Alliance of Specialty Medicine

Sound Policy. Quality Care.

October 15, 2023

The Honorable Jodey Arrington
Chair
House Budget Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Michael C. Burgess, MD
Chair
Budget Committee Health Care Task Force
U.S. House of Representatives
Washington, DC 20515

Submitted electronically to hbcr.health@mail.house.gov

RE: Solutions to Improve Outcomes and Reduce Federal Health Care Spending RFI

Dear Chairman Arrington, Representative Burgess and members of the Health Care Task Force:

The Alliance of Specialty Medicine (Alliance) represents more than 100,000 specialty physicians and surgeons across 16 specialty and subspecialty societies. The Alliance is deeply committed to fostering patient access to the highest quality specialty care by advancing sound health care policy. As patient and physician advocates, the undersigned organizations appreciate the opportunity to respond to the House Budget Committee Health Care Task Force's Request for Information on solutions to improve outcomes and reduce federal health care spending in the budget.

The Alliance has described several recommendations below, including:

- Enacting prior authorization reforms to meaningfully address utilization management in the Medicare Advantage program;
- Enacting the *Safe Step Act* (H.R. 2630);
- Providing an annual inflationary update for Medicare physician payment tied to the Medicare Economic Index (MEI);
- Ensuring that the Quality Payment Program (QPP) offers physicians more clinically relevant participation pathways;
- Taking steps to minimize the complexity, streamline and reduce the reporting burdens of the QPP;
- Ensuring that specialists have a meaningful role in new and/or existing Alternative Payment Models (APMs) and do not face barriers to participation;
- Recognizing that specialists provide procedures and services that save both lives and costs. Prevention is not just for primary care;
- Addressing overpayments to Medicare Advantage plans; and
- Ensuring that Medicare denials and overpayment recoupments are proper by requiring that a physician practicing in the same specialty or sub-specialty and with clinical expertise or knowledge of the service in question reviews the denials.

(1) Regulatory, statutory, or implementation barriers that could be addressed to reduce health care spending

The Alliance urges you to **enact prior authorization reforms and to address utilization management in the Medicare Advantage (MA) program**, including by requiring the Centers for Medicare & Medicaid Services (CMS) to expand and finalize pending rules that would reign in the overreaches of MA plans that delay and deny care through utilization management tools like prior authorization and ultimately increase costs to the health care system.

Prior authorization is a cumbersome process that requires physicians to obtain pre-approval for medical treatments or tests before rendering care to their patients. The process for obtaining this approval is lengthy and typically requires physicians or their staff to spend the equivalent of two or more days each week negotiating with insurance companies — time that would better be spent taking care of patients. Patients are now experiencing significant barriers to medically necessary care due to prior authorization requirements for items and services that are eventually routinely approved.

Specialty physicians and their patients are often subject to prior authorizations and other utilization management tactics in the MA program. Generally, utilization management processes delay enrollee access to medically necessary care and treatments and create considerable, unnecessary administrative burdens for specialty physicians. Equally concerning, these tactics are a leading cause of physician burnout, forcing many to retire early or leave the practice of medicine. While utilization management processes may be appropriate in some situations, the Office of Inspector General[1] has found that MA plans use prior authorizations to deny *medically necessary* care, that is, care that meets coverage requirements under traditional Medicare and is supported by the enrollee's medical records.

In the fall of 2022, the Alliance of Specialty Medicine surveyed specialty physicians on the topic of utilization management. The findings underscore the burden of utilization management protocols on the practice of medicine, both in terms of the negative impact on patient care and the increased administrative onus on medical practices. Respondents overwhelmingly indicated that the use of prior authorization has increased in the last five years across all categories of services and treatments:

- Over 93% of respondents answered that prior authorization has increased for procedures;
- More than 83% answered that prior authorization has increased for diagnostic tools, such as labs and even basic imaging; and
- Two-thirds (66%) responded that prior authorization has increased for prescription drugs, with physicians noting that even many generic medications now require pre-approvals.

