American College of Physicians
Leading Internal Medicine, Improving Lives

September 15, 2023

The Honorable Jason Smith
Chairman
Ways and Means Committee
United States House of Representatives
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Ways and Means Committee
United States House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Chairman
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Virginia Foxx
Chairman
Education and Workforce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Robert Scott
Ranking Member
Education and Workforce Committee
United States House of Representatives
Washington, D.C. 20515

Dear Chairmen Smith, McMorris Rogers and Foxx and Ranking Members Neal, Pallone and Scott:

On behalf of the American College of Physicians (ACP), I am writing to express support for several provisions of H.R. 5378, *Lower Costs, More Transparency Act*, ("the Act") which are consistent with our policy and would improve access to and affordability of health care for patients. This bill brings together H.R. 4822, *Health Care Price Transparency Act of 2023,* H.R. 3561, *Promoting Access to Treatments and Increasing Extremely Needed Transparency Act of 2023* or the *PATIENT Act of 2023* and other related bills reported out of your respective committees. ACP urges the inclusion of provisions to reform prior authorization and step therapy processes and supports requiring disclosure of changes in hospital or health facility ownership to reveal when private equity firms acquire hospitals, larger physician practices or nursing homes, promote price transparency among hospitals, health plans and pharmacy benefit managers and promote site neutrality for Medicare and Medicare beneficiaries. We further support the reauthorization and funding increases included for the Teaching Health Center Graduate Medical Education program, Community Health Center program and National Health Service Corps.

ACP is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians,

related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

We want to call your attention to two relevant bills that are not reflected in the current draft of H.R. 5378 and urge their inclusion before this legislation moves forward for consideration by the House. We hope that passage of this legislation will include provisions we support as outlined below.

Remove Barriers to Care for Patients and Reduce Administrative Burden for Clinicians

ACP urges you to include Section 301 of H.R. 4822, entitled "Improving Seniors Timely Access to Care Act," in the *Lower Costs, More Transparency Act.* This section requires Medicare Advantage plans to establish an electronic prior authorization process to streamline approvals and denials and the Department of Health and Human Services (HHS) to establish a process for Medicare Advantage plans to provide "real time decisions" for prior authorization requests of items and services that are routinely approved. ACP's Patients Before Paperwork initiative serves as the foundation for policy recommendations for revising, streamlining, or removing entirely burdensome administrative tasks. The framework and recommendations call attention to the untapped potential of electronic health records (EHRs) to improve care as well as provide a better understanding of the daily issues physicians face including obstacles to prior authorization. ACP supports the *Improving Seniors' Timely Access to Care Act* and the overall standardization and streamlining of the prior approval process for all patient care, including prescription drugs.

Administrative requirements force physicians to divert time and focus away from patient care and can prevent patients from receiving timely and appropriate treatment. They are also a financial burden and contribute significantly to the burnout epidemic among physicians. A survey of more than 600 medical groups in March 2023 showed that 84 percent reported an increase in their prior authorization requirements for Medicare Advantage plans. In 2022, a survey of more than 500 doctors from group practices found that 89 percent believe that regulatory burdens increased in the past year, and 82 percent responded that the prior authorization process in particular is very or extremely burdensome.

Prior authorization involves paperwork and phone calls, as well as varying data elements and submission mechanisms that force physicians to enter unnecessary data in EHRs or perform duplicative tasks outside of the clinical workflow. This inhibits clinical decision-making at the point of care and is an unnecessary burden for physicians and barrier to medical care for patients. HHS issued a report in 2022 that detailed abuse in the prior authorization process in which "Medicare Advantage insurers sometimes delayed or denied beneficiaries' access to services, even though the requests met Medicare coverage rules."

ACP also requests that H.R. 2630, the *Safe Step Act*, be added to the *Lower Costs, More Transparency Act.* This legislation would amend the Employee Retirement Income Security Act

(ERISA) to require group health plans to provide an exception process for the administering of prescription drugs in their step therapy protocols. While the legislation does not ban step therapy protocols, it does place reasonable limits on their use and creates a clear process for patients and doctors to seek exceptions to the step therapy requirements and accelerates approval, when necessary, for needed medications. Patients and their physicians would benefit greatly from requiring insurers to implement a clear and transparent process for when either party requests an exception to a step therapy protocol.

