of where the service is received.

Policy: Ensure fair billing practices for care provided by off-campus HOPDs

The Alliance also supports Section 204 of the Lower Costs, More Transparency Act, which requires each off-campus HOPDs of a Medicare provider to obtain and use a unique national provider identifier (NPI) on billings for claims for services.

This added layer of transparency is important because current Medicare and private health insurance payment policies make it difficult to tell whether a service was provided at a hospital or in an outpatient setting like a doctor's office, where care may be cheaper. Hospitals that own outpatient facilities often will use the main hospital's NPI and address on all claim forms -- even when care is provided outside the hospital at a hospital-owned doctor's office or facility. This makes it look like the care was provided within the hospital's walls even if the care was provided at an off-campus HOPD miles away from the main hospital.

By requiring off-campus HOPDs of Medicare providers to obtain and use a unique NPI, the committees will ensure patients and payers have the data necessary to dispute erroneous fees, unfair add-on costs, hospital upcharges and other junk fees.

The Alliance to Fight for Health Care

Advancing employer-provided coverage

Additional policies to lower health care costs for ALL Americans

The House-passed Lower Costs, More Transparency Act demonstrates the House's commitment to lowering health care costs for workers, employers, and the federal government. Therefore, we ask that the House also consider other Alliance-backed proposals that aim to improve access to care to ALL Americans, including:

- Advancing the Ways and Means Committee-passed Chronic Disease Flexible Coverage Act, HR 3800;
- Making permanent policies enabling employers and plans to continue offering telehealth services pre-deductible; and
- Preserving the ability of employer and multiemployer health plans to offer uniform benefits to all eligible employees across the country.

You can find a longer list of our recommended policies – including the barriers they aim to address – on our website at www.fightforhealthcare.com.

Employers' overarching mission is to drive better patient care. Employers prioritize investing in our employees' health care to support a healthy workforce. Employers and employees want the best outcomes and also to make sure that we are good stewards of their health care dollar. To do that, we need a strong and functioning health care system that places the patient at the center of care.

We thank the House Energy & Commerce Committee leadership again for their work to advance policies to lower health care costs and foster competition in health care. We look forward to working together to advance public policy that makes health care more affordable, supports continued innovation, improves job-based coverage, and advances the health care system for all patients.

The **Alliance to Fight for Health Care** is a broad-based coalition comprised of businesses, patient advocates, employer organizations, unions, health care companies, consumer groups and other stakeholders that support employer-provided health coverage. Together, we are working to ensure that employer-provided coverage remains an effective and affordable option for working Americans and their families. The coalition (previously working as the **Alliance to Fight the 40**), led the successful effort to repeal the so-called 40% "Cadillac Tax" on health care coverage.

Your health care costs went up in 2023. It won’t stop in 2024, experts say

dallasnews.com/business/2024/01/23/your-health-care-costs-went-up-in-2023-it-wont-stop-in-2024-according-to-experts/

(Michael Hogue)

Companies are scrambling to find health care plans good enough to entice employees while coverage costs are expected to rise another 6.5% in 2024, according to benefits consulting firms Mercer and Willis Towers Watson.

Health industry experts said they’re worried the current model is unsustainable.

“It’s been a steady, ongoing challenge for employers for the last 10 to 15 years,” said Marianne Fazen, executive director of the Dallas-Fort Worth Business Group on Health, which helps companies control health costs. “Butnow the costs are getting so egregiously high that employers are having a hard time managing the

costs and continuing to offer their employees the health benefits that they give them."

Rising costs have been part of an ongoing trend for Texans since at least the early 1990s, according to nonpartisan public policy nonprofit Texas 2036. But 2024′s potentially high prices could cause some employees to walk away from their plans and for companies to choose between charging employees more or reducing the quality of their plans.

"We're seeing it become more difficult for employers to continue to absorb costs, and employers definitely are going to absorb the cost of financing," said Eric Calciano, benefits adviser at employee benefits consulting firm New City Insurance. "There's only so much that they can absorb until you have to pass those higher costs down."

Who is this affecting?

Employers and employees are both feeling the pain of higher costs, experts said. Employees on a single-coverage plan are paying around $1,400 in premiums while the average employer pays over $7,000, according to a report from the Kaiser Family Foundation.

The growing problem of health care's unaffordability in Texas has gotten so out of hand that at least half of Texans said they put off getting the care they needed since 2021, according to Houston-based Episcopal Health Foundation. Over 40% of Texans also skipped a recommended medical test or treatment and 35% did not get a prescription filled due to the costs, the foundation said.

Employees skipping preventative care is a problem that's only going to catch up to people and companies in a couple of years as the employee's health gradually deteriorates, Fazen said.

Blue-collar workers will feel the pain of skipping care the most, she said.

"They're the ones who tend to have more serious conditions, more chronic conditions that play out in their lives. The incentive to treat it when it's in the earlier stages is key, but it's not often followed," Fazen said. "Then they simply don't have the money to go and buy the medications and they get worse."

Adding benefits to employer-sponsored health plans only adds to the cost for employees, Fazen said.

"Companies want to push preventive measures such as cancer screenings for early detection and prevention, but those are not used very often," she said. "Some employees may not even have transportation to go to an imaging center or may not be able to afford the time off."

Companies have to begin approaching health care strategies differently, said Charles Miller, senior policy adviser for Texas 2036, a think tank studying some of the state's biggest challenges.

"For a long time, the common wisdom in the policy world was that we need to make sure that our insurance coverage is better so that people aren't skipping care," he said. "But there's a growing realization among policy experts that insurance coverage alone cannot solve this problem."

Why are costs still going up?

Hospital consolidation has been the name of the game in health care for the last several decades. Research from Harvard Business School shows mergers can increase commercial sector prices by an average of 6%. Between 1998 and 2021, the U.S. saw 1,887 hospital mergers and a loss of 2,000 hospitals, according to the American Hospital Association.

“It started with small hospital systems merging with other smaller hospital systems,” said Vivian Ho, health economist at Rice University and Baylor College of Medicine. “There are fewer mergers and acquisitions today, but the values of the deals are so much larger, simply because there are no small players left.”

Last year, Texans saw Dallas-based Medical City Healthcare expand its network to 19 inpatient hospitals with its purchase of Wise Health System. Though acquisitions aren’t as frequent today, they can still affect thousands of Texans.

“I think acquisitions are one of the big issues that’s driving up costs. If [hospitals] buy local urgent care clinics and start providing those and smaller hospitals, then the charges at smaller clinics will go up, even in rural communities,” Fazen said. “If they’re buying a hospital on the outskirts of the D-FW area, they’re likely charging the same fees they would charge at the main hospital.”

But it’s not just consolidation that’s pushing prices up. Texas’ traditional fee-for-service Medicaid model, where health care providers are paid for each service, can become uncontrollable for employers and employees looking to keep prices low.

“It’s consolidation for sure, but it also is the fact that the health care system that the employers are paying for is fee-for-service,” Fazen said. “It’s a really cattywampus revenue model that is very difficult to control. The fees just keep going up per the more services that are provided.”

Advancing medical technology is driving prices up, hospitals are still having staff shortages and specialty drug manufacturing remains expensive, Calciano said.

“I think people are finding now that the estimations for how much prices are going to rise is the largest increase that we’ve seen in about a decade,” he said.

What can be done to prevent soaring costs?

Getting costs down requires a concerted effort from employers, employees and state and federal governments, experts said.

For employees, the most important thing they can do to keep their costs low is to be good health care recipients, Calciano said. But they also need to look into the differences between more expensive but often better quality PPO plans and the more affordable HMO plans, and should be willing to look into new options despite previous loyalties with health care providers, Fazen said.

“An employee might say ‘No, my family has always gone to this other hospital in this community. So I’m gonna go to this other one.’ Which may be even more expensive or may not deliver as good care,” she said. “Employee choice is always a factor in this as well, and they have to choose wisely.”

Beyond 2024, companies need to reinvent health care plans, Rice University’s Ho said.

“It’s the responsibility of employers to start thinking smarter about what type of health care they purchase. I’m generally disappointed with CEOs, executives of large firms and their HR offices in how they think about buying affordable, high-quality health insurance plans for their employees,” she said. “I think they throw their hands up and say, ‘Oh, it’s too complicated.’ And that leads to a completely inelastic demand for health insurance and health care.”

Companies could consider plans where pharmacy benefit managers are not commonly owned by an insurance carrier and target claims as early as possible, Calciano said. But that would mean employers need to encourage employees to get preventive care.

To do that, employers could design benefit plans around a shared savings program. It’s a model that relies on employees to go to the lowest-cost service provider. In return, the employer can reward the employee by giving them back some of the money they saved from the average price the company paid, Texas 2036′s Miller said.

“There’s true empowerment to employers to finally take advantage of this price transparency revolution and take advantage of the price variation that does exist to start steering their employees to go get that high-quality care,” Miller said. “But we need to ... reduce some of the needlessly higher prices that are being paid.”

Though it can be expensive, more companies working with navigator services that help employees and employers pick plans could help both save thousands of dollars, Ho said.

“We need to get across to health care providers that we’re not going to have an inelastic demand. If you’re going to increase prices, we’re going to find alternative, lower-cost providers,” she said. “But employers have not been smart enough to go out, find and work with them. Your HR officers have no training in economics. You need people who are willing to sit down and think systematically about the economics of this.”

If companies are tight on money, it might be time to increase the amount that gets deducted from everyone’s paychecks, increase deductibles and copays or erode the quality of health plans outright. But there are ways for employers to frame this as a working solution for employees, Ho said.

“You need to pose it to your workers as tradeoffs and say, ‘Well, suppose we took this high-cost provider out of our network. We’re not going to pay for them. But your contribution to your insurance plans can drop X% because we’ve managed to find good providers that still provide higher quality care, but they’re much cheaper,’” she said.

This will be a crucial year for companies nearing a point where paying for coverage may no longer be a possibility, Fazen said.

“Employees simply can’t afford higher costs and nor can the employer,” Fazen said. “With so many large employers here using health care systems, I think health care providers are going to need to figure out a way to make it a little bit more reasonable for employers to stay the course. It’s possible employers will just say, ‘We can’t afford to pay for health care anymore. Go on the government system.’ That’s the kind of ultimate endpoint that could be reached.”

Some 3.3 million Texans are currently covered under the Affordable Care Act, according to Texas 2036. It’s an increase of 194% since 2020, when that number was 1.1 million.

Irving Mejia-Hilario. Irving is a business writer for the Dallas Morning News. He's previously served as an environmental reporter for Bridge Michigan, a writer for Automotive News, and the sports and managing editor for the South End. He graduated from Wayne State University in 2023 with a degree in print and online journalism and psychology minor.

[redacted]

[redacted]

POLITICOPRO

Health Care PM

BY KELLY HOOPER

DRIVING THE DAY

DOCTORS WANT A MEDICARE PAY RAISE — Republican doctors in the House plan to ask Senate Majority Leader Chuck Schumer to reverse a Medicare pay cut their fellow physicians took on Jan. 1, POLITICO's Daniel Payne reports.

Unless Congress reverses the 3.4 percent cut to Medicare reimbursements, more doctors will leave their independent practices or medicine altogether, explained the leaders of the GOP Doctors Caucus — Reps. Michael Burgess of Texas, Greg Murphy of North Carolina and Brad Wenstrup of Ohio.

Doctors are "facing unprecedented burnout due to low reimbursement rates, health care consolidation, administrative burdens and record high inflationary pressures," they wrote in a letter they've drafted to Schumer and Senate Finance Chair Ron Wyden (D-Ore.).

— **Background:** Democrats have sought to pair more money for doctors with increased funding for community health centers, Medicaid and mental health care, but Republicans have resisted.

The Centers for Medicare and Medicaid Services ordered the 3.4 percent cut last year in accord with a mandated payment formula, as directed by Congress in the law that created Medicare.

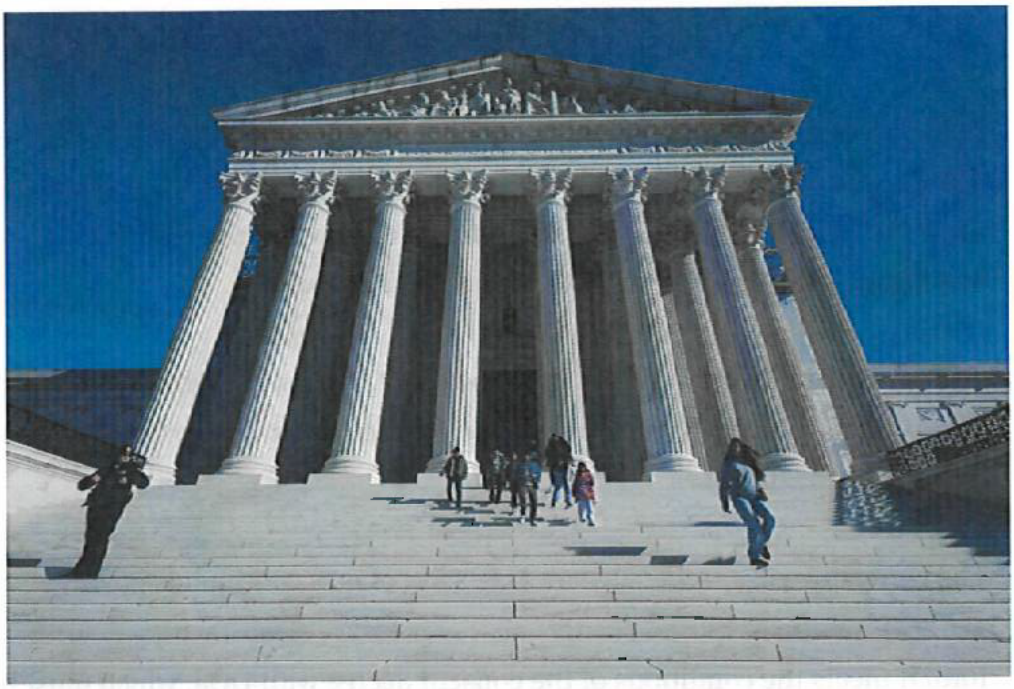
— **Why it matters:** Congress allowed a roughly 2 percent cut to Medicare pay in 2023, and this year's is compounding the pain for doctors trying to maintain independent practices, as well as hospitals struggling with financial headwinds.

