

May 8, 2024

The Honorable Roger Williams Chairman Committee on Small Business U.S. House of Representatives 2361 Rayburn House Office Building Washington, DC 20515

The Honorable Nydia Velázquez Ranking Member Committee on Small Business U.S. House of Representatives 2069 Rayburn House Office Building Washington, DC 20515

Dear Chairman Williams and Ranking Member Velázquez:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 130,000 family physicians and medical students across the country, I write to thank you both for your bipartisan leadership in addressing issues impacting family physicians and their patients through today's hearing entitled "Stifling Innovation: Examining the Impacts of Regulatory Burdens on Small Businesses in Healthcare."

Administrative functions and regulatory compliance overburden family physicians at the point of care and after patient care hours, making it one of the principal factors fueling health care consolidation and forcing many primary care practices to either sell or close their doors altogether. These functions include activities such as electronic health record (EHR) documentation, submitting claims to get paid, reporting on quality and performance measures, and navigating prior authorization and step therapy requirements. Studies have estimated that primary care physicians spend nearly 50% of their time on cumbersome administrative tasks. Many practices have to hire dedicated staff to submit claims or prior authorization requests. Administrative burden is piling up, while physician payment is failing to keep pace with inflation. These trends are taking physicians' time away from providing quality care to patients and putting financial strain on primary care practices.

Increasingly, family physicians report that independent practice is simply unsustainable. Data confirms that physician employment is growing and physician practice acquisitions have accelerated in recent years, including by health systems, payers, and corporate entities such as private equity. A 2017 study found that from 2010 to 2016, the share of primary care physicians working in organizations owned by a hospital or health care system increased by a dramatic 57% — while the shares in independent solo practice or organizations owned by a medical group decreased."

The volume of administrative tasks imposed on physicians is exacerbating physician burnout and is the most immediate threat to the future of small primary care practices and their ability to deliver high-quality, timely patient care. It is with this in mind that the AAFP offers the following feedback and recommendations to Congress to help preserve the viability of independent

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practice and relieve family physicians from the never-ending avalanche of administrative and regulatory burden.

Getting Paid for Primary Care is Unnecessarily Complex

A 2009 study found that physician practices collectively spend about \$30 billion a year alone on administrative costs related to billing and coding. One can assume that, when adjusted for inflation today, that number is significantly higher. To get paid, physicians must submit unique codes for each and every service they provide – documenting both what they did and why they did it. This is incompatible with the continuous, comprehensive nature of primary care which spans everything from basic preventive services to more complex services involving chronic care management, integrated behavioral health, and care coordination.

Every billing code has its own accompanying rules (some associated with the code set(s) and others created by Medicare and other payers) that govern when they may be reported either independently or in conjunction with other codes. This is true in almost any fee-for-service payment system, whether traditional Medicare, Medicare Advantage, or commercial insurance. Some research has concluded that creating additional billing codes for distinct activities in the MPFS may not be an effective strategy for supporting primary care, due to the burden associated with billing each one.^{iv}

The retrospective, volume-based nature of FFS also fails to account for the costs of longitudinally managing patients' overall health. It does not provide practices with the time and flexibility to invest in the care management staff and population health tools that enable practices to efficiently and effectively meet patients' individual evolving health needs.

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. We strongly believe well-designed APMs provide primary care a path out of the under-valued and overly burdensome FFS 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 in new and innovative ways. Unfortunately, a dearth of primary care APMs and the inadequacy of FFS payment rates that often underlie APMs are undermining the transition to value-based care. Because most APMs are designed based on FFS payment rates, modernizing FFS payment for primary care is one essential strategy to support physicians' transition into value-based care.

Therefore, the Academy continues to urge Congress to consider legislative solutions, including reforms to the Medicare Access and CHIP Reauthorization Act (MACRA), that would address unsustainable FFS payment rates for physicians and alleviate some of the associated administrative burden for practices, while promoting patients' access to continuous, comprehensive primary care. This includes proposals such as providing an annual inflationary update for Medicare physician payment to give small practices a fighting chance at keeping their doors open and reforming existing budget neutrality requirements that hinder CMS' ability to appropriately pay for all the services a beneficiary needs.

