AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
KATHLEEN T. CRAIG, *CEO*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org

President
ANN R. STROINK, MD
Bloomington, Illinois

CONGRESS OF
NEUROLOGICAL SURGEONS
REGINA SHUPAK, *CEO*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@cns.org

President
ELAD I. LEVY, MD
Buffalo, New York

October 31, 2022

The Honorable Ami Bera, MD
U.S. House of Representatives
172 Cannon House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Kim Schrier, MD
U.S. House of Representatives
1123 Longworth House Office Building
Washington, DC 20515

The Honorable Michael Burgess, MD
U.S. House of Representatives
2161 Rayburn House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
U.S. House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup, DPM
U.S. House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

The Honorable Bradley Schneider
U.S. House of Representatives
300 Cannon House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks, MD
U.S. House of Representatives
1716 Longworth House Office Building
Washington, DC 20515

Submitted via: macra.rfi@mail.house.gov

Subject: Request for Information (RFI) on the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015

Dear Representatives Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider and Miller-Meeks:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing more than 4,000 practicing neurosurgeons in the United States, we appreciate the opportunity to comment on the above-referenced RFI. Neurosurgeons take care of some of the sickest patients who face painful and life-threatening neurologic conditions such as brain tumors, debilitating degenerative spine disorders, stroke and Parkinson's Disease. As such, it is imperative that Medicare fulfill its promise to our seniors with a sustainable program that fosters timely access to high-quality neurosurgical care.

OVERVIEW

For more than 20 years, Medicare Physician Fee Schedule (MPFS) payments have failed to keep pace with inflation. During this period, inflation — as measured by the Consumer Price Index (CPI) — has risen by 62.3% and practice costs — as measured by the Medicare Economic Index (MEI) — have increased by 41.5%. At the same time, payments to physicians under the MPFS have only increased by 9.9%. Furthermore, added to a lack of inflation update, Medicare's budget neutrality rules and other

WASHINGTON OFFICE
KATIE O. ORRICO, Sr. VP, Health Policy & Advocacy
25 Massachusetts Avenue, NW, Suite 610, Washington, DC 20001
Phone: 202-628-2072 Fax: 202-628-5264 E-mail: korrico@neurosurgery.org

MPFS policies have contributed to steep cuts in neurosurgical payments.[1] Despite the promise of MACRA, which repealed the flawed sustainable growth rate (SGR) formula and created an onramp for a value-based payment system, the current Medicare physician payment and quality improvement systems desperately need an overhaul. Given the foundational importance of the MPFS, its use by private health plans and others to determine non-Medicare compensation and the need to maintain provider reimbursement levels that adequately incentivize high-quality care, it is imperative that Congress work with organized medicine to fix this broken system.

Beyond the problems with the fee schedule, MACRA's Quality Payment Program (QPP) — which includes the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) — is hopelessly broken. The QPP has failed to live up to the promise of delivering a well-functioning value-based care program as promised when Congress passed MACRA. Most physicians — especially specialists — have very few APMs in which to participate, and MIPS is a check-the-box program that lacks meaningful quality measures. Thus, the QPP has evolved into a pay-for-compliance rather than a pay-for-value program. Policymakers must take steps to minimize the complexity, streamline and reduce the reporting burdens of the QPP. Moreover, specialty-specific quality measures, clinical data registries and APMs developed by clinicians, not the government, must be advanced. This will ensure flexibility for physicians to adopt objectives and measures that truly enhance quality, thus meeting the needs of patients, physicians and the Medicare program.

Summary Recommendations

As Congress begins its work to overhaul these programs, it must first provide short-term relief from pending Medicare payment cuts to stabilize physician practices and allow Congress time to develop and adopt longer-term reforms. Thus, before the end of the year, we urge Congress to take the following action:

- Prevent the scheduled -4.42% MPFS cut by adopting H.R. 8800, the Supporting Medicare Providers Act;
- Provide an inflation update for at least 2023 based on the MEI;
- Waive the 4% Statutory Pay-as-you-Go Act sequester cut; and
- Direct the Centers for Medicare & Medicaid Services (CMS) to adjust the post-operative portion of the 10- and 90-day global surgery codes to reflect recent increases in the office/outpatient evaluation and management (E/M) visit codes.