Congress has moved to avert Medicare pay cuts in the past, typically in a year-end funding bill, but lawmakers' decision to punt fiscal 2024 appropriations legislation into the new year meant there wasn't the same opportunity.

— **What's next**: The GOP doctors want a fix in a pending fiscal 2024 appropriations bill that Congress must pass by March 1 to avoid a partial government shutdown. They plan to circulate the letter more widely in the House on Tuesday to gain more signatures before sending it to the Senate Democrats.

Welcome to Monday's edition of Pro Health Care PM, where we just learned about an alarming food trend in South Korea: People are deep frying and eating toothpicks. The method went viral on social media, prompting a response from the country's health officials. Send me your news tips at khooper@politico.com and follow along at @kelhoops.

ABORTION



The Supreme Court on March 26 will hear oral arguments on a case regarding patient access to a popular abortion pill. | Francis Chung/POLITICO

SCOTUS SCHEDULES ABORTION PILL HEARING — The Supreme Court today said justices will hear oral arguments on March 26 regarding a case that would decide how patients can access a commonly used abortion pill, POLITICO's Kierra Frazier reports.

— **Background:** In December, the high court said it would hear the case brought by a conservative group challenging policies expanding access to the drug mifepristone. Those policies, issued in recent years by the Food and Drug Administration, have allowed the pills to be prescribed online, mailed to patients and dispensed at brick-and-mortar pharmacies.

The court turned down a broader challenge by the same group that sought to overturn the decades-old approval of the drug for use in abortions — arguments that could have effectively banned the pills nationwide.

— **Why it matters:** The case — the Supreme Court's first significant return to the abortion issue since it overturned *Roe v. Wade* in 2022, could affect health care for millions — including those in states that protect abortion rights — because the abortion pill is the most common method of terminating a pregnancy.

EYE ON THE FDA

PHILIPS AGREES NOT TO SELL SLEEP THERAPY DEVICES IN U.S. — Philips said today it has agreed not to sell devices that treat sleep apnea in the U.S. until it complies with certain terms of a settlement with the Department of Justice, POLITICO's David Lim reports.

The agreement comes years after a subsidiary, Philips Respironics, recalled several of its medical devices used to help patients breathe during sleep due to potential health risks.

The company will specifically halt U.S. sales of new continuous positive airway pressure or bilevel positive airway pressure sleep-therapy devices until it meets the conditions of the consent decree with DOJ, which must be finalized and submitted to a U.S. court for approval.

The agreement outlines "a roadmap of defined actions, milestones and deliverables to demonstrate compliance with regulatory requirements and to restore the business," the company said.

Jeffrey Shuren, director of the FDA's device regulation center, acknowledged the Philips announcement in a statement. "Until there is a finalized agreement that has been signed and filed with the court, we cannot comment further," he said.

Philips will continue to service sleep devices that patients and health care providers in the U.S. already use under the consent decree — and supply accessories and replacement parts.

Outside the U.S., the company will continue to sell sleep devices and associated parts, subject to additional requirements that will be detailed later.

GLOBAL HEALTH

A woman holds a vaping device in Manchester, England. | Christopher Furlong/Getty Images

U.K. BANS DISPOSABLE VAPES — The British government has announced it will ban the sale of disposable vapes and restrict certain e-cigarettes flavors in an effort to combat the rise in vaping among children.

The government will introduce plain packaging and change how vapes are displayed in stores so that they don't appeal to kids, noting the "alarming rise in youth vaping." The crackdown also includes a new law making it illegal to sell tobacco products to anyone born on or after Jan. 1, 2009.

Stores in England and Wales that sell vapes illegally to children will face higher fines, the government said. It is illegal to sell vapes to anyone under 18 in the U.K., but the government noted that the number of children using vapes in the past three years has tripled, with 9 percent of 11- to 15-year-olds using them.

"As any parent or teacher knows, one of the most worrying trends at the moment is the rise in vaping among children, and so we must act before it becomes endemic," Prime Minister Rishi Sunak said in a statement.

NAMES IN THE NEWS

Claire Sheahan has been selected as the **Alliance for Health Policy**'s new president and CEO. Sheahan is currently the organization's interim COO.

WHAT WE'RE READING

New Alzheimer's drugs bring hope. But not equally for all patients. — Laurie McGinley, The Washington Post

Vaccines save lives and generate profits. Why is investment lagging? — Jonathan Saltzman, The Boston Globe and STAT

Minnesota newborns will now be screened for Duchenne muscular dystrophy — WCCO Staff, CBS Minnesota

CORRECTION: Friday's edition of POLITICO Pro Health Care PM misstated an Oregon headline. It should have been: Oregon Democrats consider recriminalizing low-level drug possession.

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Dan Goldberg @dancgoldberg

Chelsea Cirruzzo @chelseacirruzzo

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Carmen Paun @carmenpaun

Daniel Payne @_daniel_payne

Ruth Reader @RuthReader

Erin Schumaker @erinlschumaker

JANUARY 17, 2024

To: **The Honorable Phillip Swagel, *Director***
Congressional Budget Office
441 D ST SW
Washington, DC 20024

RE: A Call for New Research in the Area of New Drug Development

Attached is a response to the Congressional Budget Office's (CBO) December 20, 2023 "**Call for New Research in the Area of New Drug Development**" from investors and innovators who specialize in funding biotech R&D and represent $309B of assets under management and 624 drug candidates in development.

CBO's ability to correctly model investor decision-making is vital to our country's ability to establish policies that achieve lasting biomedical affordability and continued innovation. In support of CBO's efforts to improve its model, this letter emphasizes a number of economic and financial first principles, notably that investment is incentivized by expected returns based on discounted profits, not revenue, and adjusted for expected dilution from financings.

Making these adjustments to CBO's model would reveal why the Inflation Reduction Act (IRA) has not merely reduced incentives for the development of new small molecules but essentially eliminated incentives for the earliest stages of funding for non-exempt small molecules aimed at diseases of aging, the effects of which may not be evident today but are clear over time. The letter makes the economic case for a legislative fix to equalize negotiation for all drugs at 13 years.

The letter offers the following resources for CBO's review:

- **No Patient Left Behind's (NPLB) recommendations on how CBO can improve its Rx modeling innovation impact.**
- **An NPLB explainer on how the small molecule penalty already is impacting investor and innovator new R&D decision making,** why the IRA's "exceptions" will not work as intended, and relevant data on revenues over the course of a small molecule's product life-cycle. A more detailed discussion can be found in this **NPLB Webinar**.
- "**Beyond Total Revenues, how IRA impacts investors' early-stage R&D decision-making**," an explainer prepared by investors on how and when biotech investment decisions are made, showing how models based on global revenues need to be adjusted for profits, discounting, and dilution to recognize the impact of revenue cuts on incentives for early-stage R&D funding.

Please contact me (**prubin@nopatientleftbehind.org**) for more information about the letter or its accompanying resources.

Peter Rubin

Peter Rubin
Executive Director
No Patient Left Behind

This letter continues to gather signatures. Please click here for the most recent version.

Dear Director Swagel:

Thank you for your December 20, 2023, blog post seeking additional information on the drug development R&D process, particularly "how changes in pharmaceutical companies' expected future profits affect the development of drugs with differing characteristics, such as small- or large-molecule drugs or those that target certain diseases or patient populations (such as the elderly)."

As healthcare investors representing $309B in assets under management and executives of companies developing 624 drug candidates, we believe that the Congressional Budget Office's (CBO) ability to correctly model investor decision-making is vital to our country's ability to establish policies that achieve lasting biomedical affordability and innovation.

As such, in this letter we outline an analysis that incorporates the real-world experience of investors and drug developers, including the types of financial metrics that drive decisions around investment in portfolios of R&D projects. Our primary goal is to illuminate some of the economic first principles that have caused recent drug pricing policy changes to alter the attractiveness of all drug development with amplified cuts to incentives for funding the earliest stages, from which all else stems. We also aim to provide the foundational arguments for a legislative fix: equalizing small and large molecule negotiation timelines at 13 years after FDA approval.

Why the CBO's modeling matters to us

We appreciate that Congress looks to the CBO for the potential implications of policy proposals on the federal government's 10-year budget. What specifically concerns us is how the CBO forecasts the impacts of policy changes on innovation. When the CBO examined the implications of the Inflation Reduction Act's (IRA's) Medicare Negotiation of NDA-path medicines just nine years after they launch, what we sometimes refer to as the "nine-year small molecule penalty," it forecast only a very slight decrease in the number of such medicines coming to market in the coming decades.[1]

Yet, this is very much at odds with the fact that our funding for early-stage small molecule programs has plummeted and, in the event they even make it to market, they will have the vast majority of their US revenues subjected to the nine-year penalty. While success of any early-stage program is never assured, the seeds we *aren't* planting are the drugs that definitely *won't* come to market a decade or more from now.

That we continue to fund early-stage small molecule programs after the passage of the IRA is because of its exemptions, not because the nine-year penalty only partially discourages early-stage funding of programs with mostly Medicare revenues. For reasons we outline below, knowing that market-based pricing will be terminated after only nine years is thoroughly discouraging of early-stage investments, especially preclinical development and, even more so, drug discovery. Were the nine-year penalty applied to all drug programs without exemption, funding for both small

[1] https://www.cbo.gov/publication/57449

molecule and biologics-based early-stage programs would be similarly discouraged (it's hard to even think of possible exceptions).

We appreciate that some policymakers and policy advisors trust the CBO's predictions more than they trust the word of people actually funding drug R&D. Some policymakers have said that the IRA's nine-year small molecule penalty won't impact innovation much *because the CBO said so.*[2] This disregards our and others' relevant expertise and knowledge that such policy has already curtailed investment in such programs. We fear that policymakers will fail to grasp the IRA's impact on new medicines' and other technologies' development and potentially legislate other penalties on innovation until the CBO's forecasts better capture their real consequences.

So we hope to make a case to you and the CBO that our behavior aligns with economic and financial first principles. We believe this is not a matter of opinion but rather math, to which those of us who are economists can attest and that we believe the CBO can confirm for itself. Following that, we hope that the CBO will adjust its models to more accurately advise policymakers on the more probable consequences to innovation from the IRA and future policy proposals.

Why the Nine-year Penalty for Small Molecules Matters

For the last 40 years, investors and innovators have been calibrated by Hatch-Waxman and its patent-term restoration maximum of 14 years when making early-stage R&D investment decisions. That led to today's level of innovation and a mountain of now-generic drugs that continue to improve patients' lives and reduce overall healthcare costs. On average, drugs have gone generic approximately 14 years after launch[3,4], aligning with expectation.

When presented with early-stage preclinical projects that would end up with no more than nine years on the market before going generic due to insufficient intellectual property (IP), we have not funded them unless that entrepreneur can come up with fresh IP. Nine years is not enough to justify the risk and cost of a program in the early stages of R&D.

The IRA has now imposed that same limitation on all kinds of novel molecules and so it should be no surprise that our answer is the same. Nine years is not enough. Except fresh IP is now not a solution since the nine-year penalty disregards all IP. The workable solution would be a legislative fix that would give these molecules the same 13 years that biologics are granted under the IRA. Thirteen years is close enough to 14 that we cannot claim it will meaningfully slow the pace of innovation (or at least we cannot currently discern a meaningful change in our interest in funding early-stage biologic R&D as a result of the IRA limiting those products to 13 years).

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[2] See, e.g., Rep. Kathy Castor's remarks at 9:00 in **https://www.youtube.com/watch?v=qTBy4jubNiw**

[3] **https://pubmed.ncbi.nlm.nih.gov/30055271/**
[4] **https://pubmed.ncbi.nlm.nih.gov/34253119/**

The CBO previously has recognized that more than 70 percent of Phase III drugs emerge from small biotech companies largely funded by private investors (i.e., many of us signing this letter).[5] But we should note that even large biopharmaceutical companies make investment decisions using the same financial calculus that we do. They are similarly deterred from early-stage investing in certain programs due to the nine-year penalty. The signers among us with relevant experience at large biopharmaceutical companies can attest to that.

Appreciating Elasticity of Innovation

While in some recent instances, the CBO has moved toward a simulation model, other CBO models appear to rely on academic studies of *elasticity of innovation* that correlate the number of drug launches with the size of a market in terms of the global revenues it supports.[6] Such correlations overlook A) the costs of those revenues and therefore the resulting profits and B) when in the future those profits are realized and therefore how heavily they are discounted back to the moment when an early-stage funding decision is made.

The following is a summary of what we believe may be at the root of the difference between the CBO's forecast and how we actually make investment decisions, which we hope will be useful regardless of how the CBO decides to model innovation.