Other key findings can be found in the attached survey[2] results.

The Alliance supports efforts to reduce administrative burdens and ensure safe, timely, and affordable access to care for patients. In the 117th Congress, we endorsed the *Improving Seniors' Timely Access to Care Act* (H.R. 3173/S. 3018), which unanimously passed the House of Representatives and garnered 380 bipartisan co-sponsors. The solutions included in this legislation, along with new regulations issued by CMS, will go a long way to ensuring that our nation's seniors get the care they need when they need it.

[1] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp

[2] https://specialtydocs.org/wp-content/uploads/2022/12/ASM-2022-Survey-Summary-Findings-.pdf

The Alliance also supports the *Safe Step Act* (H.R. 2630) to reduce barriers to care and improve patient outcomes. The Senate Health, Education, Labor and Pensions Committee included the legislation as an amendment to the *Pharmacy Benefit Manager Reform Act* (S. 1339) as reported out of committee. The *Safe Step Act* will help patients and physicians by requiring insurers to implement a clear and fair appeals process that is easily accessible on the plan's website and allows step therapy to be bypassed in medically necessary circumstances, such as when a patient is already stable on a therapy. The legislation would also establish a time frame in which insurers must respond to appeals to ensure that patients can receive appropriate treatment in a timely manner.

A medication step-therapy protocol establishes a specific sequence in which a group health plan or a health insurance issuer covers prescription drugs. Step-therapy protocols may require patients to try and fail, requiring an insurer-preferred medication before being covered by the physician-prescribed medication. Many insurers have instituted this practice to help control costs by limiting the use or dosage of expensive medications. However, while this practice may initially reduce insurer costs, it can have devastating health consequences for patients and ultimately lead to more expensive health care costs in the long run. Patients who are denied first coverage of medications recommended by their physicians can end up with poor health outcomes due to adverse health events, leading to costly hospitalizations. In the era of personalized medicine, patients with chronic diseases such as inflammatory bowel disease, rheumatoid arthritis, cancer, psoriasis or age-related macular degeneration may respond differently to various medications used to treat these diseases. Health care costs increase when patients are forced to fail first on a treatment and experience adverse events that can lead to hospitalization or other interventions.

(2) Efforts to promote and incorporate innovation into programs like Medicare to reduce health care spending and improve patient outcomes

Over the last eight years, initiatives authorized under the *Medicare Access and CHIP Reauthorization Act (MACRA) of 2015*, such as the QPP — which includes the Merit-Based Incentive Payment System (MIPS) and the Advanced APM track — and the Physician-Focused Payment Model Technical Advisory Committee (PTAC), have been implemented in ways that deviate from the congressional intent of the original legislation and fail to catalyze movement towards higher-value care, particularly for specialists. Most physicians, especially specialists, have very few APMs in which to participate. At the same time, MIPS has evolved into a largely pay-for-compliance rather than a pay-for-value program that is disjointed, administratively burdensome, and, for many specialties, not clinically meaningful to physicians or their patients.

MIPS, in particular, suffers from overly complex and duplicative reporting requirements, constantly shifting goalposts from year to year, and policies that often disincentivize the development and use of specialty-specific quality measures that are meaningful to patients and physicians. As a result, many physicians struggle to find relevancy in the program and keep up with the cost of compliance. A 2021 study found that compliance with MIPS costs $12,811 per physician per year and that physicians and other clinical and administrative staff spend over 200 hours per physician per year on MIPS-related activities

physicians.[3] Also, in 2021, the U.S. Government Accountability Office issued a report[4] expressing concerns that MIPS performance feedback is neither timely nor meaningful, questioned whether the program helps improve quality and patient outcomes, and highlighted the program's low return on investment.