Long-term solutions for reforming the system should incorporate a core set of principles — Characteristics of a Rational Medicare Physician Payment System — that the AANS and the CNS helped develop and fully support. Broadly speaking, these include ensuring financial stability and predictability, promoting value-based care and safeguarding access to high-quality care. As discussed in more detail below, the AANS and the CNS also recommend the following:

1. Replace base annual payment updates (currently 0.00% through 2026, and 0.75% for physicians in an APM and 0.25% for those in MIPS, thereafter) with an appropriate inflationary index, such as the MEI, which reflects rising practice costs.

2. Exempt the following from Medicare's budget neutrality adjustments:

    - Newly covered or expanded Medicare benefits, items and services, such as preventative services and new technologies;
    - Items and services that are delivered in response to a public health emergency (PHE); and

[1] For example, according to an analysis performed in 2018, when all reimbursement data were adjusted for inflation, the average reimbursement for the 10 most comment spinal and cranial procedures decreased by an average of 25.80% from 2000 to 2018. *See* Trends in Medicare reimbursement for neurosurgical procedures: 2000 to 2018. Haglin JM, Richter KR, Patel NP. J Neurosurg. 2019 Feb 1;132(2):649-655. doi: 10.3171/2018.8.JNS181949.

- Changes in relative values due to increased practice costs (e.g., clinical labor, professional liability insurance).

3. Allow CMS the flexibility to waive or modify budget neutrality requirements in other circumstances, as appropriate.

4. Establish a "look back" option to allow the CMS to adjust for incorrect volume estimates errors in the budget neutrality calculation to return inappropriately reduced funding to the physician payment pool.

5. Raise the $20 million budget neutrality trigger threshold to at least $100 million to reflect the rate of inflation since 1992 (the year the MPFS took effect).

6. Direct CMS to adjust the post-operative portion of the 10- and 90-day global surgery codes to reflect recent increases in the office/outpatient evaluation and management (E/M) visit codes. The agency should also use the American Medical Association/Specialty Society RVS Update Committee (RUC) to address any misvalued global surgery codes.

7. Prevent CMS from implementing the G2211 add-on code for inherently complex E/M services.

8. Improve MACRA's QPP by:

   - Streamlining MIPS to allow physicians to earn credit across the four performance categories;
   - Providing CMS with the flexibility regarding measure adoption, participation pathways, scoring and performance thresholds;
   - Enhancing the role of clinical data registries, such as deeming physicians who participate in CMS-approved qualified clinical data registries (QCDRs) as having earned QPP bonus/incentive payments;
   - Including better access to Medicare claims data as outlined in H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act; and
   - Extending the MIPS and APM bonus/incentive payments into the future, including enacting H.R. 4587, the Value in Health Care Act, which would extend the APM incentive through 2030 and address other challenges that might assist specialists with their participation.

9. Congress should repeal Medicare's Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging and encourage CMS to incorporate AUC into the QPP.