1. **Investors and companies are mindful of profits, not just revenues**. So US and ex-US revenues are not equivalent in our models because US margins are much higher than ex-US margins, due to lower prices and higher commercialization costs abroad.[7]
2. **All profits are discounted in our models**. So a reduction in revenues more than 13 years after product launch matters less than the same magnitude of reduction imposed nine years after launch. And since ex-US revenues and profits often take longer to scale due to many countries dragging their feet on reimbursement[8], ex-US profits contribute even less to investment incentives than their modest share of overall profits might suggest. Taking time and discounting into account reveals that lowering the price of a drug 13 years after it launches has a notably lesser impact on its NPV than lowering the price after just nine years.
3. **The dilutive effect on early-stage investment returns from future financings amplifies the effect of revenue cuts such that a small reduction in the NPV of an approved drug may be a big reduction in the NPV of the portfolio of early-stage investments required to yield that approved drug.** After all, the IRA does not alter the risks of R&D nor how

[5] **https://www.cbo.gov/publication/57126** "Small drug companies (those with annual revenues of less than $500 million) now account for more than 70 percent of the nearly 3,000 drugs in phase III clinical trials."

[6] **https://www.jstor.org/stable/43895619**

[7] The observation that what matters is not revenue but profit was actually made recently in **an NBER paper**, though it came out after the CBO modeled the impact of the nine-year penalty. Still, it's good to see the academic literature starting to advance beyond just correlating global revenue with innovation.

[8] Resulting in delayed access to medicines for their patients.

much capital it takes to fund the entire portfolio of projects required to yield one approved drug. Therefore, the NPV on the early investments into a portfolio of projects may fall substantially (even become negative) from what seems like only a moderate reduction in the value of the successful drug that emerges from that portfolio, explaining why it's important to look for the effects of pricing regulations on funding at the origin point separately from overall funding (*See "A coin flip analogy" sidebar below.*)

4. **One should not assume that drugs that end up generating lower revenues on the market had lower development costs**, as CBO states on slide 23 of this deck.[9] When we fund a portfolio of projects, we often hope that a drug will be a blockbuster and invest accordingly, but only after the drug launches do we realize that it will disappoint. There may be surprisingly weak correlation between the cost to develop a drug and what it earns once it's on the market. However, there is a strong correlation between what we expect a drug to earn and our willingness to fund its development. To the extent that our predictions are borne out, there should be correlation between the cost of development and revenues. However, we are often wrong in our predictions of revenues, especially in the early stages of a project. When we realize that we are wrong, we apply what we learn to future decisions. Therefore, you would expect a greater correlation between the revenues of a drug and investors' willingness to fund the costs of future such medicines. If a heart failure drug sells well, then we are more likely to invest more in the development of better heart failure medicines, some of which may not sell well despite significant R&D investment. Therefore, cutting the value of the blockbuster drugs will reduce incentives for investment in **a whole portfolio of drugs** that will result in lack of development of not only more blockbusters but also drugs that would earn middling and low revenues.

Today, investors continue to fund development of small molecules that will be subject to the nine-year penalty, but increasingly these are at least somewhat de-risked programs already in the middle stages of development. This activity masks the loss of funding for the earliest-stage programs, making any analysis of total venture funding or late-stage small molecule program discontinuations irrelevant (the relevant research question would be: how much venture funding is going towards seeding small molecule programs that will be subject to the "penalty"? Which would be better answered through surveys such as the one we highlight in our "conclusions" section, below).

Therefore, it is no surprise that the CBO did not notice any change in investment immediately before or after the passage of the IRA[10]; cuts to early-stage funding (discovery of molecules) would be hard to perceive in the context of so much venture capital flowing to mid-stage programs already in development. But the impact of not planting those seeds may become more evident in the future from not only fewer small molecule drugs launched for diseases of aging but also the fewer

[9] **https://www.cbo.gov/publication/57449**

[10] **https://www.cbo.gov/system/files/2023-12/59792-Letter.pdf**

indications listed on the labels of those drugs that do launch (e.g., due to orphan exemption), though even then it's hard to see what's not there.

The early-stage programs receiving funding today are those whose future revenues are unlikely to be significantly curtailed by the nine-year penalty, which include drug candidates for diseases that affect younger populations, single-orphan indications, or biologics. And the proposed SMART Prices Act[11], with its five-year penalty for all drugs, would expand investor disinterest to many more programs, not because nine years isn't already discouraging of early-stage investment (once an incentive isn't big enough to incentivize early-stage investing, it hardly matters how small it is) but because of its breadth. Proposals to extend these penalties to the commercial market (non-Medicare) would mean that investors would have no expectations of a return from funding any early-stage biopharmaceutical R&D. And a policy like H.R.3 that would have imposed

A Coin Flip Analogy

While the statistics governing drug development are hardly as knowable as those of coin flips, consider the following example. Let's say you have to pay $1 per coin flip and four heads in a row results in a $50 payout. You'll need a portfolio of 16 such attempts to get four in row. Those first 16 flips cost $16. Eight attempts land tails and terminate after that one flip, and the other eight cost $8 for a second flip. Four of the remaining eight terminate after the second flip, and the other four cost $4 for a third flip. Two of the remaining four terminate on the third flip, and the final two cost $2 for the fourth flip. The cost of developing the portfolio ($16+$8+$4+$2) adds up to $30. On average, one of the initial 16 attempts wins the $50. That winning series of flips will cost $4 yet pay out $50, a highly profitable blockbuster.

Reduce that reward from $50 to $30 (a $20 penalty) and, compared to $4, winning would still seem compelling. But consider that it cost $30 to fund the entire portfolio of coin flips. Spending $30 to make $30 is not an investment. That's a waste of time (and note that we haven't even discounted for time). Reducing the reward for winning by even 40% results in eliminating the incentive to fund those first 16 coin flips. If the penalty is introduced after many projects are underway, then the eight projects that survived the first flip (e.g., the drug candidates that are past discovery and are in develpoment) would only cost $14 to play out to the end ($8+$4+2), so a $30 reward for success still yields a positive expected return.

And now consider that the $20-penalty only applies in a special case we'll call the "non-exempt medicine" and the reward remains the same for all others. Let's say that each coin can only be flipped once per year and investors fund a large portfolio of coin flips such that every year there are 160 first-flips, 80 second-flips, 40 third-flips, 20 fourth-flips, and therefore 10 medicines are successfully developed. Only a tenth (16) of the 160 first-flips are aimed at winning the reward for what will turn out to be the penalized class.

This portfolio of coin flips costs $300 per year with a total expected reward of $500. But once Congress passes the penalty and the $50 reward has been cut to $30 for the non-exempt class, they stop funding the non-exempt 16 first-flips each year. Therefore, in the first year after the penalty is implemented, the reward drops by 4% from $500 to $480 and R&D investment drops by 5.3% immediately from $300 to $284, a difference that is only clear in this coin flip example but would be hard to discern in the normally volatile real world (if the difference were even 5.3%). Over the next three years, as the 2nd, 3rd, and 4th flips for the non-exempt portfolio have played out and the consequences of no longer doing first-flips flow through the pipeline, R&D investment drops by 10% from $300 to $270 and and rewards drop from $500 to $450. After four years, we stop seeing any new non-exempt medicines coming to market.

Therefore, as soon as the penalty is announced, it may appear that many projects are still being funded and that the reward reduction did not reduce investor interest in funding coin flips, but that's wrong. Because to understand the impact on innovation in the long run, one must stay focused on the origin point (the first flip) of the non-exempt field of R&D. As long as those first flips aren't worth funding, the pipeline eventually runs dry.

[11] https://www.baldwin.senate.gov/news/press-releases/baldwin-colleagues-introduce-legislation-to-cut-seniors-prescription-drug-costs

price setting at launch would wipe out an expectation of return from even late-stage investing. To us, the effects of such policies are clear from the first principles of an NPV model.

The CBO's writings suggest it recognizes that there would be a delayed effect from the IRA since the reduction in incentives would be felt most acutely at the earliest R&D stages and take time to show up in the number of launched drugs. We think that, for the above reasons, the CBO has notably underestimated the degree to which the nine-year penalty reduces incentives to fund the earliest stages of R&D.

A Comment on the CBO's Assumptions about Launch Prices and CMS Price Reductions

The CBO makes a number of assumptions about how market participants will respond to the IRA that differ from investors' expectations. We highlight some key differences below and would encourage the CBO to revisit these assumptions with input from the investor community and pharmaceutical decision-makers.

5. **Investors cannot assume that companies will compensate for the nine-year penalty by launching at higher net prices.** The CBO has stated that it believes that drug companies will compensate for the shortening of their profitable period of market exclusivity by raising launch prices.[12] We cannot make this assumption without also considering how payors might introduce more friction into coverage decisions (e.g., utilization management such as prior authorization, step therapy, and high patient out-of-pocket costs), thereby reducing volume. After all, we already assume that if drug companies could charge more without sacrificing volume, they likely would. Consider also taking the nine-year penalty to an extreme. If it were five years, as the SMART Prices Act bill proposes, should we assume that launch prices would be yet higher? How about three years? Or one year?
6. **We have to assume that CMS price setting will reduce drug prices by >50%.** As the CBO notes,[13] the consequences of not agreeing to the price "negotiated" by CMS are so severe (excise tax of up to 1900%, withdrawal from all HHS agreements) that companies are unlikely to opt-out of offering their drug at the final price proposed by CMS. We consider the nine-year penalty is functionally rendering a drug as barely profitable as a generic because Medicare Negotiation has no floor on how low the government can set the price, and we have to assume some future administration will seek maximal savings regardless of how benign the cuts might be on the first sets of drugs negotiated.

Quantifying the Impact of the IRA Market Distortions - Beyond the Mere Number of Drugs

The CBO analyzes the impact of the IRA on the number of new drugs that come to market. However, the IRA introduces a number of market distortions that will impact the type of drugs that

[12] https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

[13] Slide 10, https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf

come to market, the overall utility of those drugs, and competition among branded drugs. Finally, when fewer drugs reach the market, this will ultimately impact spending on healthcare services, which should also be factored in. We would encourage the CBO to expand their analysis to include these consequences to more fully characterize the impact of the law.

7. **The IRA will result in lower investment in small molecules for diseases of aging** in broad indications such as heart failure, Alzheimer's disease, or breast cancer. This may not result in merely fewer drugs launching but in our inability to justify development of existing drugs for these indications. For example, SGLT2 inhibitors were first approved for diabetes, which would have started their nine-year clock had the IRA been in place 10 years ago. But signals of their efficacy in heart failure resulted in companies funding large trials in this primarily Medicare-covered indication, and the first of these drugs was approved for heart failure five years after its launch for diabetes.[14] Under Hatch-Waxman, that drug still had at least nine years of patent protection before it would go generic. But under the IRA, it would have had only four years, which might not have been enough to motivate funding of the large, risky, and expensive trials necessary to get the drugs approved in heart failure (or in chronic kidney disease [CKD], another primarily Medicare-covered indication for which SGLT2s eventually gained approval).

   So had the IRA passed 10 years ago, we would still have SGLT2 inhibitors but would not fully appreciate how effectively this class could help manage heart failure or CKD. Considering that these medicines will soon be generic and continue to help manage heart failure and CKD inexpensively for the rest of time, this would have been a costly error. So although it's good that the nine-year penalty wasn't in place back then, it is in place now and imposing the same disutility on medicines going forward.

8. **The IRA will result in fewer approved indications and formulations for small molecule drugs**. In response to the nine-year penalty, investment in small molecules for diseases of aging has shifted towards those with a large enough single orphan exemption to justify development. This means that the law creates a strong incentive to constrain to a single, large orphan indication any such drug that could have utility in other indications, orphan or non-orphan. We are not suggesting that the proper fix is to expand the exemption but to address the nine-year penalty itself by changing nine years to 13 years.

   Because the first approval starts the clock, companies are also discouraged from seeking approval in the later lines of cancer therapy where they typically first demonstrate efficacy; the law creates a strong incentive to delay launching an effective drug until it has approval for an earlier line of therapy that will serve more patients.

   Because the IRA treats any drug with the same API (active pharmaceutical ingredient) the same, the nine-year penalty also cuts incentives to develop better formulations of existing drugs.

[14] https://www.drugs.com/history/farxiga.html

9. **The IRA will also result in fewer approved indications for biologics.** While biologics have historically enjoyed a longer period of branded pricing, the upside of that has been that companies have continued to develop them for more uses long after they launched. The lack of incentives to develop aging small molecules for new uses as they become known (because they will soon go generic) has long been a shortfall of the Hatch-Waxman framework.[15] It is outside of the scope of this letter to explore how to fix that, but at the very least it is important for the CBO to take into account the IRA's reduction in incentives for developing marketed biologics for new uses as they approach 13 years on the market. Policymakers might consider granting extensions to the pre-negotiation period as an incentive for meaningful upgrades to a drug post-launch, akin to how the six-month pediatric extension incentivizes companies to study how a drug meant for adults might work in children.

10. **The IRA will result in less branded competition within the same indication for small molecules impacted by the nine-year penalty**. Even if there were a case where investors were willing to back early-stage funding to develop a drug that would have its revenues substantially curtailed by the nine-year penalty, there would be less competition in that drug class once it came to market because the entire class's clock essentially starts with the first drug.

    Currently, the typically 14-year clock started by the first-to-market drug still means that a laggard that comes to market four years later can compete with the first-in-class drug for a decade. With the nine-year penalty, coming four years late would leave only five years on the market before the first drug's price is reduced by Medicare Negotiation. Investors would likely abandon funding that laggard as soon as it became clear that it was more than one-to-two years behind the first drug. It's often not clear at the early stages which drug will be the first to market. And even then, it's not clear which will work best for patients.