Finally, federal policymakers should provide more opportunities for primary care practices to participate in APMs that provide upfront or advanced payments and other supports to enable the investments required to be successful in value-based payment. While value-based payment does not eliminate the administrative burden associated with coding and billing *entirely*, prospective, population-based payments provide practices with the resources and flexibility needed to handle administrative functions more efficiently while delivering and investing in high-quality, patient-centered care.

Quality and Performance Measurement

Quality and performance measurement has proliferated in the past 25 years, leading to significant burdens on physicians. This is especially true for primary care physicians, who are disproportionately accountable for a growing number of disease-specific process measures that fail to capture the true nature and value of comprehensive, patient-centered primary care.

While quality measurement is essential to moving toward a value-based health care system, our current approach fails to measure what matters to patients and clinicians or drive meaningful quality improvement. The eagerness to measure has burdened family physicians with the onerous task of capturing structured electronic data to feed an excessive number of measures, taken time away from patients, and led to loss of joy in practice. Quality measurement has become a high-burden, high-cost administrative exercise, focused on financial concerns with little benefit to patient care, population health, and cost reduction.

We must standardize quality and performance measures with a single universal set – across payers and programs – that meets the highest standards of validity and reliability and is derived from data extracted from multiple data sources. The measures should focus on outcomes that matter most to patients and that have the greatest overall impact on better health of the population, better health care, and lower costs. Right now, it is a logistical nightmare to try and meet all of the different quality measures across plans. On average, family medicine practices contract with about ten different payers. Keeping track of and successfully reporting different measures for each of these payers creates confusion and additional reporting burden and can actually undermine meaningful practice improvements. Aligning measures across payers will also help to identify disparities in care quality (and, in some cases, utilization and access) across different payers, states, and lines of service. Greater alignment will also drive improvements in data collection automation, which will reduce reporting burden on family physicians and other clinicians.

Importantly, measures must reflect things which a physician can control instead of penalizing them for the things they can't. For example, there is a code available for physicians to bill to indicate that they offered the patient a vaccine but they refused to take it. However, the measures only reflect that the patient chose not to get a recommended vaccine - the fact that the physician offered it has no impact. Performance measurement should focus on improving outcomes that matter most to patients and have the greatest impact on improving the health of the population, creating a better experience of care, and lowering the per capita cost of care, while also returning joy to the practice of caregiving for physicians and other clinicians.

Medicare's Quality Payment Program

The Quality Payment Program (QPP), implemented as part of the passage of MACRA in 2015, have been a significant source of burden for practices, particularly small practices. MACRA was intended to serve as an on-ramp to value-based payment by giving physicians experience with being measured on their performance and quality. While the AAFP supported the intent of MACRA, it has not led to quality improvement and has also not achieved its original goal to streamline Medicare's existing quality programs and simplify reporting requirements.

There is broad consensus that the QPP has increased administrative burden and complexity as its requirements change year after year. While all programs should be flexible and make improvements, the QPP has primarily changed the requirements without making improvements or reducing burden. For example, one qualitative study found that the average per-physician cost to participate in QPP's Merit-based Incentive Payment System (MIPS) was \$12,811, and physicians and staff together spent 201.7 hours annually per physician on MIPS activities. The costs were higher for small and medium primary care practices (\$18,466 and \$13,631, respectively). Importantly, this study *only* analyzed the time and financial costs for participating in MIPS. Previous studies have found that practices spend an average of 785.2 hours \$40,069 per physician per year on quality reporting requirements.

Since there is a dearth of APMs and the MIPS requirements do not closely align with any existing APM, MIPS is primarily a reporting program with arbitrary requirements that do not meaningfully contribute to improved patient outcomes. The significant burden associated with these programs forces practices to direct their time and resources on complying with reporting requirements rather than building the skills and infrastructure that would allow them to succeed in value-based payment.

In addition, MIPS must be budget neutral – meaning the total value of annual positive adjustments are equal to the total value of negative adjustments. This has led to many practices who met their performance requirements getting a negative adjustment, and for those that receive a positive one, it is very modest. Therefore, MIPS adds administrative burden without leading to a meaningful increase in payment. The program particularly disadvantages small and rural practices, who consistently have lower than average MIPS scores. As the performance threshold increases, it will become more difficult for small and rural practices to avoid a negative payment adjustment, which can be up to 9% to their Medicare Part B services.