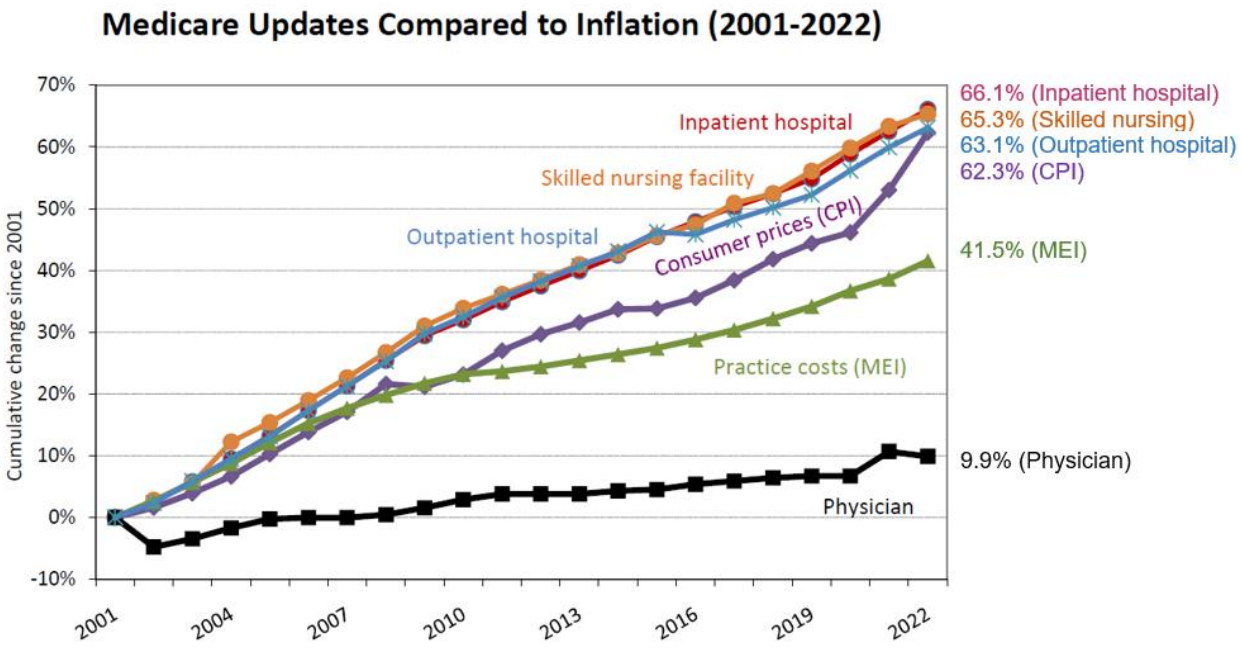
The AANS and CNS would also like to associate ourselves with the comment letters submitted by the Alliance of Specialty Medicine and the Physician Clinical Registry Coalition, of which we are members. These letters are included in the Appendix.

OPTIONS FOR REFORMING MEDICARE PHYSICIAN FEE SCHEDULE

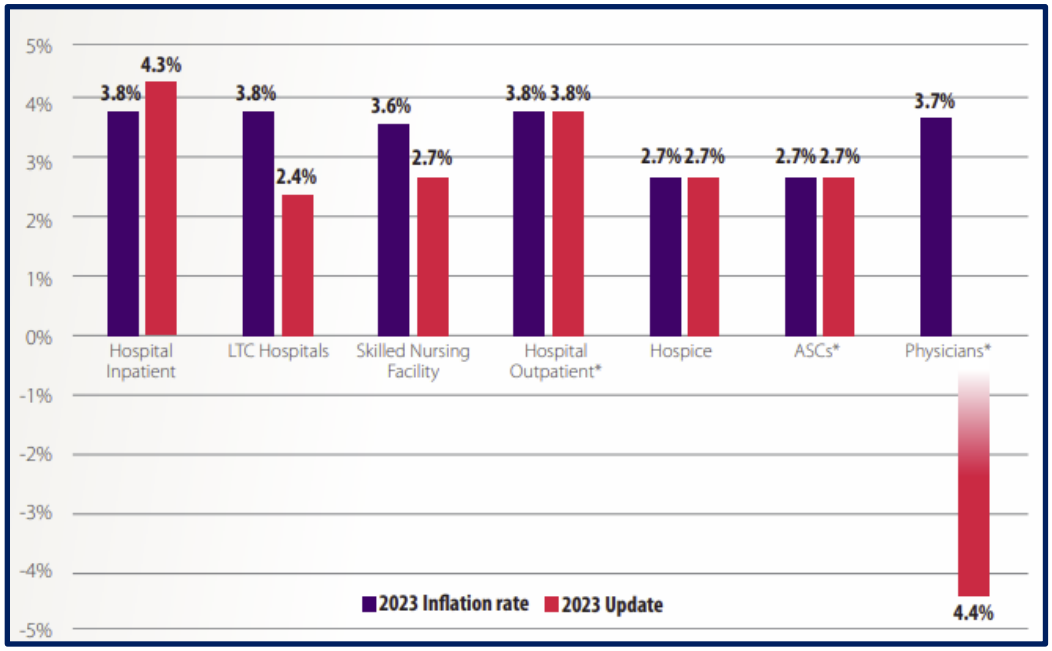
Physicians Lack an Annual Inflation Update

As mentioned above and depicted in the following chart, a lack of annual inflation updates leaves physicians constantly losing ground to ever-increasing practice costs.[2] Furthermore, payments to other Medicare providers — including hospitals and skilled nursing facilities — which have a built-in inflation update are keeping pace with or exceeding key inflation indicators such as the CPI and MEI. This system is patently unfair to physicians who face the same economic pressures.