This legislation is necessary because Pharmacy Benefit Managers (PBMs) and group health insurers have developed a series of price management tools to curb the rising cost of prescription drugs that can delay and potentially hinder patient care. Among these, step therapy policies, commonly called "fail-first" policies, require patients to be initiated on lower priced medications before being approved for originally prescribed medications. Carriers can also change coverage in an attempt to force patients off their current therapies for cost reasons, a practice known as nonmedical drug switching. Evidence concerning the effectiveness of these protocols is mixed. Some studies have found they can successfully drive cost savings without negatively impacting patient care. Others have shown that overall health spending actually increased due to an uptick in hospitalizations and other services resulting from new symptoms or complications. Meanwhile, these policies have drawn scrutiny for restricting patient access to effective treatments, putting patient health and safety in jeopardy by subjecting patients to potential adverse effects, interfering with the patient— physician relationship, and absorbing practice resources with burdensome approvals and documentation requirements.

Increase Transparency and Data Collection in Health Care Consolidation

ACP supports measures to increase transparency and data collection regarding vertical integration and consolidation in the health care industry. Section 108 of the Act requires Medicare Advantage Organizations (MAOs) to report to HHS certain information relating to health care providers, pharmacy benefit managers (PBMs), and pharmacies with which they share common ownership and charges MedPAC to study and report on vertical integration between MAOs, health care providers, PBMs, and pharmacies and how it affects beneficiary access, cost, quality, and outcomes. Section 110 of the Act also contains a provision requiring the Secretary of HHS to submit an annual report on the effect of Medicare regulations on health care consolidation and to analyze the effects of Centers for Medicare and Medicaid Innovation demonstrations on health care consolidation.

In our paper entitled "Financial Profit in Medicine: A Position Paper From the American College of Physicians," ACP considers the effect of mergers, integration, private equity investment, nonprofit hospital requirements, and conversions from nonprofit to for-profit status on patients, physicians, and the health care system. For physician practices, private equity investment and management could alleviate administrative burdens, provide financial stability,

and accelerate adoption of health information technology.[1] Research is needed to better understand the effect of private equity investment in health care.

ACP recommends longitudinal research on the effect of private equity investment on physicians' clinical decision making, health care prices, access and patient care, including the characteristics of models that may have adverse or positive effects on the quality and cost of care and the patient–physician relationship. These bills will enhance the ability for research of private equity investment. Moreover, ACP supports transparency regarding corporate and private equity investment in the health care industry. Policymakers, stakeholders, and regulators should provide oversight of private equity activity to prevent practices like unwarranted self-referral, overreliance on nonphysician health care professionals, or consolidation that results in uncompetitive markets.

While greater transparency and data collection of vertical integration activity is an important first step, ACP recommends that lawmakers and regulators scrutinize in advance and regularly evaluate after approval all mergers, acquisitions, and buyouts involving health care entities, including insurers, pharmacy chains, large physician groups, and hospitals. The appropriate public representative (for example, federal or state attorney general, trade regulator, or insurance commissioner) should evaluate the potential effect on the communities served, competition, health care prices, insurance premiums, innovation, and access to physicians.[2]

Physician–hospital consolidation into vertically integrated health systems has accelerated in recent years, with for-profit and church-affiliated systems growing especially large in size.[3] Market concentration among primary care physician organizations has increased as well.[4] Consolidation, which could conceivably increase efficiency and value-based payment

[1] Zhu JM. Private equity investment in physician practices. Leonard Davis Institute of Health Economics. University of Pennsylvania. 18 February 2020. Accessed at https://ldi.upenn.edu/healthpolicysense/private-equity-investment-physician-practices on 8 June 2021.
[2] Beaulieu ND, Dafny LS, Landon BE, et al. Changes in quality of care after hospital mergers and acquisitions. N Engl J Med. 2020;382:51-9. [PMID: 31893515] doi:10.1056/NEJMsa1901383
[3] Furukawa MF, Kimmey L, Jones DJ, et al. Consolidation of providers into health systems increased substantially, 2016-18. Health Aff (Millwood). 2020;39:1321-5. [PMID: 32744941] doi:10.1377/hlthaff.2020.00017
[4] Fulton BD. Health care market concentration trends in the United States: evidence and policy responses. Health Aff (Millwood). 2017;36:1530-1538. [PMID: 28874478] doi:10.1377/hlthaff.2017.0556

initiatives[5][6] may also lead to higher prices.[7][8] Because the trend is a recent phenomenon, the full effect of physician–hospital vertical integration on prices and competition remains unknown.[9]