MIPS also fails to fully utilize the robust data collection and performance analyses already taking place through clinician-led clinical data registries. These registries collect and analyze data on a wide range of medical procedures, diagnostic tests and clinical conditions, allowing specialties to build a real-world evidence base on appropriate indications and clinical outcomes that is simply impossible to glean from administrative claims data. Registries also develop more focused and nuanced quality measures, including patient-reported outcomes measures, which are often more useful to specialists and their patients than the inventory of traditional MIPS measures. Additionally, clinician-led data registries are more nimble and can provide more timely and actionable performance feedback than is currently available under MIPS. Given these attributes, clinical data registries are uniquely positioned to drive meaningful improvements in physician quality and the overall value of health care.

Unfortunately, to date, CMS has adopted policies that seem to conflict with language in MACRA requiring the Secretary of the Department of Health and Human Services to encourage the use of qualified clinical data registries (QCDRs) for reporting quality data under MIPS. These policies include unnecessarily burdensome requirements that impede the critical role that registries play in improving patient outcomes and quality of care. While QCDRs were supposed to offer specialists a pathway to introduce more focused and potentially innovative measures, the experience has been so disappointing that numerous prominent specialty society registries have decided it is not a worthy investment.

Furthermore, Section 105(b) of MACRA directs the Secretary to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety."[5] However, CMS has failed to provide clinician-led clinical data registries with a practical way to gain continuous, timely access to Medicare claims data, which has hindered their ability to perform more comprehensive data analyses, including meaningful assessments of cost-effectiveness, which is something that CMS is struggling with on its own under MIPS.

The QPP also fails to encourage and prepare physicians to move into APMs as intended. As of 2021, only about 270,000 clinicians qualified for the QPP's APM track — which includes incentives to reward investments in value-based care models and exemption from MIPS — compared to almost 700,000 clinicians who were instead eligible for MIPS. Specialists, in particular, face barriers in terms of identifying relevant models in which to participate. Even when they join a model, their contributions to higher-value care often go unrecognized due to methodological constraints.

Additionally, specialty physicians have faced challenges getting the Center for Medicare & Medicaid Innovation (CMMI) to test alternative payment and delivery models that are meaningful and feasible for specialists. Part of the problem is the agency's unwillingness to test models recommended by PTAC. Although PTAC has reviewed over 35 models and recommended several for implementation, CMS has yet to advance *any* of them in their original form. This has been frustrating for Alliance members, many of

[3] This study was conducted based on 2019 data, prior to full MIPS implementation, and these costs are likely even higher today. https://jamanetwork.com/journals/jama-health-forum/fullarticle/2779947

[4] https://www.gao.gov/assets/gao-22-104667.pdf

[5] MACRA, Pub. L. No. 114-10, § 105(b)(1)(A)

whom have invested significant resources in developing more impactful models and providing their expertise on ways that APMs could improve clinical practice and patient outcomes. This not only discourages the development of more innovative models but significantly limits the movement of specialists into value-based models. As alluded to earlier, even in situations where specialists participate in existing APMs, the models often do little to meaningfully capture or incentivize the quality and overall value of specialists compared to their non-specialty colleagues.

Looking more broadly across CMS' value-based initiative portfolio, it is also evident that CMS suffers from internal disorganization, resulting in excess spending and regulatory burden. Multiple offices within CMS manage similar but separate value-focused initiatives authorized by MACRA, with little apparent coordination. For example, the staff responsible for administering the QPP seem disconnected from the CMMI staff responsible for administering APMs — despite the intrinsic link between the two. Additionally, to carry out these initiatives, CMS relies on numerous separate contractors who are not aligned or coordinated with one another, which leads to confusion, inefficiencies, and situations where individuals are making important decisions with no institutional history and very little understanding of the clinical implications of their recommendations and actions.