[2] *See* "Medicare updates compared to inflation" chart. American Medical Association. https://www.ama-assn.org/system/files/medicare-updates-inflation-chart.pdf (last accessed on Oct. 31, 2022).



This trajectory is clearly unstainable as no business — and physician practices are business — can remain viable under such circumstances. It is particularly problematic while the country faces hyperinflation. Furthermore, as the following chart demonstrates, physicians are the *only* provider group getting cut in 2023 — despite an MEI inflation rate of 3.7%.[3]



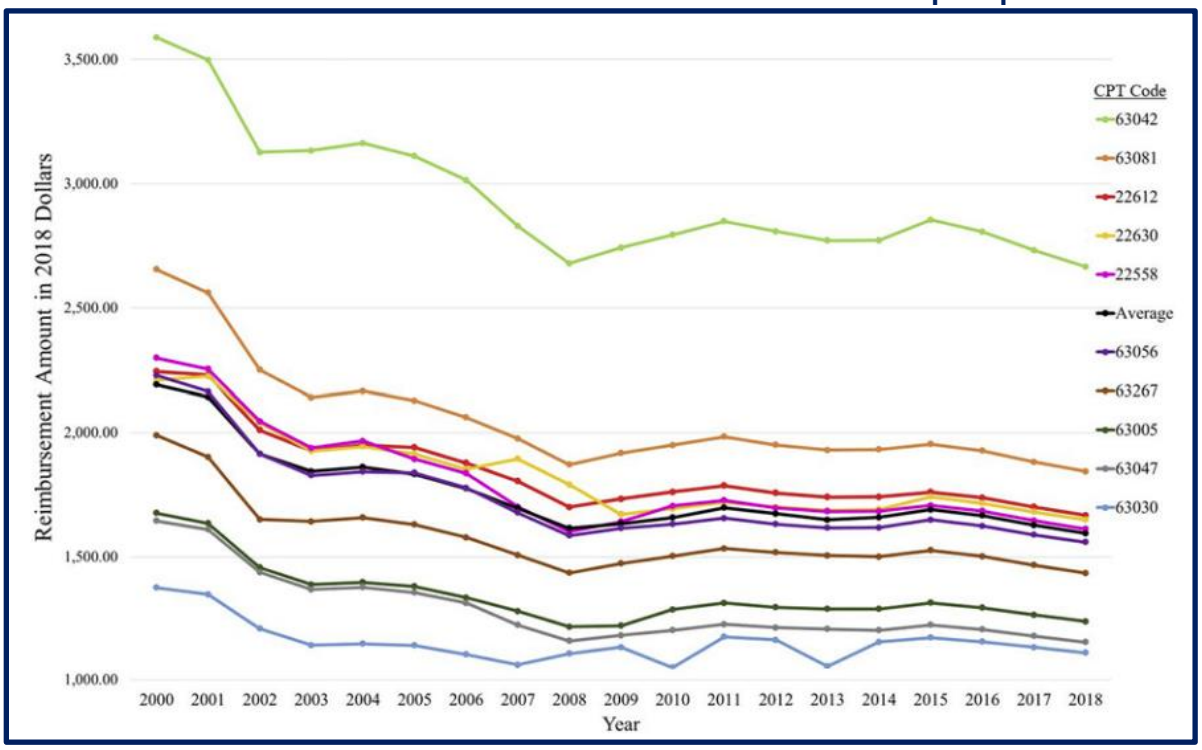
Recommendation 1: Replace base annual payment updates (currently 0.00% through 2026, and 0.75% for physicians in an APM and 0.25% for those in MIPS, after that) with an appropriate inflationary index, such as the MEI, which reflects rising practice costs.