    Under the 14-year framework of Hatch-Waxman, drug development is not a winner-take-all proposition, which is why there are so many competitive drug classes; most drug classes have two or more drugs and it's not uncommon for there to be as many as four, offering payors ample leverage to negotiate lower prices (though most plans still make patients pay full list prices until they hit their deductible). But nine years requires investors to back what they think will be the one winning horse and maybe a close second. A smaller window for market-based branded pricing shrinks the margin for error. Yet drug development timelines are highly uncertain, especially in the earlier stages. With only a nine-year window before the first drug is negotiated, the consequences of coming to market when the clock has been run down by a few years result in a follow-on drug not being worth launching.

    The end result will be that even in the rare cases when the nine-year penalty does not discourage the development of a drug, it will discourage the development of a competitive field of candidates in that class. There will be less competition during the nine-year period

[15] SGTL2s were an exception because their potential utility in heart failure was discovered around when they first launched for diabetes, so they were not yet too aged to pursue new uses.

and less of a chance that the best possible drug will even come to market. Consider that the best drugs in many drug classes were not the first of their class. And yet, once those best drugs go generic, those are the drugs that everyone benefits from forever, inexpensively.

11. **Fewer drugs will lead to higher spend on healthcare services.** Drugs go generic, while services do not. In the long run, if there are fewer drugs, that means more spending on healthcare services. It's also important to take into account the aging of the population, that healthcare services costs have been climbing faster than inflation for a long time, and that the US will be facing labor shortages due to demographic inversion in the coming decades, which will exacerbate the problem of staffing hospitals and nursing homes. Meanwhile, drugs keep people productive and out of hospitals. The spillover consequences of cutting incentives to develop new medicines, particularly the kinds that readily will go generic, should not be underestimated.[16]

On Affordability vs Value to Society

We include this section for anyone reading this letter who is understandably focused on affordability for patients, something we have not touched on and yet is very much on all our minds. We are all patients or else someday will be. And there are people we care about who need treatment. So the issue of both affordability of today's medicines and the development of new medicines is not only a professional matter but personal for all of us.

We all support the idea that appropriately prescribed medicines must be affordable to patients who need them. We don't fund drug development for any patient to then have to go without access.

We believe that the solution to affordability is insurance reform to lower what plans can charge patients out of pocket. Very little in healthcare can be expected to be affordable without health insurance, and when someone has health insurance, it's only delivering on its promise if people can actually afford what their physicians prescribe.

Ostensibly, plans charge an out-of-pocket cost to ensure that patients only take the medicines they need and don't over-utilize them. Yet insurance already has the electronic means to confirm when a medicine is inappropriate for a patient and often does, in those cases, simply deny coverage. But when even insurance knows that a medicine is right for a patient, we don't understand why it would then impose a cost that patients can't afford. It's not clear to us why there should be any out-of-pocket cost for chemotherapy or insulin, for example; it strikes us that no one tries to take these treatments unless they really need them, in which case why would insurance deter access? This feels unjust. The IRA's capping of out-of-pocket costs in Part D is therefore an initial step in the right direction to solving affordability.

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[16] https://www.thewellnews.com/opinions/fix-bbbs-rx-provisions-so-patients-arent-stuck-with-high-bills-and-more-needles/

On the other hand, forcing down prices of novel medicines, except maybe in the extreme, does not do much to solve affordability. Someone with a high deductible they cannot afford will still face that deductible even if the cost of any novel specialty cancer treatment were cut in half or more, and yet such a cut would eliminate incentives for investment in innovation. However, this does not mean that there is no role for policy to lower the prices of drugs; consistent with how the IRA treats biologics, the role for such policy is to ensure that all medicines eventually become inexpensive, as intended by the patent system, saving all of us money on what we pay for insurance, without interfering with innovation.

The intent of the patent system is to incentivize the development of novel technologies that then enter the public domain and become essentially inexpensive public goods for the rest of time. In the case of medicines, that has long been the case for small molecule drugs that went generic on average about 14 years after they launched, as intended by Hatch-Waxman. When biologics and other drugs fail to abide by the intent of the patent system and remain expensive for longer, we recognize the utility of regulation to bring down prices.

So while price-setting has a role to play in ensuring that the pricing of older drugs abides by the intent of the patent system, using it to attempt to solve affordability of today's novel medicines has implications for investment in tomorrow's.

We hope that policymakers will fix the nine-year penalty to restore incentives for innovation and continue to focus on insurance reform and lowering out-of-pocket costs to ensure that patients can afford the treatments that are right for them. By generating more complete models of the IRA's impact on early-stage investment in innovative therapies, the CBO can help guide them toward policies that benefit all Americans – today and in the future.

In Conclusion

As policymakers consider potential changes to the IRA, such as implementing Medicare price negotiation just five years after FDA approval, extending IRA's timelines to all market segments, or equalizing small and large molecule timelines at 13 years after FDA approval, the CBO has the sober responsibility to advise policymakers on the actual, real-world impact of their decision-making.

As the CBO works to revise its modeling assumptions, we encourage you and your team to review the below resources that reflect the decision making of biotech investors that fund and advise a significant portion of new US and global biotech private R&D:

A) **No Patient Left Behind's recommendations on how CBO can improve its Rx modeling innovation impact.** In particular, NPLB emphasizes the need for the CBO to i) incorporate the net present value of when in the product life-cycle revenue cuts occur to reveal that the earlier price cuts are introduced the bigger the impact on future innovation, ii) take a longer modeling view (70 years), and iii) incorporate an appropriate societal discount rate when evaluating a

policy's Rx innovation impact, consistent with long-range models used to inform energy and carbon capture provisions of the IRA.

B) An explainer prepared by some of the signatories, **"Beyond Total Revenues, how IRA impacts investors' early-stage R&D decision-making,"** that illustrates investor decision-making at each stage of drug development and warns about the significant impact arbitrary price-setting will have on the number of future drugs and their utility to treat new indications post-FDA approval.

C) **An NPLB Webinar** that goes into detail about how investors and industry executives think through the IRA and what business model changes would or would not work to preserve the profitability of programs targeted by the IRA as well as the potential impact on drug commercialization of changes to how Medicare reimburses payors.

D) An **explainer on how the small molecule penalty already is impacting investor and innovator new R&D decision making,** why the IRA's "exceptions" will not work as intended, and data on revenues over the course of a small molecule's product life-cycle.

Thank you for taking the time to review our feedback to CBO's information request. Please contact Peter Rubin (**prubin@nopatientleftbehind.org**) if you would like us to share additional information and relevant examples with your team.

Sincerely,

David Beier, Bay City Capital, *Investor*

Tess Cameron, RA Capital Management, *Investor*

Grace E. Colón, Inaya Therapeutics, *Executive*

Lou Garrison, University of Washington, *Economist*

Peter Kolchinsky, RA Capital Management, *Investor*

Peter Thompson, Orbimed Advisors, *Investor*

Co-Signers,

INVESTORS:	INVESTORS:
David Kroin Deep Track Capital	**Brook H. Byers, PhD Hon.** Kleiner Perkins
Elena Viboch General Catalyst	**Reid Huber** Third Rock Ventures
Roderick Wong, MD RTW Investments, LP	**James B Tananbaum, MD, MBA** Foresite Capital
Ellen Hukkelhoven, PhD Perceptive Advisors	**Alex Karnal** Braidwell

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INVESTORS:

Jason Rhodes
Atlas Venture

Bong Y. Koh, MD
Venrock Healthcare Capital Partners

Rajeev Shah
RA Capital Management

Jay Lichter, PhD
Avalon Bioventures

Luba Greenwood
Binney Street Capital

Nick Olsen
Innovation Endeavors

D.A. Wallach
Time BioVentures

Derek DiRocco
RA Capital Management

Andrew Levin, MD PhD
RA Capital Management

Clay B. Thorp
Hatteras Venture Partners

Vasudev Bailey, PhD
ARTIS Ventures

Joseph E Edelman
Perceptive Advisors

Alexis Borisy
Curie Bio

Fuad Naser, PhD
RA Capital Management

Alex Strasser
RA Capital Management

Laura Tadvalkar, PhD
RA Capital Management

David H. Crean, PhD, MBA
Coast Bioventures LLC

Nikhil Thatte
Lumira Ventures

Zach Scheiner, PhD
RA Capital Management

Jorge Becerril, PhD
Novo Holdings

Takashi Moriguchi, MBA
Globalbrain

Geeta Vemuri
Agent Capital

Richard Gaster, MD, PhD
venBio Partners

INVESTORS:

Bihua Chen
Cormorant Asset Management

Jørgen Søberg Petersen, MD, PhD, DMSc, MBA
Novo Holdings

David Sable, MD
Special Situations Life Sciences Fund

Jeff Huber
Triatomic Capital

Gregory I Frost, PhD
F1 BioVentures

David Steinberg
Longwood Fund

Evan Markegard, PhD
AuGC Partners

JF Formela
Atlas Venture

Linda Ave,
Humain Ventures

Jory Bell
Playground Global

Vicki Campbell
LYFIX

Rich Aldrich
Longwood Fund

Steve Derby
General Ventures

Paul Weiss, PhD
Venture Investors Health Fund

Douglas M. Fambrough, PhD
KCap Biotechnology Fund

Kate Moreau, PhD
RA Capital Management

Kenneth N. Horne
AN Venture Partners

Matthew Duffy
Lucius Partners, LLC

Matthew Hammond, PhD
RA Capital Management

Paulina Hill, PhD
Sanofi Ventures

John Averill, MBA
RA Capital Management

Derek Yuan, PhD
LYFE Capital

Thomas Michael Brady, BS
Brady family fund

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INVESTORS:

Peter Haberz, PhD
LYZZ Capital

Armando Cuesta, MD
Korion Life Sciences

Allan Gobbs
ATEM Capital

Jacqueline Rhuda
RA Capital Management

Otello Stampacchia, PhD
Omega Funds

Walter H. Moos, PhD
Pandect

Jeff Williams
Summit Life Science Partners

Nate Chang
Playground Global

Neil Littman
Bioverge Ventures

Gerry Brunk
Lumira Ventures

Drew Zhu
TB VC

Jens Eckstein, PhD
Hevolution, Apollo Health Ventures

Mike Amend

Josh Baldwin
RTW Investments, LP

Philip M Maurer, MD
PMM Investments

Benjamin Chen
Crimson Capital

Norman T. Ferguson Jr., MBA

Lily Yi Li, PhD
Sixty Degree Capital

Steven S Lehmann
Portal Innovations

Dylan Reid
Zetta Venture Partners

Giovanni, Rizzo, PhD, MBA
Indaco Venture Partners

INVESTORS:

Sonia Maryam Setayesh, PhD
Civilization Ventures

Stuart Hwang, PhD
Remiges Ventures

Arjun Goyal
Vida Ventures

Brian Bloom
Bloom Burton & Co.

Garrett Vygantas, MD, MBA
Riverine Ventures

Patrick Nosker, PhD
Affinity Asset Advisors

Ahmad El Naggar
Piper Heartland Healthcare Capital

Adam Stone
Perceptive Advisors

Prithviraj Singha Roy
RA Capital Management

Shinichiro Fuse
TPG Life Sciences Innovations

Matt Renna
Westfield Capital Management

Daniel S Lyons, PhD, CFA
Janus Henderson Global Life Sciences

Anish Kaushal, MD
Amplitude Ventures

Granville A. Ungerleider
NSIP LLC

Art Pappas
Pappas Capital, LLC

Karen Drexler, MBA
Astia, Portfolia

Assad Aslam
Desire Ventures Inc.

Jonathan Hostens
Insight Partners

Peter Balogh
RA Capital Management

Chris Garabedian
Perceptive Advisors

Mary E Wheeler, PhD MBA
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A Study of the Cost of Care Provided in Physician Owned Hospitals Compared to Traditional Hospitals

Analysis of 20 High-Cost Diagnostic Related Groups Using 2019 Medicare Claims Data

Robert H. Aseltine, Jr., PhD
Professor and Chair, Behavioral Sciences and Community Health
Director, Center for Population Health
UConn Health

Gregory J. Matthews, PhD
Director, Center for Data Science and Consulting
Associate Professor, Department of Mathematics and Statistics
Loyola University Chicago

Technical Report submitted to the Physician's Advocacy Institute and The Physicians Foundation, October 2023.

Introduction

The research literature on the cost and quality of care provided by physician owned hospitals (POHs) relative to traditional hospitals is sparse. In a recent systematic review of the literature, Miller et al. (2021) found only 21 studies published between 2005 – 2019 that met inclusion criteria based on the study population, the outcomes measured, and study design considerations.[1] Emerging from these studies, however, was a clear pattern of POHs providing higher quality care at lower or comparable cost, particularly in the cardiac and orthopedic specialty service markets. These findings were supported in a recent study by Wang et al. that found median commercial negotiated prices and cash prices were approximately one-third lower in general acute care POHs relative to traditional hospitals in their service areas for most common hospital procedures.[2] In contrast, two recent reports submitted to the American Hospital Association and Federation of American Hospitals found a number of cost and quality differences favoring traditional hospitals relative to POHs.[3,4]

To add to and further clarify the data on cost differences between POHs and traditional hospitals, this report summarizes results from an investigation comparing the cost of care in POHs with traditional hospitals for Medicare patients in the 20 most expensive diagnostic related groups (DRGs) for 2019. Cost of care is defined in this report as the total amounts paid by Medicare plus any beneficiary or primary insurer payments. By estimating a series of mixed effects regression models to predict the total cost associated with discharges for each DRG, we were able to compare POHs to traditional hospitals within the same hospital referral region (HRR) to adjust for regional differences in reimbursement. Separate models were estimated for each DRG, and all models controlled for patient demographic characteristics – age, sex, and race and ethnicity – as well as measures of patient comorbidities to account for potential differences in the patient populations among traditional hospitals and POHs.