As a result of these pervasive and ongoing challenges, CMS physician-focused value-based initiatives have done little to raise the bar on care delivery, patient outcomes, and the overall value of healthcare. Going forward, **the Alliance urges Congress to work with CMS to:**

- **Ensure that the QPP offers physicians more clinically relevant participation pathways,** which result in actionable performance data that are useful to the physician and meaningful to the patient. CMS should incentivize the development and use of more specialty-specific performance measures, payment models, and other innovative approaches that demonstrate physician value in a more comprehensive yet flexible manner. CMS should also recognize physician participation in robust clinical data registries as an alternative for satisfying traditional MIPS requirements and incorporate the use of clinical data registries into future specialty-focused payment models.
- **Adopt policies that provide clinical data registries with meaningful access to Medicare claims data,** which will allow registries to conduct more comprehensive analyses of physician performance, including more meaningful evaluations of cost-effectiveness and overall value of care.
- **Ensure that alternative participation pathways, such as MIPS Value Pathways, remain voluntary and that physicians have the flexibility to choose how to demonstrate their value most appropriately.**
- **Take steps to minimize the complexity, streamline and reduce the reporting burdens of the QPP**. As noted below, physician Medicare reimbursement has failed to keep pace with rising inflation, making it even more challenging for practices to prioritize investment in quality reporting compliance, particularly when many of those programs are of questionable value.
- **Test and implement specialty-specific payment and delivery models developed by specialties and ensure that specialists have a meaningful role and do not face barriers to participation in existing APMs, where appropriate.**

(3) Comments on CBO's modeling capabilities on health care policies, including limitations or improvements to such analyses and processes

The Alliance urges Congress to empower the Congressional Budget Office (CBO) to use dynamic scoring to assess the potential long-term savings of health care-related legislative proposals and notes that the *Preventive Health Savings Act* (H.R. 766) seeks to accomplish this goal.

We urge the Task Force to recognize that Medicare physician reimbursement has failed to keep pace with rising inflation, leading to inadequate reimbursement due to a failed statutory formula that does not recognize the value of care provided to Medicare beneficiaries.

In the calendar year 2024 Medicare Physician Fee Schedule (MPFS), CMS proposes another sharp reduction in Medicare payments to physicians, estimated at -3.4% (or a $1.14 cut to the conversion factor), due to the implementation of statutory requirements and regulatory changes discussed in the rule. In contrast, most other Medicare providers anticipate sizeable increases in their 2024 payments (e.g., inpatient hospitals (3.1%); inpatient rehabilitation facilities (3.4%); hospices (3.1%); hospital outpatient departments (2.8%); and Medicare Advantage plans (3.32%)).

As you know, physician practices endure the same inflation rates as hospitals and other medical facilities but have received pay cuts rather than positive adjustments. The multiple layers of cuts imposed on physicians due to the applicable statutes create immense challenges in maintaining solvent practices, retaining and recruiting qualified staff, and ensuring patient access to health care. The price of skilled labor, medical equipment and supplies, and rent have increased considerably over the past several years, particularly during the COVID-19 public health emergency. These increases impact physician practices — particularly those that are small, rural and treating underserved beneficiaries — just as much as they impact other Medicare providers. Yet, physician updates do not consider the growing rate of inflation.

The Medicare Trustees[6] and other policy experts have raised concerns about the lack of an inflation measure in the MPFS. This downward financial pressure on physicians and their practices has forced many to sell their practices to health systems and private equity groups and enter into employment arrangements with these entities, further consolidating health care systems and increasing health care costs to taxpayers and beneficiaries, according to MedPAC.[7]

The Alliance believes that a permanent solution is necessary to address the systemic issues with the MPFS and return financial stability and predictability to the flawed physician payment system. Strengthening the Medicare physician payment system is essential to increase competition and reduce health care system spending in the long term. The Alliance supports Congress taking immediate steps to stabilize Medicare physician payments and has endorsed the *Strengthening Medicare for Patients and Providers Act* (H.R. 2474), which would provide an annual inflationary update for Medicare physician payment tied to the MEI.