[3] See "Why is Medicare proposing payment updates in 2023 for all providers EXCEPT physicians?" chart. American Medical Association. https://www.ama-assn.org/system/files/medicare-provider-updates-chart-2023.pdf (last accessed on Oct. 31, 2022).

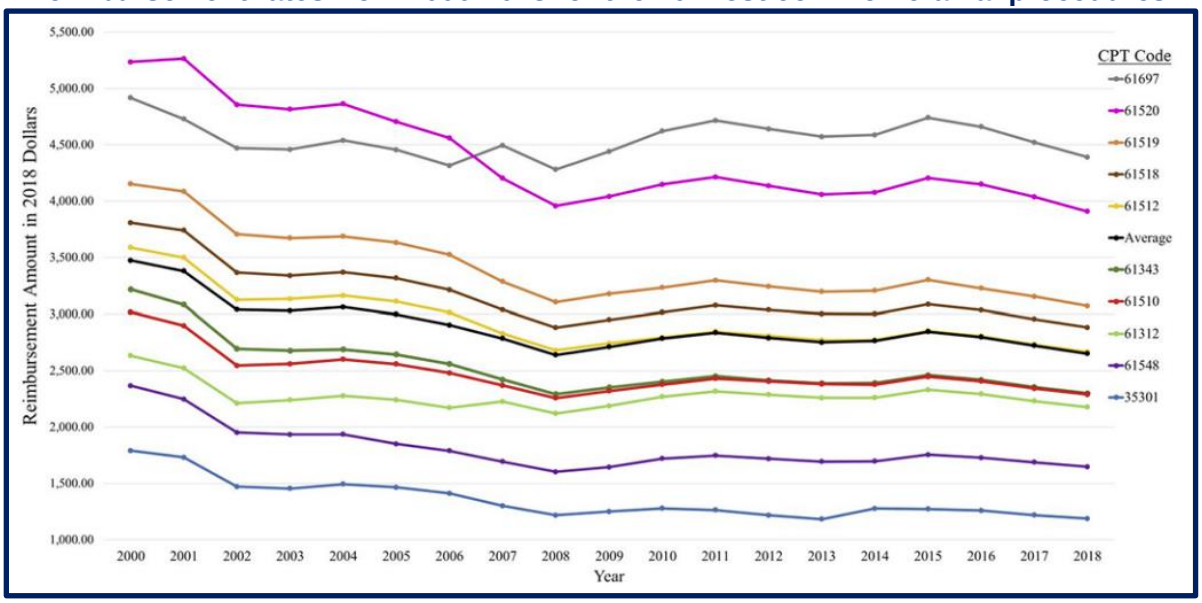
Budget Neutrality Inappropriately Drives Down Payments

As noted above, beyond the problems associated with a lack of annual inflation rate, Medicare's budget neutrality requirements and other MPFS policies also contribute to yearly cuts in neurosurgical reimbursement. When these policies are included, neurosurgeons have experienced even steeper cuts. For example, the following charts depict reimbursement trends for the 10 most common spinal and cranial procedures.

Reimbursement rates from 2000-2018 for the 10 most common spine procedures:



Reimbursement rates from 2000-2018 for the 10 most common cranial procedures:



While time and space do not permit an exhaustive review, the AANS and CNS would like to highlight a few examples of these additional challenges.

Under existing statutory budget neutrality requirements, any MPFS changes cannot increase or decrease expenditures by more than $20 million in a year. Thus, anytime CMS increases the relative value units (RVUs) for a given service or procedure, the agency must also decrease outlays if these changes exceed this $20 million threshold. The adjustments to maintain budget neutrality are typically applied to the MPFS conversion factor. This "rob Peter to pay Paul" budget neutrality policy has been a source of consternation since the inception of the MPFS as it can lead to steep cuts in the conversion factor — even for those physicians who should be benefiting from increased service-level values.

One recent example of the perverse effects of this policy involves the recent revaluation of office/ outpatient visit E/M Codes. In 2019, CMS finalized broad changes related to E/M services to reduce administrative burden, improve payment rates and reflect current clinical practice. The health care community supported restructuring and revaluing the office-based E/M codes, which increased payments for primary care and other office-based services. Unfortunately, these policies would have increased Medicare spending by roughly $10 billion, necessitating a drastic 10.6% cut to the conversion factor and correspondingly steep cuts for most specialists, including a proposed 7% cut for neurosurgery. While Congress temporarily mitigated these cuts, this structural problem with the fee schedule remains, and once the temporary payment relief expires at the end of this year, physicians will experience a 4.42% budget neutrality cut.