The inflexibility of the MACRA statute has created significant barriers to implementation of reforms aimed at moving physicians from payment on volume to value. Health care markets, value-based care models, and other factors can change quickly and additional flexibility is needed to ensure programs keep pace with these changes without awaiting congressional intervention. For all these reasons, the AAFP continues to Congress advance MIPS and QPP reforms to alleviate the administrative costs of reporting to the program, ensure it drives meaningful quality improvement, and assist physician practices in building the necessary competencies to transition into APMs. Specific recommendations include:

• Granting CMS the authority to provide credit across multiple performance categories. MIPS uses four siloed performance categories – all with different measures

- and reporting requirements. Despite multiple calls for consolidation and cross-category credit, CMS argues that they do not have the statutory authority to alter the program in that regard. One significant step toward reducing burden would be to give CMS the flexibility to provide cross-category credit. For example, a physician who reports a quality measure related to depression screening should automatically receive credit for the corresponding improvement activity.
- Allowing practices to attest to using certified electronic health record technology (CEHRT) in place of reporting on Promoting Interoperability measures. The AAFP has advocated for practices to be able to attest to their use of CEHRT rather than requiring multiple burdensome measures, but CMS does not have the authority to offer such an option. Years of policy changes to the legacy Meaningful Use program and now the promoting interoperability category have failed to move the needle on health information exchange. It is beyond time to move away from such burdensome requirements doing so would be an important step toward reducing the burden of the MIPS program.
- Providing CMS with the authority to modify the qualifying participant threshold through rulemaking to ensure advanced APM participation is attainable. Existing thresholds set in federal statute are creating barriers for physician practices seeking to move into more advanced models. Providing CMS with the authority to modify the thresholds will help ensure the QPP is facilitating the transition to APMs instead of preventing it.
- Providing technical assistance, shared learning collaboratives, and data infrastructure to support all primary care practices to transition to APMs. Primary care's information needs are particularly complex which requires technical capabilities and a reliance on others to fill information gaps, including payers and other provider organizations. Often, IT departments may be non-existent or staffed by non-IT personnel, posing challenges when implementing new or updated hardware or software, connecting to regional health information exchanges (HIEs), and setting up registries. Additionally, building and understanding reports from an EHR is time-consuming, burdensome, and can be costly if there is a need for custom reports. Safety nets also face additional reporting burden on top of payer reports due to other reporting requirements based on their funding streams (grants, Uniform Data System, etc.).
- Funding technical assistance programs to support overall adoption of APMs by all practices in all settings. MACRA provided funding to support small practices with direct assistance through tools and resources to help them navigate the complex MIPS reporting requirements. In response, CMS created the QPP Small, Underserved, and Rural Support (QPP SURS) program which provided small practices in rural and health professional shortage areas with technical assistance at no cost to them. Unfortunately funding for the QPP SURS expired in February 2022 and has not been renewed.

Prior Authorization

Prior authorization (PA) is the process by which physicians must obtain advanced approval from a health plan before delivering a procedure, device, supply, or medication for insurance to cover that service's cost. Health plans – including 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 Department of Health and Human Services (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.^{vi}

In addition to enrollees in MA plans, enrollees in other health plans needing care for their own chronic illness, vii their children's chronic illness, viii and rare diseases 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. Meanwhile, an OIG report published in July 2023 found that Medicaid MCOs denied one out of every eight prior authorization requests in 2019. Approximately 2.7 million Medicaid beneficiaries were enrolled in MCOs with prior authorization denial rates greater than 25%. However, minimal data collection on and oversight of these practices is being done by state Medicaid agencies. This is largely because current federal rules do not require states to collect and monitor data needed to assess access to care, monitor the clinical appropriateness of denials, or require that states publicly report information on plan denials and appeals outcomes.

In an American Medical Association (AMA) survey of physicians, 94% reported that prior authorization delays access to care, while 80% reported that it led to patients abandoning their treatment and 33% reported that it had led to a serious adverse event for their patient.xii Additionally, 86% 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.