[6] https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf
[7] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_medpac_ch15_sec.pdf

(4) Examples of evidence-based, cost-effective preventive health measures or interventions that can reduce long-term health costs

Cost-effective preventive health measures or interventions are not just for primary care. The Alliance notes that **specialists provide procedures and services that save both lives and costs**. For example, the cost of care for individuals who have experienced a stroke is high, and surgical interventions like carotid endarterectomy or thrombectomy can help prevent strokes and provide significant long-term health savings. Congress recognized this potential for long-term savings when it passed the *Furthering Access to Stroke Telemedicine (FAST) Act* in 2018. The *FAST Act* allowed Medicare to reimburse for "telestroke" services regardless of where a patient receives treatment, thus allowing stroke patients to be examined by off-site neurologists who can quickly examine the patient and make treatment recommendations to reduce long-term complications, improve outcomes for patients and save costs for the health care system.

Similarly, colorectal cancer screenings at appropriate intervals by gastroenterologists can yield cost savings in the treatment of cancer. Colorectal cancer (CRC) is the second leading cause of cancer death for men and women combined. However, it is preventable if caught early through timely screening, which is important due to significant increases in the incidence of CRC in those under age 50 and emerging data showing the benefit of screening in this population. CRC will be the leading cause of cancer-related death among 20 to 49-year-olds by 2030. Therefore, catching it early can help reduce long-term health costs.

(5) Recommendations to reduce improper payments in federal health care programs

Medicare Advantage (MA) plan revenue continues to increase at an inappropriate rate and should be reviewed. MedPAC estimates that MA plans will be overpaid by $27 billion this year.[8] Key issues identified by MedPAC that contribute to the overpayments include favorable selection of enrollees and higher diagnostic coding intensity.

Furthermore, the use of "chart audits" is driven by the plans to increase their risk scores and seek higher payments from the Medicare program and taxpayers. The strategy is working, judging by the payment increases for MA plan revenue. However, it adds insult to injury for physicians: many face double-digit payment cuts, while they must spend an ever-increasing portion of unreimbursed time fighting MA plans on the audits by which MA plans increase their own payments. This is a winning formula only for insurance companies. Every other stakeholder in the Medicare program, from beneficiary to taxpayer, experiences higher costs, reduced access to quality care, or both.

The Alliance of Specialty Medicine is also increasingly concerned with CMS' approach to program integrity, which places numerous, burdensome requirements on physician practices. These initiatives are duplicative and disruptive to physician practices. CMS also provides little transparency with respect to the scope, authority and operations of initiatives they undertake, thereby creating additional uncertainty for the physician community and limiting accountability for CMS and its contractors. CMS' program integrity efforts also often lead to penalties based on technicalities or inconsistent application of program requirements. Further, they do not include sufficient safeguards to ensure that contractors make appropriate determinations concerning the denial of claims or services or identification of overpayments. In addition, penalties are often incommensurate with the identified errors, particularly given that

[8] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch4_MedPAC_Report_To_Congress_SEC.pdf

improper payments are largely due to unintended coding and billing errors of providers acting in good faith rather than bad actors committing fraud.

The Alliance urges Congress to work with CMS to **implement safeguards to ensure that Medicare denials and overpayment recoupments are proper by requiring a physician practicing in the same specialty or sub-specialty and with clinical expertise or knowledge of the service in question to validate whether a medical necessity denial is warranted.** In addition, Medicare auditors should face a financial penalty when their denials are overturned on appeal in order to strengthen incentives to make correct determinations from the start.

Thank you for considering our feedback as you develop legislation to modernize and personalize the health care system, support innovation, and increase patient access to quality and affordable care. Please contact us at info@specialtydocs.org if you have any questions or would like to discuss these issues in greater detail.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society of Interventional Radiology

CC: The Honorable Drew Ferguson
The Honorable Buddy Carter
The Honorable Lloyd Smucker
The Honorable Blake Moore
The Honorable Rudy Yakym