Another example involves recent adjustments to the clinical labor cost component of the MPFS. In the 2022 MPFS proposed rule, CMS recommended updates to the payment formula to account for increased wages paid to clinical staff. Clinical staff labor inputs were last updated in 2002. As with the E/M changes, these updates would have caused MPFS spending to exceed the $20 million budget neutrality threshold. Ultimately, CMS decided to phase in these changes, blunting the impact of the cuts. However, the AANS and the CNS believe it is particularly inappropriate to apply budget neutrality adjustments when the values of services are specifically adjusted to reflect increased practice costs.

CMS must also estimate the impact of RVU changes on budget neutrality. We contend that the agency often misses the mark and overestimates the effect of such modifications, translating into steeper conversion factor cuts. Such is likely the case with the new G2211 E/M add-on code to report inherently complex services provided by eligible physicians. When calculating the budget neutrality adjustment, the agency assumed that it would be used 100 percent of the time, which is highly unlikely. However, if CMS proves incorrect in its estimate, there is no mechanism to adjust the conversion factor in future years and reallocate those unspent dollars back into the physician payment pool.

Finally, we point out that the $20 million budget neutrality threshold was established in 1989 and implemented with the MPFS in 1992. This threshold has not been adjusted for inflation since its inception. While the AANS and the CNS urge Congress to raise this amount to $500 million to $1 billion, at a minimum, the budget neutrality trigger threshold should be increased to approximately $100 million to reflect the past 30 years of inflation.

While we understand that the costs associated with permanently repealing the budget neutrality requirement are prohibitive, below are several specific recommendations that Congress should consider to reduce the harmful effects of this policy:

Recommendation 2: Exempt the following from Medicare's budget neutrality adjustments:

- Newly covered or expanded Medicare benefits, items and services, such as preventative services and new technologies;
- Items and services that are delivered in response to a PHE; and

- Changes in relative values due to increased practice costs (e.g., clinical labor, professional liability insurance).

Recommendation 3: Allow CMS the flexibility to waive or modify budget neutrality requirements in other circumstances, as appropriate.

Recommendation 4: Establish a "look back" option to allow CMS to adjust for incorrect volume estimates errors in the budget neutrality calculation to return inappropriately reduced funding to the physician payment pool.

Recommendation 5: Raise the $20 million budget neutrality trigger threshold to at least $100 million to reflect the rate of inflation since 1992 (the year the MPFS took effect).

CMS Policies Arbitrarily Reduce the Value of Surgical Care

Budget neutrality is not the only challenge neurosurgeons are encountering. A significant policy driver resulting in an across-the-board devaluation of surgical care is CMS's refusal to adjust the 10- and 90-day global surgery codes to reflect recent increases in the office/outpatient E/M visit codes.

Medicare currently pays surgeons and other specialists a single fee (global payment) when they perform major or minor surgery, such as back surgery or brain tumor removal. This single fee covers the costs of the surgery plus related care immediately before surgery and follow-up care — including E/M services — within a 10- or 90-day timeframe. CMS's failure to incorporate the RUC-recommended work and incremental time increases for the revised office/outpatient visit E/M codes into the global codes is unacceptable. Consider the following:

- Disrupts the relativity in the fee schedule. Changing the values for some E/M services but not others disrupts the relativity mandated by Congress as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (P.L. 101-239), which was implemented in 1992 and refined over the past 30 years. Until now, each time the payments for new and established office visits were increased, CMS also adjusted the bundled payments to account for the increased values for the E/M portion of the global codes.

- Create specialty differentials. The Medicare statute specifically prohibits CMS from paying physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician." Failing to adjust the global codes is equivalent to paying some physicians less for providing the same E/M services.

- Conflict with section 523(a) of MACRA. Through MACRA, Congress required CMS to collect data on global codes. Section 523(a) explicitly authorizes CMS to adjust surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project.