ACP has expressed concern about potential unintended consequences of market concentration and system consolidation, calling for health care organizations to provide detailed claims data so that public agencies and private researchers can assess the full effect on costs and quality of care.[10] Antitrust enforcement agencies need to have the necessary data to effectively weigh the tradeoff between desirable outcomes, like more coordination, and undesirable outcomes, like less competition, when examining the effect of mergers on health care markets.[11] At the same time, oversight activities should be implemented in a way that does not unduly burden physicians, particularly those in small and independent practices with limited financial and legal resources that may also be most prone to vertical consolidation.

ACP's policy also urges more stringent oversight of PBM mergers/acquisitions. The consolidation of the PBM market raises concerns about potential antitrust issues and has been shown to increase prices for patients.[12] Although many smaller regional PBMs exist, the large national PBMs that take up the vast majority of the market share continue and continue to wield leverage with pharmaceutical companies. As consolidation continues, agreements between PBMs, insurers and other entities should undergo strict review for both antitrust implications and effects on other aspects of drug supply chain, such as generic and biosimilar market entry.

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[5] California Health Care Foundation. Balancing act: consolidation and antitrust issues in health care. 16 June 2015. Accessed at www.chcf.org/wp-content/uploads/2017/12/PDF-BalancingConsolidationAntitrust.pdf on 8 June 2021.

[6]Gaynor M. Examining the Impact of Health Care Consolidation. Statement before the Committee on Energy and Commerce Oversight and Investigations Subcommittee. U.S. House of Representatives. Accessed at https://docs.house.gov/meetings/IF/IF02/20180214/106855/HHRG-115-IF02-Wstate-GaynorM-20180214.pdf on 8 June 2021.

[7] Provider consolidation: the role of Medicare policy. In: Report to the Congress: Medicare and the Health Care Delivery System. MedPAC; 2017:289-314.

[8] Melnick GA, Fonkych K. Hospital prices increase in California, especially among hospitals in the largest multi-hospital systems. Inquiry. 2016;53. [PMID: 27284126] doi:10.1177/0046958016651555

[9] Provider consolidation: the role of Medicare policy. In: Report to the Congress: Medicare and the Health Care Delivery System. MedPAC; 2017:289-314.

[10] Crowley R, Daniel H, Cooney TG, et al. Envisioning a better U.S. health care system for all: coverage and cost of care. Ann Intern Med. 2020;172:S7-32. [PMID: 31958805] doi:10.7326/M19-2415

[11] Baicker K, Levy H. Coordination versus competition in health care reform. N Engl J Med. 2013;369:789-91. [PMID: 23944255] doi:10.1056/NEJMp1306268

[12] U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Office. Manufactured Crisis: How Devastating Drug Price Increases Are Harming America's Seniors. Accessed at www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf on 9 August 2019.

Recent consolidation of the PBM market has placed greater leveraging and negotiating power in the hands of a few large PBMs. Although approximately 60 PBMs operate in the United States, consolidation has resulted in three of them (CVS Caremark, OptumRx, and Express Scripts) representing as much as 85 percent of the market share. [13] Two mergers between PBMs and health insurers have raised concerns among providers, patients, and other stakeholders that the increased market concentration resulting from the mergers may result in reduced competition and increased prices for patients. The first merger involved the acquisition of Express Scripts by Cigna and was approved by the Department of Justice in September 2018.[14] The second involved CVS Health acquiring Aetna as CVS sought to expand its MinuteClinic model and provide additional medical services at its locations. [15] The American Medical Association strongly opposed the merger, citing the potential for reduced competition in the market and increased prices for consumers.[16] On 10 October 2018, the Department of Justice approved the merger, with a requirement that CVS divest Aetna's Medicare Part D prescription drug plan business.[17]