Methods

Data and Measures

A list of 216 POHs operating in the United States was obtained from Physician Hospitals of America. Comparator hospitals in the same hospital referral regions as the POHs were identified using data from the Dartmouth Atlas Project.[5]

Cost data and patient characteristics were derived from the 2019 Medicare inpatient dataset (the MedPAR Limited Data Set) purchased from the Centers for Medicare and Medicaid Services. Patient-level Medicare fee-for-services claims in this dataset were aggregated by facility for each of the DRGs included in the analysis. Total payment was calculated by summing Medicare, beneficiary and primary payer paid amounts.[6] Discharges for which the total Medicare and beneficiary payment was zero (reflecting procedures lacking prior authorization, noncovered services or circumstances, coordination of benefit issues, or never events) were excluded from the analysis. Note that while this filtering reduced the number of discharges in POHs to slightly less than 1000 for DRGs 468 and 473, we retained these DRGs in the analysis.

The clinical conditions included in this analysis consisted of the 20 DRG codes accounting for the largest cumulative total payments in POH hospitals (excluding DRGs with fewer than 1000 total discharges across all POHs). DRGs included in the analysis were: Respiratory infections and inflammation with MCC (DRG 177); Pulmonary edema and respiratory failure (189); Chronic obstructive pulmonary disease with MCC (190); Simple pneumonia and pleurisy with MCC (193); Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries (246); Percutaneous cardiovascular procedures with drug-eluting stent without MCC (247); Acute myocardial infarction, discharged alive with MCC (280); Heart failure and shock with MCC (291); Combined anterior and posterior spinal fusion with CC (454); Combined anterior and posterior spinal fusion without CC/MCC (455); Spinal fusion except cervical without MCC (460); Revision of hip or knee replacement without CC/MCC (468); Major hip and knee joint replacement or reattachment of lower extremity without MCC (470); Cervical spinal fusion without CC/MCC (473); Major joint or limb reattachment procedures of upper extremities (483); Renal failure with MCC (682); Kidney and urinary tract infections without MCC (690); Infectious and parasitic diseases with operating room procedures with MCC (853); septicemia or severe sepsis without MV >96 hours with MCC (871); Septicemia or severe sepsis without MV >96 hours without MCC (872).

Measures of patient's demographic characteristics and level of comorbid health conditions were derived from the MedPAR LDS and included patient's age (<65; 65-74; 75-84; 85+), sex (male vs. female), and race/ethnicity (White/non-Hispanic; Black/non-Hispanic; Hispanic/Latino, Other race). Patient comorbid health conditions were measured by the Elixhauser comorbidity index, a widely used and empirically validated measure consisting of 30 categories of comorbid diagnoses.[7] The Elixhauser summary score reflects the sum of the patient's number of comorbid conditions across these 30 diagnostic categories.[8]

Analysis

We estimated mixed effects regression models predicting total payments for each DRG using R version 4.1.3.[9] Total payments were log transformed to account for the right skewness of the payment distribution. A random intercept was included in each model to account for the differences in reimbursement rates across hospital referral regions. The key predictor variable was a binary indicator for POH/non-POH status, and all models controlled for patient demographic characteristics and the Elixhauser comorbidity score.

Results

From the initial list of 216 POHs we removed 30 that either did not treat Medicare patients or did not treat patients with any of the DRGs included in our analysis, resulting in a total of 186 POHs providing 89,217 patient discharges for analysis. We then identified traditional hospitals within the same HRRs as POHs (N = 1230). For each DRG we limited the analysis to traditional hospitals operating within the same HRR as at least one POH and included only those facilities

with greater than 10 discharges within each DRG. This yielded a total number of traditional hospitals included in the analysis to 1230 and the total number of discharges across the 20 DRGs to 650,386.

Figure 1 presents a map of the US displaying POHs (red dots) and traditional hospitals (gray dots) included in the analysis. The numbers of POHs and traditional hospitals included in the analysis by state and hospital referral region is presented in Table 1. In Table 2 we present the numbers of facilities and numbers of discharges for each DRG analyzed.

Figure 1

Table 1

Table 2

Table 3 presents differences in patient demographic characteristics between POHs and traditional hospitals for each DRG. Given the large sample sizes, statistically significant differences at the .01 level in the age distributions of patients were observed in 11 of the 20 DRGs. In most cases, however, the percentages of patients in the more challenging age groups – i.e., under 65 and over 85 – varied by no more than a few percentage points between the two hospital types. Moreover, there was no clear pattern to these differences; for several DRGs POHs had a slightly more challenging age profile than did traditional hospitals. The only notable age difference was DRG 470 (Major hip and knee joint replacement or reattachment of lower extremity without MCC), where traditional hospitals had twice as many patients over 85 than did POHs (10.8% vs 4.7%).

Statistically significant differences at the .01 level in the race/ethnic distributions of patients in POHs and traditional hospitals were observed in 14 of the 20 DRGs, with traditional hospitals having a higher percentage of White patients. As was the case with age, however, the magnitude of the differences in the percent of White patients treated in these hospitals was very small, generally varying by 2-3 percentage points. In only two DRGs did the proportion of White patients differ by 4 percentage points: DRG 291 (Heart failure and shock with MCC: 78.2% POH vs. 74.0% traditional) and DRG 189 (Pulmonary edema and respiratory failure: 84.6% POH vs. 80.5% traditional).

Statistically significant differences at the .01 level in the comorbidity counts among patients in POHs and traditional hospitals were observed in only 9 of the 20 DRGs. Lower counts were observed in POHs relative to traditional hospitals in all but one case, but these differences were of very small magnitude, ranging between .1 and .25 comorbidities. Finally, there were virtually no statistically or substantively meaningful sex differences in these two patient populations.

Table 3

Table 4 presents a crude comparison of the mean payment per discharge in each DRG for POHs and traditional hospitals. Note that these numbers do not include controls for differences in patient characteristics. Across all 20 DRGs the mean total payments were substantially lower in POHs. The smallest difference in average payment was for cervical spinal fusion without CC/MCC (DRG 473), where the average payment was 10.1% lower in POHs compared to traditional hospitals. The largest difference in payment was for septicemia or severe sepsis without MV >96 hours with MCC (DRG 872), where the average payment was 19.3% lower for POHs.

Table 4

Table 5 presents results from mixed effects regression models in which the log of total payments were regressed on POH status, patient demographic characteristics and Elixhauser comorbidity scores. A random intercept for HRR was included in all models to account for variability in payment across hospital referral regions. Table 5 shows that for all 20 DRGs, the coefficients for the POH indicator variables were negative and highly statistically significant (with p-values adjusted for multiple comparisons using the Benjamini-Hochberg adjustment).[10] This indicates that POHs received significantly lower average total payments than traditional hospitals for all DRGs, controlling for patient's demographic characteristics and comorbid health conditions. To derive cost differences between POHs and traditional hospitals when controlling for patient demographics and comorbidities, we used the regression coefficients from this model to calculate the expected differences in average total payments. Results from this analysis are presented in Table 6 and indicate that the differences in payments between POHs and traditional hospitals across all 20 DRGs ranged between 8.6% and 15.2% when adjusting for differences in patient mix.

Table 5

Table 6

Conclusions

For the 20 highest cost DRGs treated by POHs in the US, our analysis of 2019 Medicare claims data indicates that total payments were between 8-15% lower than in traditional hospitals within the same market. Mixed effects regression models indicated that differences between POHs and traditional hospitals in the demographic characteristics or comorbidity profiles of their respective patient populations did not account for these payment differences. In general, the patient populations of POHs and traditional hospitals were very similar, with few substantively meaningful differences by race and ethnicity, sex, age and patient sickness.

Our analysis indicates that substantial savings to the Medicare program could be achieved were traditional hospitals able to provide care at the same cost as POHs in their area. According to the MedPAR data we analyzed for this report, the total cost of care for these 20 DRGs in

traditional hospitals in these markets would have been reduced by approximately $1.1 billion in 2019, a 12.2% reduction, if reimbursed at the same rate as POHs. When considered in light of Wang et al.'s (2023) findings of substantially lower commercial reimbursement rates among POHs, our results suggest that POHs may offer an opportunity to achieve considerably lower costs of care across a range of health conditions and patient populations.

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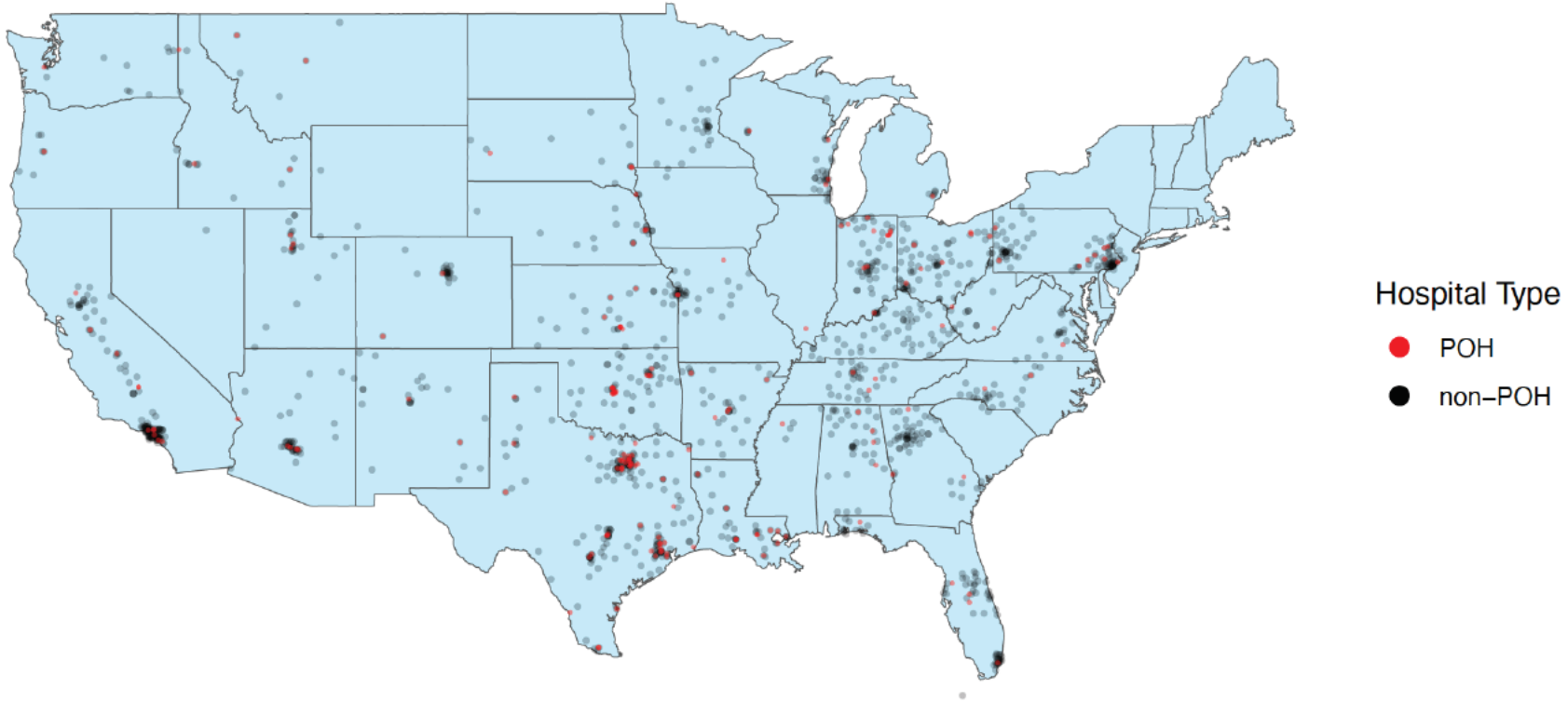
Figure 1. Distribution of physician owned hospitals and traditional hospitals operating in the same hospital referral regions.



Note. Darker colors indicate a greater concentration of hospitals in an area.

Table 1. Numbers of POHs and traditional hospitals included in the analysis, by hospital referral region and state.