We remain frustrated that CMS has refused to appropriately adjust the 10- and 90-day global surgery codes to reflect the increases in the separately billable/stand-alone E/M codes — even though the agency has done so each time the E/M codes were revalued to comply with the Medicare statute's relativity and specialty payment differential requirements. For nearly a decade, the surgical community has engaged in a good-faith dialogue with the agency, yet issues related to the global surgery codes remain unresolved.

While MACRA requires CMS to improve the accuracy of the valuation of surgical services under the MPFS, the law does not mandate a wholesale revaluation of all 10- and 90-day global codes. CMS should, therefore, use the RUC's misvalued procedures process to identify targeted codes rather than any formulaic or flawed methodology applied to all global codes. The agency's ongoing refusal to adjust the global codes amounts to an arbitrary, across-the-board cut for all surgical services — in contravention of the Medicare statute. Congress should again step in and direct the agency to make these adjustments.

> **Recommendation 6**: Direct CMS to adjust the post-operative portion of the 10- and 90-day global surgery codes to reflect recent increases in the office/outpatient evaluation and management (E/M) visit codes. The agency should also use RUC to address any misvalued global surgery codes.

Additional E/M Complexity Code is Unnecessary

To reduce the burdens associated with E/M documentation, in 2018, CMS proposed restructuring the coding system for office and outpatient visits by collapsing the E/M codes from five to two levels. Because certain specialties would experience payment cuts under this scheme, CMS proposed add-on codes to provide an additional payment — specifically for primary care and certain specialty visits — to minimize payment cuts associated with these code changes. Ultimately, CMS did not move forward with the single payment proposal and instead retained the multiple levels of E/M codes. Nevertheless, the agency moved forward and finalized a new code — G2211, inherently complex visits — even though the agency's justification for including an add-on code in the new E/M approach no longer existed. Instead of correcting a system that would have resulted in unfair payment reductions to certain specialties, the agency created a new coding scheme that inappropriately discriminates among physician specialties — over-inflating payments to certain specialties and causing steep cuts to others.

Joining the chorus of stakeholders, including the AMA, American College of Surgeons, Medicare Payment Advisory Commission and others, the AANS and the CNS opposed the G2211 add-on code.[4] More than $3.3 billion will be redistributed between specialties if this code is implemented, contributing to another steep reduction in the conversion factor. Since there is no longer a need for the add-on code, Congress should prevent CMS from implementing this code, which is scheduled to go into effect in 2024.

> **Recommendation 7:** Prevent CMS from implementing the G2211 add-on code for inherently complex E/M services.

OPTIONS FOR REFORMING MEDICARE VALUE-BASED CARE PROGRAMS

As noted above, the QPP needs a significant overhaul. The program is unworkable, burdensome and costly to physician practices. Most specialists perceive the QPP as an enormous administrative hassle that diverts critical resources away from more meaningful activities that could directly impact the quality

[4] In its Sept. 13, 2019, comment letter to CMS, MedPAC stated the following: "We do not support CMS's proposal to combine the two new add-on codes for primary care visits (GPC1X) and specialized medical care visits (GCG0X) that use additional resources into a single add-on code (GPC1X) that describes the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition." MedPAC raised numerous questions about the proposed add-on code, noting, "Even though CMS proposes to revise the standard codes for E&M office/outpatient visits, the agency states that this new add-on code is needed to account for the additional resource costs inherent in furnishing some kinds of E&M visits. However, CMS does not specify these additional resources or the types of visits that require additional resources. CMS's proposed definition for this code appears to cover a very wide range of visits. Does CMS intend for this code to be billed along with all or the majority of E&M office/outpatient visits? How will clinicians document the necessity of billing this code? Assuming that CMS increases the work RVUs for the standard codes for E&M office/outpatient visits, what is the rationale for creating this add-on code?"

and value of specialty care. Due to the paucity of available quality measures, neurosurgeons, in particular, have no choice but to report on marginally relevant measures that are of little or no use to the surgeons or their patients. Furthermore, there is zero evidence that the QPP is improving the quality of care and lower Medicare costs. Indeed, MIPS is administratively burdensome and costly, and researchers have found it costs $12,811 and 201 hours per physician per year to comply with the complex and ever-changing MIPS requirements. Additionally, in an October 2021 report, the Government Accountability Office also questioned whether the program helps improve quality and patient outcomes, highlighting the program's low return on investment.