As the market continues to consolidate, companies like Amazon are exploring the option of becoming market disrupters by selling prescription drugs and medical devices directly to consumers, in the belief that eliminating the middleman will result in cost savings. Some insurance companies have decided to end their relationship with PBMs indefinitely and create their own in-house PBMs. For example, Anthem announced in 2017 that it would end its relationship with Express Scripts and develop its own pharmacy benefit management arm, called IngenioRx, by 2020.[18]

In the U.S. pharmaceutical market, where competition and consumer choice are cornerstones of a healthy market system, consolidation that limits these factors can create scenarios in which

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[13] The Brookings Institution. Ten Challenges in the Prescription Drug Market—and Ten Solutions. Hutchins Center Policy Brief. May 2017. Accessed at www.brookings.edu/wp-content/uploads/2017/05/rx-drugs-policy-proposal.pdf on 9 August 2019.

[14] Abelson R. Merger of Cigna and Express Scripts gets approval from Justice Dept. The New York Times. 17 September 2018. Accessed at www.nytimes.com/2018/09/17/health/cigna-express-scripts-merger.html on 9 August 2019

[15] Rohr-Kirchgraber T. Here's how the proposed CVS-Aetna merger could increase costs, restrict access. CNBC. 10 August 2018. Accessed at www.cnbc.com/2018/08/10/how-the-proposed-cvs-aetna-merger-could-boost-costs-restrict-access.html on 9 August 2019.

[16] Madara JL; American Medical Association. Letter to U.S. Department of Justice Antitrust Division (The Honorable Makan Delrahim) on the acquisition of Aetna, Inc. by CVS Health Corporation. 7 August 2018. Accessed at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-8-7-Letter-to-Delrahim-CVS-Aetna-Merger.pdf on 9 August 2019.

[17] U.S. Department of Justice. Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D Prescription Drug Plan Business to Proceed with Merger [news release]. 10 October 2018. Accessed at www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d on 9 August 2019.

[18] Ramsey L. A huge health insurer just decided to build its own middleman to manage prescriptions. Business Insider. 18 October 2017. Accessed at www.businessinsider.com/anthem-creates-pharmacy-benefit-manager-ingeniorx-2017-10 on 9 August 2019.

PBMs are not motivated to bargain with manufacturers to keep drug costs down. In addition, PBMs have been criticized for "clawbacks," which occur when patient copayments or coinsurance are set at a rate that is higher than the acquisition cost of the drug for the insurer. A recent study showed that in 2013, patients overpaid for their prescriptions by at least $2.00 twenty-three percent of the time, with an average overpayment of $7.69 and total overpayments of $135 million.[19] With the increased visibility and criticism of PBMs, lawsuits, including class action lawsuits, have been filed against PBMs claiming illegal pricing schemes, violations of anti-kickback statutes, and other misconduct.[20]

Increase Pricing Transparency in Health Care

ACP supports pricing transparency by health care organizations. Sections 101 –106 of the Act requires price publication requirements for hospitals, ambulatory surgical centers, imaging services, clinical laboratories, health insurers and PBMs. With respect to PBMs, the Act requires them to semi-annually provide employers with detailed data on prescription drug spending, including the acquisition cost of drugs, total out-of-pocket spending, formulary placement rationale, and aggregate rebate information. Additionally, this section requires the Government Accountability Office to submit a report on the practices of pharmacy networks of group health plans, including networks that have pharmacies under common ownership with group health plans. The Act requires hospitals to publish an annual list of shoppable services they provide, including specified pricing information, requires providers of diagnostic laboratory tests under Medicare to publish online certain price information, and health insurance plan issuers (or the PBM providing services on behalf of the plan) to report to the plan sponsor specified information about prescription drugs dispensed under the plan. This includes rebates, fees, alternative discounts, or other remuneration the plan receives from drug manufacturers.

ACP supports transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. Health plans and health care facilities should clearly communicate to a consumer whether a provider or clinician is in-network or out-of-network and the estimated out-of-pocket payment responsibilities of the consumer. ACP recommends that payers, plans, and other health care organizations develop patient-targeted health care value decision-making tools that are written for patients at all levels of health literacy that make price, estimated out-of-pocket cost, and quality data available to consumers. This information should be communicated in an easy- to-understand way.

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[19] Van Nuys K, Joyce G, Ribero R, et al. Overpaying for Prescription Drugs: The Copay Clawback Phenomenon. Los Angeles: Leonard D. Schaeffer Center for Health Policy & Economics; 2018. Accessed at https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-4.pdf on 9 August 2019.