HRR City	State	Traditional hospitals	Physician owned hospitals
Anchorage	AK	7	1
Birmingham	AL	30	3
Huntsville	AL	5	1
Jonesboro	AR	3	1
Little Rock	AR	21	3
Springdale	AR	5	1
Texarkana	AR	2	1
Mesa	AZ	10	2
Phoenix	AZ	25	3
Bakersfield	CA	8	2
Fresno	CA	5	1
Los Angeles	CA	71	4
Modesto	CA	5	1
Orange County	CA	21	2
Sacramento	CA	18	1
Denver	CO	21	1
Hudson	FL	4	1
Miami	FL	21	1
Orlando	FL	28	2
Pensacola	FL	13	1
Atlanta	GA	44	1
Columbus	GA	3	1
Savannah	GA	10	1
Sioux City	IA	2	1
Boise	ID	7	1
Idaho Falls	ID	2	1
Fort Wayne	IN	9	6
Gary	IN	5	2
Indianapolis	IN	31	2
South Bend	IN	6	1
Topeka	KS	4	1
Wichita	KS	16	6
Lexington	KY	27	1
Louisville	KY	14	1
Paducah	KY	6	1
Alexandria	LA	3	1
Baton Rouge	LA	6	3
Houma	LA	3	1
Lafayette	LA	11	2
Metairie	LA	3	2
Shreveport	LA	6	1
Slidell	LA	3	1

HRR City	State	Traditional hospitals	Physician owned hospitals
Royal Oak	MI	5	1
Minneapolis	MN	27	1
Columbia	MO	10	1
Kansas City	MO	29	2
Oxford	MS	3	1
Great Falls	MT	2	1
Missoula	MT	4	1
Charlotte	NC	20	1
Durham	NC	13	1
Lincoln	NE	4	1
Omaha	NE	15	2
Albuquerque	NM	21	3
Akron	OH	3	2
Cincinnati	OH	14	1
Columbus	OH	27	1
Dayton	OH	11	2
Youngstown	OH	7	1
Oklahoma City	OK	27	10
Tulsa	OK	24	4
Eugene	OR	6	1
Allentown	PA	11	2
Erie	PA	8	1
Lancaster	PA	5	1
Philadelphia	PA	30	2
Pittsburgh	PA	32	1
Reading	PA	4	1
York	PA	4	1
Rapid City	SD	2	1
Sioux Falls	SD	12	2
Nashville	TN	35	3
Amarillo	TX	4	1
Austin	TX	14	3
Beaumont	TX	4	1
Bryan	TX	3	1
Corpus Christi	TX	2	1
Dallas	TX	42	19
Fort Worth	TX	22	4
Houston	TX	40	12
Lubbock	TX	10	1
McAllen	TX	4	2
Odessa	TX	2	1
San Antonio	TX	20	3
Tyler	TX	5	1
Wichita Falls	TX	1	1
Ogden	UT	4	1
Salt Lake City	UT	24	2

HRR City	State	Traditional hospitals	Physician owned hospitals
Richmond	VA	15	1
Olympia	WA	2	1
Spokane	WA	12	1
Green Bay	WI	7	1
Milwaukee	WI	23	2
Charleston	WV	9	1
Huntington	WV	2	1
Totals		1230	186

Table 2. Numbers of facilities and discharges for each DRG, separately for POHs and traditional hospitals.

DRG Code	DRG Description		Physician owned hospitals	Traditional hospitals
177	Respiratory infections and inflammations with MCC	Total N discharges	1311	12853
		Total N facilities	43	329
189	Pulmonary edema and respiratory failure	Total N discharges	1913	26106
		Total N facilities	47	458
190	Chronic obstructive pulmonary disease with MCC	Total N discharges	2658	26419
		Total N facilities	62	530
193	Simple pneumonia and pleurisy with MCC	Total N discharges	2547	31509
		Total N facilities	62	560
246	Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries	Total N discharges	1259	5575
		Total N facilities	36	155
247	Percutaneous cardiovascular procedures with drug-eluting stent without MCC	Total N discharges	2441	13105
		Total N facilities	48	266
280	Acute myocardial infarction, discharged alive with MCC	Total N discharges	1885	15710
		Total N facilities	56	370
291	Heart failure and shock with MCC	Total N discharges	6875	93892
		Total N facilities	76	743
454	Combined anterior and posterior spinal fusion with CC	Total N discharges	1317	3612
		Total N facilities	37	105
455	Combined anterior and posterior spinal fusion without CC/MCC	Total N discharges	2212	3961
		Total N facilities	55	137
460	Spinal fusion except cervical without MCC	Total N discharges	4208	12367
		Total N facilities	90	296
468	Revision of hip or knee replacement without CC/MCC	Total N discharges	908	2131
		Total N facilities	38	88
470	Major hip and knee joint replacement or reattachment of lower extremity without MCC	Total N discharges	35830	140975
		Total N facilities	152	1020
473	Cervical spinal fusion without CC/MCC	Total N discharges	925	1039
		Total N facilities	33	65
483	Major joint or limb reattachment procedures of upper extremities	Total N discharges	5728	18562
		Total N facilities	103	449
682	Renal failure with MCC	Total N discharges	1548	18618
		Total N facilities	50	374
690	Kidney and urinary tract infections without MCC	Total N discharges	2063	28115
		Total N facilities	57	577

DRG Code	DRG Description		Physician owned hospitals	Traditional hospitals
853	Infectious and parasitic diseases with OR procedures with MCC	Total N discharges	1035	14540
		Total N facilities	39	307
871	Septicemia or severe sepsis without MV >96 hours with MCC	Total N discharges	9285	147533
		Total N facilities	69	686
872	Septicemia or severe sepsis without MV >96 hours without MCC	Total N discharges	1977	33764
		Total N facilities	58	590

Table 3. Demographic characteristics and comorbidity levels among patients in POHs and traditional hospitals. Chi-square tests of significance were performed for age, race, and sex; Welch's t-test was used for the Elixhauser scale.

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
177	Respiratory infections and inflammations with MCC	Age					
			< 65	16.63	13.32	15.67	<0.001
			65-74	23.65	26.04		
			75-84	29.98	28.36		
			85+	29.75	32.28		
		Sex					
			Female	48.89	47.86	0.46	<0.001
			Male	51.11	52.14		
		Race					
			White	81.39	81.52	8.46	<0.001
			Black	8.85	9.58		
			Hisp/Latino	2.06	2.84		
			Other race	7.70	6.06		
		Elix mean		3.14	3.09	-1.26	0.208
189	Pulmonary edema and respiratory failure	Age					
			< 65	21.33	21.21	5.26	<0.001
			65-74	35.81	37.21		
			75-84	29.01	26.79		
			85+	13.85	14.79		
		Sex					
			Female	61.84	58.45	8.31	<0.001
			Male	38.16	41.55		
		Race					
			White	84.58	80.46	20.50	<0.001
			Black	9.83	13.00		
			Hisp/Latino	1.67	1.81		
			Other race	3.92	4.73		
		Elix mean		2.60	2.74	3.69	<0.001

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
190	Chronic obstructive pulmonary disease with MCC	Age					
			< 65	17.38	18.80	10.30	<0.001
			65-74	35.82	37.48		
			75-84	31.41	29.82		
			85+	15.39	13.89		
		Sex					
			Female	60.08	58.07	3.95	<0.001
			Male	39.92	41.93		
		Race					
			White	86.83	83.80	29.27	<0.001
			Black	7.41	10.50		
			Hisp/Latino	1.81	2.26		
			Other race	3.95	3.44		
		Elix mean		2.21	2.19	-0.53	0.599
193	Simple pneumonia and pleurisy with MCC	Age					
			< 65	13.78	16.33	12.76	<0.001
			65-74	30.82	30.74		
			75-84	29.45	28.66		
			85+	25.95	24.27		
		Sex					
			Female	54.77	54.53	0.05	<0.001
			Male	45.23	45.47		
		Race					
			White	84.33	80.89	27.70	<0.001
			Black	7.30	8.94		
			Hisp/Latino	2.59	4.34		
			Other race	5.77	5.83		
		Elix mean		2.70	2.79	2.49	0.013

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
246	Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries	Age					
			< 65	13.50	16.48	18.75	<0.001
			65-74	40.19	42.78		
			75-84	31.06	28.93		
			85+	15.25	11.80		
		Sex					
			Female	40.11	40.47	0.04	<0.001
			Male	59.89	59.53		
		Race					
			White	85.54	82.57	17.56	<0.001
			Black	7.39	9.96		
			Hisp/Latino	1.75	3.16		
			Other race	5.32	4.32		
		Elix mean		2.54	2.81	4.96	<0.001
247	Percutaneous cardiovascular procedures with drug-eluting stent without MCC	Age					
			< 65	10.61	11.32	8.53	<0.001
			65-74	45.06	47.52		
			75-84	33.59	31.06		
			85+	10.73	10.11		
		Sex					
			Female	35.68	36.50	0.56	<0.001
			Male	64.32	63.50		
		Race					
			White	89.92	88.00	13.33	<0.001
			Black	4.55	6.42		
			Hisp/Latino	1.76	1.58		
			Other race	3.77	4.01		
		Elix mean		1.50	1.58	2.61	0.009

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
280	Acute myocardial infarction, discharged alive with MCC	Age					
			<65	13.63	15.43	5.13	<0.001
			65-74	32.36	32.20		
			75-84	28.97	27.37		
			85+	25.04	25.00		
		Sex					
			Female	50.50	48.13	3.69	<0.001
			Male	49.50	51.87		
		Race					
			White	77.98	74.91	14.35	<0.001
			Black	14.27	14.96		
			Hisp/Latino	2.44	3.86		
			Other race	5.31	6.28		
		Elix mean		3.06	3.40	8.25	<0.001
291	Heart failure and shock with MCC	Age					
			< 65	13.08	14.71	15.01	<0.001
			65-74	29.48	28.57		
			75-84	29.63	28.84		
			85+	27.81	27.87		
		Sex					
			Female	50.82	51.96	3.27	<0.001
			Male	49.18	48.04		
		Race					
			White	78.17	73.99	71.05	<0.001
			Black	13.32	16.80		
			Hisp/Latino	3.07	3.80		
			Other race	5.44	5.41		
		Elix mean		3.58	3.70	5.52	<0.001

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
454	Combined anterior and posterior spinal fusion with CC	Age					
			< 65	16.10	15.25	3.06	<0.001
			65-74	59.15	57.70		
			75-84	23.39	25.30		
			85+	1.37	1.74		
		Sex					
			Female	61.66	58.55	3.72	<0.001
			Male	38.34	41.45		
		Race					
			White	89.67	90.03	0.71	<0.001
			Black	5.16	4.79		
			Hisp/Latino	0.61	0.78		
			Other race	4.56	4.40		
		Elix mean		1.64	1.67	0.72	0.470
455	Combined anterior and posterior spinal fusion without CC/MCC	Age					
			< 65	13.20	13.96	6.04	<0.001
			65-74	63.34	60.21		
			75-84	22.06	24.31		
			85+	1.40	1.51		
		Sex					
			Female	52.35	54.30	2.10	<0.001
			Male	47.65	45.70		
		Race					
			White	89.78	91.29	15.35	<0.001
			Black	4.97	3.21		
			Hisp/Latino	0.54	0.98		
			Other race	4.70	4.52		
		Elix mean		1.14	1.00	-4.84	<0.001

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
460	Spinal fusion except cervical without MCC	Age					
			< 65	13.36	15.72	41.97	<0.001
			65-74	57.75	52.14		
			75-84	26.52	29.13		
			85+	2.38	3.01		
		Sex					
			Female	56.32	55.65	0.55	<0.001
			Male	43.68	44.35		
		Race					
			White	91.75	89.66	34.36	<0.001
			Black	3.54	5.83		
			Hisp/Latino	0.78	0.91		
			Other race	3.92	3.60		
		Elix mean		1.22	1.37	7.10	<0.001
468	Revision of hip or knee replacement without CC/MCC	Age					
			< 65	10.57	13.14	11.76	<0.001
			65-74	60.35	54.48		
			75-84	25.55	27.17		
			85+	3.52	5.21		
		Sex					
			Female	55.62	57.48	0.83	<0.001
			Male	44.38	42.52		
		Race					
			White	90.42	88.13	7.30	<0.001
			Black	5.07	6.71		
			Hisp/Latino	0.22	0.89		
			Other race	4.30	4.27		
		Elix mean		1.14	1.05	-2.06	0.040

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
470	Major hip and knee joint replacement or reattachment of lower extremity without MCC	Age					
			< 65	5.46	6.99	1723.18	<0.001
			65-74	60.72	51.18		
			75-84	29.12	31.09		
			85+	4.70	10.75		
		Sex					
			Female	61.53	63.41	43.50	<0.001
			Male	38.47	36.59		
		Race					
			White	91.29	89.35	241.65	<0.001
			Black	3.53	5.46		
			Hisp/Latino	0.76	0.98		
			Other race	4.43	4.21		
		Elix mean		1.17	1.30	19.76	<0.001
473	Cervical spinal fusion without CC/MCC	Age					
			< 65	22.70	23.97	12.61	<0.001
			65-74	60.22	54.67		
			75-84	16.54	19.44		
			85+	0.54	1.92		
		Sex					
			Female	54.59	54.57	0.00	<0.001
			Male	45.41	45.43		
		Race					
			White	88.86	87.58	4.22	<0.001
			Black	6.81	6.93		
			Hisp/Latino	0.65	1.64		
			Other race	3.68	3.85		
		Elix mean		1.02	0.96	-1.33	0.182

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
483	Major joint or limb reattachment procedures of upper extremities	Age					
			< 65	5.64	7.21	46.14	<0.001
			65-74	54.68	51.49		
			75-84	35.11	35.02		
			85+	4.57	6.29		
		Sex					
			Female	57.91	59.14	2.70	<0.001
			Male	42.09	40.86		
		Race					
			White	93.07	92.88	33.50	<0.001
			Black	2.22	3.38		
			Hisp/Latino	0.40	0.47		
			Other race	4.31	3.26		
		Elix mean		1.15	1.27	7.12	<0.001
682	Renal failure with MCC	Age					
			< 65	18.86	17.11	4.75	<0.001
			65-74	29.97	29.21		
			75-84	27.58	28.47		
			85+	23.58	25.21		
		Sex					
			Female	51.49	51.72	0.02	<0.001
			Male	48.51	48.28		
		Race					
			White	71.32	69.14	6.31	<0.001
			Black	18.35	18.65		
			Hisp/Latino	3.94	5.22		
			Other race	6.40	6.99		
		Elix mean		3.94	3.90	-1.06	0.291