In March, the Medicaid and CHIP Payment and Access Commission (MACPAC) convened to discuss denials and appeals within Medicaid managed care. In their research, they noted the lack of federal requirements for collecting key data as described above. They also identified some of the challenges and barriers impeding the ability for individuals to pursue appeals in Medicaid; for example, MCOs are required to mail denial notices, but beneficiaries do not always receive these denial notices in time to pursue an appeal within the allotted time frames. In light of these findings, MACPAC put forward seven recommendations to improve the appeals and denials process for individuals enrolled in Medicaid:

- States should be required to establish an independent, external medical review process that can be accessed at the beneficiary's choice;
- CMS should issue guidance to improve the clarity and content of denial notices and clarify how Medicaid funding may be used to support external entities, such as ombudsperson services;
- MCOs should be required to provide beneficiaries with the option to receive electronic denial notices in addition to mailed notices;
- CMS should extend the timeline for beneficiaries to request continuation of benefits and issue guidance to improve beneficiary awareness of their rights to continue receiving services while an appeal is pending;

- CMS should require states collect and report data on denials, use of continuation of benefits, and appeals outcomes, and use the data to improve delivery of care to patients;
- States should be required to conduct routine clinical appropriateness audits of managed care denials and ensure access to medically necessary care; and
- CMS should publicly post all state Managed Care Program Annual Reports and require states to include denials and appeals data on their quality rating system websites to ensure beneficiaries can access this information when selecting a plan.

The AAFP strongly urges Congress to act upon these MACPAC recommendations to improve the denials and appeals processes for Medicaid beneficiaries and ensure patients have timely access to medically necessary care as recommended by their physician.

Additionally, we also <u>applauded</u> CMS for finalizing a regulation earlier this year that will streamline prior authorization processes, implement electronic prior authorization, and improve transparency across all of its payers, including Medicare Advantage and Medicaid managed care, as well as address inappropriate coverage denials. However, we continue to advocate for the passage of legislation to enshrine these necessary reforms into statute. Specifically, **the Academy continues to push for reintroduction and passage of the Improving Seniors' Timely Access to Care Act**, which passed the House last Congress and would codify many of the regulatory provisions by requiring implementation of an electric prior authorization program in MA and streamlining and standardizing of PA processes.

Additionally, Congress should advance other legislation to reign in prior authorization across all Medicare plans. Specifically, the AAFP supports the Getting Over Lengthy Delays in Care as Required by Doctors (GOLD CARD) Act (H.R.4968), which exempts qualifying physicians from prior authorization requirements under Medicare Advantage plans. Physicians would qualify if at least 90% of their prior PA requests were approved in the preceding twelve months. This approval, referred to as a "gold card," would remain in effect for a year. Further, we have endorsed the Reducing Medically Unnecessary Delays in Care Act (H.R. 5213), which would require all PAs be made by a licensed physician who is board certified in the specialty relevant to the item or service requested. It would also require plans to create policies based on medical necessity and written clinical criteria.

Step Therapy and Prescription Drug Formularies

Step therapy is another utilization management protocol used by insurers, which requires patients to try one or more insurer-preferred medications prior to the medication their physician prescribed. This practice can take weeks or months and can result in patients not being able to access the treatments they need in a timely manner. Physicians can request exceptions to step therapy requirements, but insurers may not respond promptly to such requests, resulting in a further delay of treatment.

Health plans often use step therapy protocols as a tool to reduce prescription drug spending; however, studies suggest that any savings may be offset by increased care costs resulting from additional outpatient visits, hospitalizations, and more. Xiii, Xiv, Xv, Xvi Most concerning is that health

plans' step therapy protocols are frequently more stringent than recommended treatment guidelines or inconsistent with recommended treatment pathways, and as a result they create a barrier for patients to receive timely, medically-indicated treatment.^{xvii} Research has also found that step therapy requirements prevent patients from adhering to effective medication regimens, which can lead to worse health outcomes.^{xviii}

Family physicians see patients lose control of their previously well-managed diabetes and hypertension as a result of these tactics, in addition to requiring more office visits and in some cases emergency department visits and hospital stays. Therefore, the AAFP urges Congress to pass the Safe Step Act (S. 652 / H.R. 2630), which would require employer-sponsored health plans to provide a clear and transparent exception process for any step therapy protocol.