[20] PBM Watch. Federal and State Litigation Regarding Pharmacy Benefit Managers. Accessed at www.pbmwatch.com/pbm-litigation-overview.html on 9 August 2019.

ACP policy also supports transparency in the pricing, cost, and comparative value of all pharmaceutical products. As such, improved transparency, standards, and regulation for PBMs, including a ban on "gag clauses." PBMs are for-profit companies that act as intermediaries for health insurers, self-insured employers, union health plans, Medicare Part D prescription drug benefit plans, and government purchasers in the selection, purchase, and distribution of pharmaceutical products for more than half the U.S. population. ACP believes increased transparency is needed on the part of PBMs and health plans to provide greater understanding of drug prices, help patients make informed decisions and support a more sustainable health care system. The continued lack of transparency from PBMs and insurers can hinder how patients, physicians, and others view the drug supply chain and can make it difficult to identify whether a particular entity is inappropriately driving up drug prices. This lack of transparency can also prevent viable policy solutions from being identified and further delay reforms that would help to rein in spending on prescription drugs.

ACP supports the availability of accurate, understandable, and actionable information on the price of prescription medication. ACP believes health plans, PBMs, and pharmaceutical manufacturers should report the amount paid for prescription drugs, aggregate number of rebates, and nonproprietary pricing information to HHS and make it publicly available. Any disclosure mandate should be structured in a way that deidentifies negotiated rebates with specific companies and protects confidential information that could be considered trade secrets or could have the effect of increasing prices.

Support of Site Neutral Payments in Medicare

ACP believes that site neutrality is good policy for Medicare, Medicare beneficiaries, and the health care system as a whole. Section 203 of the Act requires Medicare to reimburse off-campus hospital outpatient departments (HOPDs) administering Medicare Part B drugs at the same rate it reimburses physicians under the Medicare Physician Fee Schedule. The Act also requires the HHS Office of the Inspector General to review the compliance of previous Medicare site neutral payment policies.

Historically, Medicare has typically paid a higher rate for the same service when performed at a HOPD rather than a physician's office. Site of service payment differentials create an incentive for hospitals to acquire physicians' practices and rebrand them as HOPDs, causing the magnitude of this problem to grow over time. While site of-service payment differentials are not the only factor driving hospitals to acquire physician practices, they likely do play a major role. Embracing a policy of site-neutral payments could thus save Medicare considerable dollars.

ACP supports this section of the Act because we do not believe that care delivered in a HOPD should be paid a higher rate when that care is not dependent on the hospital facility and its associated technologies. Rather, in line with the College's High-Value Care initiative, ACP supports delivery of care in the most efficient setting, while maintaining quality of care. Additionally, any changes must not negatively impact Safety-Net organizations, deny or restrict

coverage of care provided by qualified and approved clinicians, or jeopardize access to primary and preventive care for millions of Americans who rely on our Nation's already stretched health care safety net. Coverage decisions should be based solely on medical evidence, best practices, and qualifications. Provider-based billing should not be used as a mechanism for hospitals to recoup/stabilize funding or as a means of ensuring access to care. Ensuring adequate hospital funding and patients' access to care can better be addressed and supported through other means, such as increased/improved health insurance coverage, strengthened workforce policies, and delivery system reforms.

Reauthorize and Fund Essential Health Care Access and Workforce Programs

ACP supports funding for Teaching Health Centers, National Health Service Corp, and Community Health Centers. We believe, at a minimum, Congress should provide funding consistent with levels established in the Fiscal Responsibility Act. The Act extends $175,000,000 for each of fiscal years 2024 and 2025 to the Teaching Health Centers That Operate Graduate Medical Education Program; $225,000,000 for each of fiscal years 2026 and 2027; and $275,000,000 for each of fiscal years 2028 and 2029. It funds Community Health Centers by $4,200,000,000 for each of fiscal years 2024 and 2025 and extends funding for the National Health Service Corps $350,000,000 for each of fiscal years 2024 and 2025.

We encourage your support for this legislation and stand ready to serve as a resource to promote these policies as these bills are considered further by the House. If you have any questions, please contact George Lyons at glyons@acponline.org.

Sincerely,

Omar T. Atiq, MD, FACP

President