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
690	Kidney and urinary tract infections without MCC	Age					
			< 65	10.81	11.44	5.85	<0.001
			65-74	26.13	24.28		
			75-84	33.49	32.81		
			85+	29.57	31.47		
		Sex					
			Female	71.98	71.07	0.74	<0.001
			Male	28.02	28.93		
		Race					
			White	80.27	80.82	10.99	<0.001
			Black	8.53	9.81		
			Hisp/Latino	4.65	4.19		
			Other race	6.54	5.19		
		Elix mean		2.31	2.34	0.98	0.326
853	Infectious and parasitic diseases with OR procedures with MCC	Age					
			< 65	24.54	25.06	4.29	<0.001
			65-74	37.87	38.33		
			75-84	26.96	24.50		
			85+	10.63	12.11		
		Sex					
			Female	48.21	44.98	3.95	<0.001
			Male	51.79	55.02		
		Race					
			White	74.88	71.75	7.22	<0.001
			Black	12.75	15.25		
			Hisp/Latino	5.80	5.34		
			Other race	6.57	7.66		
		Elix mean		3.53	3.59	1.09	0.277

DRG Code	DRG Description			Physician owned hospitals	Traditional hospitals	Test Statistic	p-value
871	Septicemia or severe sepsis without MV >96 hours with MCC	Age					
			< 65	16.44	16.47	2.73	<0.001
			65-74	31.37	30.92		
			75-84	28.91	28.61		
			85+	23.28	24.00		
		Sex					
			Female	51.63	51.37	0.24	<0.001
			Male	48.37	48.63		
		Race					
			White	78.05	77.02	47.29	<0.001
			Black	9.22	11.30		
			Hisp/Latino	5.09	4.34		
			Other race	7.64	7.33		
		Elix mean		3.21	3.23	1.09	0.274
872	Septicemia or severe sepsis without MV >96 hours without MCC	Age					
			< 65	18.36	17.92	0.75	<0.001
			65-74	32.63	33.49		
			75-84	30.05	29.59		
			85+	18.97	18.99		
		Sex					
			Female	55.99	53.21	5.70	<0.001
			Male	44.01	46.79		
		Race					
			White	81.39	79.22	26.66	<0.001
			Black	7.08	8.98		
			Hisp/Latino	6.07	4.53		
			Other race	5.46	7.26		
		Elix mean		2.53	2.55	0.61	0.540

Table 4. Crude comparisons of average paid amounts by DRG in traditional and physician owned hospitals.

		Traditional hospitals			Physician owned hospitals			Differences	
DRG	DRG Description	Mean payment	Number of discharges	Number of facilities	Mean payment	Number of discharges	Number of facilities	Mean payment difference	Percent difference
177	Respiratory infections and inflammations with MCC	$13,168.00	12853	329	$11,404.67	1311	43	$1,763	13.4%
189	Pulmonary edema and respiratory failure	$9,730.10	26106	458	$8,386.55	1913	47	$1,344	13.8%
190	Chronic obstructive pulmonary disease with MCC	$9,088.75	26419	530	$7,760.24	2658	62	$1,329	14.6%
193	Simple pneumonia and pleurisy with MCC	$9,930.46	31509	560	$8,534.96	2547	62	$1,395	14.1%
246	Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries	$23,384.09	5575	155	$20,473.08	1259	36	$2,911	12.4%
247	Percutaneous cardiovascular procedures with drug-eluting stent without MCC	$15,250.00	13105	266	$13,209.82	2441	48	$2,040	13.4%
280	Acute myocardial infarction, discharged alive with MCC	$12,912.44	15710	370	$10,484.35	1885	56	$2,428	18.8%
291	Heart failure and shock with MCC	$10,426.71	93892	743	$8,573.01	6875	76	$1,854	17.8%

		Traditional hospitals			Physician owned hospitals			Differences	
DRG	DRG Description	Mean payment	Number of discharges	Number of facilities	Mean payment	Number of discharges	Number of facilities	Mean payment difference	Percent difference
454	Combined anterior and posterior spinal fusion with CC	$50,190.24	3612	105	$40,826.29	1317	37	$9,364	18.7%
455	Combined anterior and posterior spinal fusion without CC/MCC	$38,454.47	3961	137	$31,932.94	2212	55	$6,522	17.0%
460	Spinal fusion except cervical without MCC	$30,055.65	12367	296	$24,860.04	4208	90	$5,196	17.3%
468	Revision of hip or knee replacement without CC/MCC	$21,110.67	2131	88	$17,064.63	908	38	$4,046	19.2%
470	Major hip and knee joint replacement or reattachment of lower extremity without MCC	$14,655.22	140975	1020	$12,336.71	35830	152	$2,319	15.8%
473	Cervical spinal fusion without CC/MCC	$17,918.28	1039	65	$14,452.57	925	33	$3,466	19.3%
483	Major joint or limb reattachment procedures of upper extremities	$17,305.34	18562	449	$14,731.96	5728	103	$2,573	14.9%
682	Renal failure with MCC	$11,463.52	18618	374	$9,772.06	1548	50	$1,691	14.8%
690	Kidney and urinary tract infections without MCC	$6,508.79	28115	577	$5,608.81	2063	57	$900	13.8%

		Traditional hospitals			Physician owned hospitals			Differences	
DRG	DRG Description	Mean payment	Number of discharges	Number of facilities	Mean payment	Number of discharges	Number of facilities	Mean payment difference	Percent difference
853	Infectious and parasitic diseases with OR procedures with MCC	$38,334.41	14540	307	$32,540.65	1035	39	$5,794	15.1%
871	Septicemia or severe sepsis without MV >96 hours with MCC	$14,165.61	147533	686	$12,729.31	9285	69	$1,436	10.1%
872	Septicemia or severe sepsis without MV >96 hours without MCC	$8,513.41	33764	590	$7,463.53	1977	58	$1,050	12.3%

Table 5. Results from mixed effects regression models regressing total payments on POH status controlling for patient demographics and comorbidities, by DRG.

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
177	Respiratory infections and inflammations with MCC	(Intercept)	9.388	0.024	393.57	<0.001
		Black	0.030	0.009	3.23	0.001
		Hispanic	0.036	0.017	2.12	0.034
		Other	0.001	0.011	0.13	0.898
		Male	0.011	0.005	1.99	0.046
		Age <65	0.048	0.009	5.30	<0.001
		Age 75-84	-0.037	0.007	-5.10	<0.001
		Age 85+	-0.059	0.007	-8.26	<0.001
		Comorbidity scale	0.011	0.002	6.62	<0.001
		POH	-0.092	0.009	-10.01	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
189	Pulmonary edema and respiratory failure	(Intercept)	9.090	0.022	419.91	<0.001
		Black	0.056	0.006	9.93	<0.001
		Hispanic	0.058	0.014	4.19	<0.001
		Other	-0.018	0.009	-2.07	0.039
		Male	0.024	0.004	6.59	<0.001
		Age <65	-0.002	0.005	-0.31	0.757
		Age 75-84	-0.022	0.004	-4.82	<0.001
		Age 85+	-0.025	0.005	-4.55	<0.001
		Comorbidity scale	0.009	0.001	8.35	<0.001
		POH	-0.108	0.007	-14.81	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
190	Chronic obstructive pulmonary disease with MCC	(Intercept)	9.038	0.022	408.90	<0.001
		Black	0.059	0.007	8.54	<0.001
		Hispanic	0.027	0.014	1.91	0.056
		Other	-0.032	0.012	-2.77	0.006
		Male	0.009	0.004	2.23	0.026
		Age <65	0.015	0.006	2.64	0.008
		Age 75-84	-0.006	0.005	-1.32	0.188
		Age 85+	-0.026	0.006	-4.16	<0.001
		Comorbidity scale	0.006	0.001	4.78	<0.001
		POH	-0.129	0.007	-18.13	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
193	Simple pneumonia and pleurisy with MCC	(Intercept)	9.135	0.019	471.95	<0.001
		Black	0.034	0.006	5.67	<0.001
		Hispanic	0.029	0.008	3.47	<0.001
		Other	0.001	0.007	0.19	0.849
		Male	0.010	0.003	3.02	0.003
		Age <65	0.018	0.005	3.67	<0.001
		Age 75-84	-0.027	0.004	-6.48	<0.001
		Age 85+	-0.037	0.004	-8.52	<0.001
		Comorbidity scale	0.008	0.001	7.74	<0.001
		POH	-0.118	0.006	-18.92	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
246	Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries	(Intercept)	9.988	0.021	485.92	<0.001
		Black	0.032	0.013	2.42	0.016
		Hispanic	0.059	0.024	2.43	0.015
		Other	0.027	0.018	1.52	0.130
		Male	0.027	0.008	3.58	<0.001
		Age <65	-0.001	0.011	-0.09	0.929
		Age 75-84	-0.036	0.009	-4.01	<0.001
		Age 85+	-0.054	0.012	-4.45	<0.001
		Comorbidity scale	0.004	0.002	1.63	0.103
		POH	-0.133	0.010	-12.69	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
247	Percutaneous cardiovascular procedures with drug-eluting stent without MCC	(Intercept)	9.592	0.019	493.83	<0.001
		Black	0.056	0.010	5.65	<0.001
		Hispanic	0.059	0.019	3.19	0.001
		Other	0.027	0.012	2.36	0.018
		Male	0.022	0.005	4.50	<0.001
		Age <65	-0.015	0.008	-1.88	0.060
		Age 75-84	-0.058	0.005	-10.88	<0.001
		Age 85+	-0.081	0.008	-10.25	<0.001
		Comorbidity scale	0.004	0.002	2.49	0.013
		POH	-0.117	0.007	-16.96	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
280	Acute myocardial infarction, discharged alive with MCC	(Intercept)	9.310	0.022	426.30	<0.001
		Black	0.053	0.007	7.06	<0.001
		Hispanic	0.063	0.014	4.49	<0.001
		Other	0.002	0.011	0.20	0.839
		Male	0.010	0.005	1.94	0.053
		Age <65	0.025	0.008	3.20	0.001
		Age 75-84	-0.015	0.006	-2.35	0.019
		Age 85+	-0.033	0.007	-4.87	<0.001
		Comorbidity scale	0.011	0.001	7.47	<0.001
		POH	-0.148	0.008	-17.49	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
291	Heart failure and shock with MCC	(Intercept)	9.136	0.018	506.29	<0.001
		Black	0.064	0.003	22.15	<0.001
		Hispanic	0.045	0.005	8.25	<0.001
		Other	0.013	0.005	2.77	0.006
		Male	0.013	0.002	6.48	<0.001
		Age <65	0.024	0.003	7.36	<0.001
		Age 75-84	-0.021	0.003	-7.89	<0.001
		Age 85+	-0.043	0.003	-16.15	<0.001
		Comorbidity scale	0.009	0.001	15.50	<0.001
		POH	-0.143	0.004	-35.02	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
454	Combined anterior and posterior spinal fusion with CC	(Intercept)	10.704	0.024	443.37	<0.001
		Black	-0.083	0.020	-4.17	<0.001
		Hispanic	0.062	0.056	1.11	0.267
		Other	0.055	0.020	2.68	0.007
		Male	0.029	0.009	3.36	<0.001
		Age <65	0.042	0.012	3.41	<0.001
		Age 75-84	-0.043	0.010	-4.12	<0.001
		Age 85+	-0.094	0.034	-2.74	0.006
		Comorbidity scale	0.005	0.003	1.60	0.109
		POH	-0.141	0.011	-12.67	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
455	Combined anterior and posterior spinal fusion without CC/MCC	(Intercept)	10.483	0.022	484.60	<0.001
		Black	0.017	0.018	0.94	0.345
		Hispanic	-0.006	0.042	-0.15	0.884
		Other	-0.003	0.016	-0.18	0.858
		Male	0.011	0.007	1.54	0.123
		Age <65	0.035	0.010	3.39	<0.001
		Age 75-84	-0.058	0.008	-7.07	<0.001
		Age 85+	-0.049	0.028	-1.74	0.081
		Comorbidity scale	0.002	0.003	0.74	0.459
		POH	-0.120	0.008	-14.94	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
460	Spinal fusion except cervical without MCC	(Intercept)	10.238	0.015	706.07	<0.001
		Black	0.025	0.009	2.68	0.007
		Hispanic	-0.066	0.023	-2.81	0.005
		Other	0.040	0.011	3.61	<0.001
		Male	0.009	0.004	2.13	0.033
		Age <65	0.030	0.006	4.85	<0.001
		Age 75-84	-0.038	0.005	-7.79	<0.001
		Age 85+	-0.056	0.013	-4.37	<0.001
		Comorbidity scale	0.004	0.002	2.61	0.009
		POH	-0.132	0.006	-23.54	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
468	Revision of hip or knee replacement without CC/MCC	(Intercept)	9.870	0.020	505.17	<0.001
		Black	-0.006	0.020	-0.32	0.746
		Hispanic	-0.060	0.059	-1.01	0.310
		Other	0.028	0.024	1.17	0.244
		Male	0.022	0.009	2.39	0.017
		Age <65	0.091	0.015	6.24	<0.001
		Age 75-84	-0.032	0.011	-2.92	0.003
		Age 85+	-0.028	0.022	-1.24	0.217
		Comorbidity scale	-0.003	0.004	-0.74	0.457
		POH	-0.165	0.011	-15.59	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
470	Major hip and knee joint replacement or reattachment of lower extremity without MCC	(Intercept)	9.545	0.011	832.50	<0.001
		Black	0.050	0.003	18.71	<0.001
		Hispanic	0.016	0.006	2.60	0.009
		Other	0.016	0.003	5.57	<0.001
		Male	0.015	0.001	12.30	<0.001
		Age <65	0.025	0.002	10.56	<0.001
		Age 75-84	-0.051	0.001	-39.00	<0.001
		Age 85+	-0.050	0.002	-24.81	<0.001
		Comorbidity scale	0.001	0.000	2.96	0.003
		POH	-0.165	0.002	-102.17	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
473	Cervical spinal fusion without CC/MCC	(Intercept)	9.746	0.024	404.57	<0.001
		Black	0.009	0.023	0.40	0.687
		Hispanic	-0.029	0.063	-0.47	0.641
		Other	-0.012	0.035	-0.35	0.727
		Male	-0.022	0.012	-1.91	0.056
		Age <65	0.021	0.014	1.49	0.135
		Age 75-84	-0.049	0.015	-3.19	0.001
		Age 85+	0.021	0.051	0.40	0.688
		Comorbidity scale	-0.007	0.006	-1.32	0.188
		POH	-0.154	0.013	-12.02	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
483	Major joint or limb reattachment procedures of upper extremities	(Intercept)	9.718	0.014	692.18	<0.001
		Black	0.024	0.008	2.90	0.004
		Hispanic	-0.018	0.021	-0.87	0.387
		Other	0.003	0.008	0.33	0.744
		Male	0.018	0.003	6.18	<0.001
		Age <65	0.052	0.006	8.78	<0.001
		Age 75-84	-0.032	0.003	-10.27	<0.001
		Age 85+	-0.032	0.006	-5.05	<0.001
		Comorbidity scale	0.001	0.001	0.56	0.575
		POH	-0.156	0.004	-41.61	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
682	Renal failure with MCC	(Intercept)	9.220	0.025	366.01	<0.001
		Black	0.053	0.007	8.09	<0.001
		Hispanic	0.015	0.011	1.36	0.174
		Other	0.028	0.010	2.90	0.004
		Male	0.007	0.005	1.48	0.139
		Age <65	0.036	0.007	4.89	<0.001
		Age 75-84	-0.029	0.006	-4.62	<0.001
		Age 85+	-0.047	0.007	-7.22	<0.001
		Comorbidity scale	0.012	0.002	7.56	<0.001
		POH	-0.097	0.009	-10.59	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
690	Kidney and urinary tract infections without MCC	(Intercept)	8.711	0.021	421.73	<0.001
		Black	0.062	0.006	11.16	<0.001
		Hispanic	0.069	0.009	7.93	<0.001
		Other	0.070	0.008	9.09	<0.001
		Male	0.003	0.004	0.77	0.441
		Age <65	0.045	0.006	7.81	<0.001
		Age 75-84	-0.018	0.004	-4.16	<0.001
		Age 85+	-0.034	0.004	-7.86	<0.001
		Comorbidity scale	0.005	0.001	4.32	<0.001
		POH	-0.127	0.007	-19.52	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
853	Infectious and parasitic diseases with OR procedures with MCC	(Intercept)	10.306	0.029	354.25	<0.001
		Black	0.043	0.011	3.98	<0.001
		Hispanic	-0.041	0.017	-2.41	0.016
		Other	-0.001	0.014	-0.09	0.929
		Male	0.038	0.007	5.27	<0.001
		Age <65	0.037	0.010	3.85	<0.001
		Age 75-84	-0.042	0.009	-4.46	<0.001
		Age 85+	-0.087	0.012	-7.28	<0.001
		Comorbidity scale	0.016	0.002	6.96	<0.001
		POH	-0.104	0.015	-7.02	<0.001