Additionally, when medication coverage changes, physicians are often only told that the medication is not covered – they are not given any additional information, such as a list of alternatives that *are* covered. This means they can spend a great deal of time going back-and-forth with the pharmacy trying to figure out what alternative medicine is covered by a patient's plan. Physicians often find themselves prescribing a medication that is not covered, or not preferred by the patient's insurance company, which can lead to the patient not taking the prescribed medication. Therefore, Congress should pass the Real-Time Benefit Tool Implementation Act (H.R. 7512), which requires prescription drug plan sponsors to implement at least one electronic real-time benefit tool to allow physicians to see drug costs before prescribing.

Further, the AAFP <u>has</u> and continues to strongly urge that the recently finalized regulation from CMS on electronic prior authorization be expanded to Medicare Part D plans and prescription drug coverage across other impacted payers.

Health Information Technology and Interoperability

Federal regulations – particularly those pertaining to health information technology (HIT) – can be confusing for practices because, while the Office of the National Coordinator for HIT (ONC) is generally considered the administration lead on HIT, regulations are issued by multiple agencies and often use differing definitions for the same terms. Therefore, in addition to the burdens each individual regulation brings, the volume of regulations and the pace at which they are updated is overwhelming to small and independent practices and causes change fatigue for staff and physicians.

Physicians are dependent on their CEHRT to provide them the functionality and interoperability needed to support the requirements that are placed on them by health IT regulations. When regulations do not sequence requirements appropriately or do not allow enough time for technical development and deployment, the regulations can cause significant burden on practices and physicians. We also recommend Congress work with ONC to advance real-world testing through various authorities, including ensuring new standards perform successfully in real-world testing before mandating their adoption.

In addition, the lack of standardization across EHR platforms burdens physicians and inhibits effective information sharing and care coordination across the patient's care team. The AAFP has long supported efforts to advance interoperability and data sharing standards, including ONC's development of information blocking regulations. Information blocking is when an individual or entity impedes the delivery or utilization of an EHR, making interoperability impossible. Below are some examples of this lack of interoperability shared by family physicians:

- One family physician shared that they use a different EHR than their local hospital system, and the emergency department (ED) and inpatient services cannot see the physician practice's updated medication list despite both organizations being connected through Epic's Care Everywhere. When patients are discharged from the hospital, they are routinely discharged on a medication list that has no reflection of their home medications because the medication list in the hospital system was wrong in the ED, stayed wrong upon admission, was never corrected during the hospitalization, and therefore, was of course still wrong upon discharge.
- Another physician stated that consulting subspecialists in their two main systems assume that "everyone" can see their notes and no longer send chart notes in response to referrals. The practice's referral coordinator spends time every day trying to track down consult notes from subspecialists who think their notes are visible throughout the system due to their "connected" systems. When notes do come in as an electronic "Record of Care," they are not tied back to the referral order to close the loop automatically. Instead, they must be manually labelled as a consult note and attached to the order that generated the initial referral by a staff person or the physician.

However, while the Academy supported the development of information blocking regulations, we continue to urge federal policymakers to provide support in implementing these requirements, particularly for small practices. Despite ONC's longstanding efforts to reach and educate the health care community about information blocking, significant knowledge gaps still exist regarding the implementation and enforcement of these regulations. Several independent, small, rural, and solo medical practices are still unaware or underinformed about information blocking requirements.

The AAFP <u>has urged</u> the Department of Health and Human Services, ONC, CMS, and other agencies to develop an intra-agency communications plan and educational outreach program specifically designed to reach physicians in underserved communities and small practices. Family physicians want to follow regulations and appropriately share information with their patients and other members of their patients' care team, and significantly more education is needed for practices to be able to achieve those goals.

Thank you for your leadership to address one of the most pressing challenges facing family physicians, especially small practices. We look forward to working with you to advance policies that will alleviate administrative burden and ensure physicians can spend more time on what truly matters: their patients. Should you have any questions, please contact Natalie Williams, Senior Manager of Legislative Affairs, at nwilliams@aafp.org or Anna Waldman, Associate of Legislative Affairs, at awaldman@aafp.org.

Sincerely,

Prolinker Maline
Mis, MPH, MBA

Tochi Iroku-Malize, MD, MPH, MBA, FAAFP American Academy of Family Physicians, Board Chair [remove once approved]

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