DRG	DRG Description	Covariate	Value	Standard Error	t-value	p-value
871	Septicemia or severe sepsis without MV >96 hours with MCC	(Intercept)	9.433	0.019	506.96	<0.001
		Black	0.054	0.003	18.90	<0.001
		Hispanic	0.037	0.004	8.42	<0.001
		Other	0.016	0.003	4.73	<0.001
		Male	0.014	0.002	8.46	<0.001
		Age <65	0.032	0.003	12.16	<0.001
		Age 75-84	-0.032	0.002	-14.46	<0.001
		Age 85+	-0.055	0.002	-23.61	<0.001
		Comorbidity scale	0.010	0.001	18.81	<0.001
		POH	-0.090	0.004	-24.14	<0.001
DRG	**DRG Description**	**Covariate**	**Value**	**Standard Error**	**t-value**	**p-value**
872	Septicemia or severe sepsis without MV >96 hours without MCC	(Intercept)	8.969	0.018	490.91	<0.001
		Black	0.084	0.006	14.51	<0.001
		Hispanic	0.061	0.008	7.62	<0.001
		Other	0.058	0.006	9.00	<0.001
		Male	0.001	0.003	0.41	0.681
		Age <65	0.016	0.005	3.35	<0.001
		Age 75-84	-0.049	0.004	-12.12	<0.001
		Age 85+	-0.055	0.005	-12.06	<0.001
		Comorbidity scale	0.003	0.001	3.14	0.002
		POH	-0.096	0.007	-13.48	<0.001

Table 6. Estimated differences in payments in POHs and traditional hospitals, by DRG.

DRG	DRG Description	Mean payment difference POHs vs. traditional hospitals **	Percent difference
177	Respiratory infections and inflammations with MCC	-$1,090	-8.8%
189	Pulmonary edema and respiratory failure	-$926	-10.2%
190	Chronic obstructive pulmonary disease with MCC	-$1,036	-12.1%
193	Simple pneumonia and pleurisy with MCC	-$1,057	-11.2%
246	Percutaneous cardiovascular procedures with drug-eluting stent with MCC or 4+ arteries	-$2,729	-12.4%
247	Percutaneous cardiovascular procedures with drug-eluting stent without MCC	-$1,623	-11.0%
280	Acute myocardial infarction, discharged alive with MCC	-$1,582	-13.8%
291	Heart failure and shock with MCC	-$1,275	-13.3%
454	Combined anterior and posterior spinal fusion with CC	-$5,925	-13.2%
455	Combined anterior and posterior spinal fusion without CC/MCC	-$4,053	-11.3%
460	Spinal fusion except cervical without MCC	-$3,469	-12.3%

DRG	DRG Description	Mean payment difference POHs vs. traditional hospitals **	Percent difference
468	Revision of hip or knee replacement without CC/MCC	-$2,931	-15.2%
470	Major hip and knee joint replacement or reattachment of lower extremity without MCC	-$2,128	-15.2%
473	Cervical spinal fusion without CC/MCC	-$2,419	-11.2%
483	Major joint or limb reattachment procedures of upper extremities	-$2,405	-14.3%
682	Renal failure with MCC	-$975	-14.5%
690	Kidney and urinary tract infections without MCC	-$734	-9.2%
853	Infectious and parasitic diseases with OR procedures with MCC	-$3,127	-12.0%
871	Septicemia or severe sepsis without MV >96 hours with MCC	-$1,105	-9.9%
872	Septicemia or severe sepsis without MV >96 hours without MCC	-$726	-8.6%

** Reference levels for these calculations were White, females, aged 65-74 at the average level of comorbidities for each DRG.

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CMS Site-Neutral Payments Affect Small Share of Spending

 Kolton Gustafson

 Sean Creighton

 Melissa Morley

Summary

Payments to off-campus hospital sites affected by site-neutral payment policy amount to only 2.3% of Medicare outpatient spending.

The Centers for Medicare & Medicaid Services (CMS) has paid for Medicare fee-for-service (FFS) services at certain off-campus provider-based departments (PBDs) at a reduced rate since calendar year (CY) 2018. The policy was intended to reduce differences in payments between hospital-affiliated locations and independent physician offices. A review of claims processed in CY 2022 shows that only 2.3% of CMS payments for outpatient services are made at the site-neutral rate for off-campus PBDs.

Background

Under Medicare FFS reimbursement policies for outpatient services, payment can vary based on whether a service is provided in a hospital outpatient department or in a physician office that is unaffiliated with a hospital. When services are provided in a hospital outpatient department, Medicare makes two payments: one payment under the outpatient prospective payment system (OPPS) for hospital services and one payment under the physician fee schedule (PFS) for physician services. When outpatient services are provided in physician offices, payment is only made under the PFS. Therefore, prior to 2018, this approach resulted in wide disparities in payment rates for similar patients receiving similar services depending on where they sought care.

The Bipartisan Budget Act of 2015 allowed Medicare to make site-neutral payments at certain off-

campus PBDs. The policy only applies to sites that opened after passage of the law and excludes certain services. Unaffected sites are referred to as “excepted off-campus PBDs.” CMS fully implemented the policy in 2018, applying a PFS-equivalent rate for affected sites and services, set at 40% of the OPPS rate, phased in over 2 years. In operationalizing these requirements, CMS introduced a new claim modifier (the ‘PN’ modifier) to identify services that should be paid at the lower PFS-equivalent rate. In 2019, CMS expanded its site-neutral policies by applying a site-neutral rate for clinic visit services billed by excepted off-campus PBDs under G0463 (Hospital outpatient clinic visit for assessment and management of a patient); this change was fully implemented in 2020. There is continued discussion and consideration among stakeholders about further expansions of site-neutral payment policies.

Part B Site-Neutral Payment Analysis Results

In a review of CY 2022 spending on Medicare Part B services at hospitals, Avalere utilized claims data to determine the amount Medicare paid for services provided in three categories: on-campus outpatient department services, off-campus services provided at grandfathered (or excepted) sites paid at the OPPS rate, and off-campus services provided at non-excepted sites and paid at the PFS-equivalent rate. In CY 2022, $1.34B in spending was made under the PFS-equivalent rate to non-excepted off-campus PBDs, representing 2.3% of total Medicare outpatient spending.

Table 1. Share of Outpatient CMS Payments to Hospitals By Site of Care

	Through On-Campus HOPD	Through Non-Excepted Off-Campus PBD	Through Excepted Off-Campus PBD
All Hospitals	87.4%	2.3%	10.3%

Rural hospitals receive a smaller share of their outpatient revenue through off-campus PBDs than urban hospitals (8.6% versus 13.1%).

Table 2. Share of Outpatient CMS Payments to Hospitals By Site of Care and Rural vs. Urban Location

	Through On-Campus HOPD	Through Non-Excepted Off-Campus PBD	Through Excepted Off-Campus PBD
Urban Hospitals	86.9%	2.4%	10.7%
Rural Hospitals	91.4%	1.3%	7.3%

Overall, rural hospitals represent a much smaller share of Part B spending than urban hospitals (10.8% of total Part B spending). Rural hospitals also generate less revenue through off-campus PBDs than urban hospitals; of all the payments made to off-campus PBDs, rural hospitals represent

7.6% of payments to excepted off-campus PBDs and 6.2% of payments to non-excepted off-campus PBDs.

In a review of regional trends, Avalere found that hospitals in New England and the East North Central regions derived the greatest share of their outpatient revenue from off-campus PBDs (16.4% and 15.8% respectively). Hospitals in the West South Central and Pacific regions had the smallest share of revenue generated through off-campus PBDs (8.0% and 9.5% respectively). However, hospitals in the Pacific region have the greatest share of off-campus revenue that is excepted from site-neutral policies, while the Mountain region has the lowest share of off-campus revenue through excepted sites.

Table 3. Share of Outpatient CMS Payments to Hospitals By Site of Care and Geographic Location

	Through On-Campus HOPD	Through Non-Excepted Off-Campus PBD	Through Excepted Off-Campus PBD
East North Central	84.2%	2.4%	13.4%
East South Central	86.4%	4.0%	9.6%
Middle Atlantic	85.2%	2.2%	12.6%
Mountain	89.2%	3.3	7.6%
New England	83.6%	2.7	13.7%
Pacific	90.5%	0.9%	8.6%
South Atlantic	87.9%	2.6%	9.5%
West North Central	88.2%	1.5%	10.3%
West South Central	92.0%	1.7%	6.3%

Considerations

Policymakers continue to consider potential cost savings associated with site-neutral payment that would reduce the differential between similar services provided at different settings. Changes implemented to date have been limited in scope; as policymakers assess options, some important considerations may include:

- **Narrowing Exceptions**: While site-neutral payments to non-excepted off-campus PBDs accounted for 2.3% of Part B spending in 2022, policymakers may consider whether site-neutral rates should be applied more broadly to excepted sites, which accounted for an additional 10.3% of spending. Under the current policy, excepted sites have also been able to add new service lines (or clinical families of service) that benefit from the site's 'excepted' status and are exempt from site neutral payment policies.
- **Applicable Services**: The site-neutral payment changes for outpatient clinic visits (under G0463), which standardize payment at the PFS-equivalent rate for both on- and off-campus outpatient

sites, could be adopted for a broader set of services that can be safely provided in hospital or physician office settings.
- **Rural Impact**: Policymakers may be particularly sensitive to the impact of site-neutral payment changes on providers in rural settings where access to care is of highest concern. However, revenue generated via off-campus PBDs is lower for rural providers than for urban providers.

Methodology

Avalere conducted an analysis of hospital outpatient department claims using 2022 Medicare Standard Analytic Files. Hospital outpatient department claims were identified from the 2022 Medicare Outpatient Standard Analytic Files based on facility type and service classification codes. Off-campus excepted provider-based departments (PBDs) were identified using the PO modifier and off-campus non-excepted PBDs were identified using the PN modifier. Claims were limited to those occurring in the United States with payment amount greater than zero. The CMS Data Use Agreement does not permit analysis of beneficiary samples reflecting more than 20 percent of the total Medicare fee-for-service population. To remain in compliance with this requirement, Avalere conducted the analysis on a 20 percent sample and multiplied all estimates by 5 to estimate totals reflective of the full Medicare FFS population.