The Alliance of Specialty Medicine has further elaborated in detail the myriad problems and challenges with the QPP, and we won't restate those in this letter (again, the Alliance letter is included in the Appendix to this letter). Suffice it to say that Congress needs to take steps to streamline MIPS, improve participation pathways and direct CMS to adopt measures that are relevant to physicians and their patients.

Clinical Practice Guidelines and Data Registries Hold the Most Promise for Value-based Care in Neurosurgery

Challenges to value-based approaches include the fact that optimal health care outcomes for many medical conditions remain poorly defined, and high-level evidence regarding the effectiveness of many diagnostic and therapeutic services is limited. Furthermore, valid methods to continuously measure, promote, and report safety and quality in health care are underdeveloped (particularly in specialty medicine). Prospective clinical data registries are observational data collection systems designed to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure while measuring and adjusting for the patient, disease and health services covariates influencing those outcomes. The use of patient care data to measurably improve the quality of care and more efficiently allocate health care resources is reshaping modern medical practice and represents the future of health care. Aggregating large registry data sets will provide significant insights into the treatment, outcomes, and well-being of patients who receive care over time.

Many years ago, leaders in neurosurgery recognized the power of collecting patient outcomes data to improve quality in our field and drive value in the health care system. Ultimately, in 2008, organized neurosurgery established the NeuroPoint Alliance (NPA), whose mission is "to improve the quality of neurosurgical care through the acquisition, analysis and reporting of clinical data via registries and related studies." NPA has a suite of condition-specific registries that cover the specialty's scope. As the number of NPA-sponsored registries has grown, we remain committed to the proposition that collecting and analyzing clinical outcomes data is one of the best mechanisms for identifying best practices, lowering costs and improving patient care. As you can see from the Appendix, NPA-sponsored registries positively impact neurosurgical practice, contributing to improved quality for the patients we serve.

Unfortunately, CMS has failed to realize the promise of clinical data registries in its quality improvement programs. Many specialty societies, including the AANS and the CNS, that have made significant investments in these registries are not seeking approval by CMS to serve as Medicare-recognized QCDRs. Like other aspects of the QPP, this program is costly and labor-intensive for specialty societies, which is unfortunate given the promise registries hold for value-based care. Furthermore, contrary to Section 105(b) of MACRA, CMS has not provided clinician-led clinical data registries with a meaningful way to gain continuous access to Medicare claims data. Without access to this claims data, registries cannot reach their full potential of assessing the *value* of care provided to patients. Tying Medicare claims data to clinical outcome information would enable clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments and provide them with the information necessary to evaluate the cost-effectiveness of alternative therapies.

The AANS and the CNS also firmly believe that clinical practice guidelines are valuable tools for improving the quality of clinical patient care. As such, our specialty has invested significant resources to develop and disseminate high-quality clinical practice guidelines to help clinicians confront a rapidly changing health care environment and improve patient outcomes.[5] When combined with information derived from clinical data registries, evidence-based practice guidelines will help guide value-based care.

Recommendation 8: Improve MACRA's QPP by:

- Streamlining MIPS to allow physicians to earn credit across the four performance categories;
- Providing CMS with the flexibility regarding measure adoption, participation pathways, scoring and performance thresholds;
- Enhancing the role of clinical data registries, such as deeming physicians who participate in CMS-approved QCDRs as having earned QPP bonus/incentive payments;
- Including better access to Medicare claims data as outlined in H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act; and
- Extending the MIPS and APM bonus/incentive payments into the future, including enacting H.R. 4587, the Value in Health Care Act, which would extend the APM incentive through 2030 and address other challenges that might assist specialists with their participation.

Medicare's AUC Program for Advanced Diagnostic Imaging is Unnecessary and Should be Repealed

Before MACRA was enacted, Congress passed the Protecting Access to Medicare Act (PAMA), establishing the Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging. Under this program, ordering professionals must consult AUC for every advanced diagnostic imaging order using a federally approved clinical decision support mechanism (CDSM) before a radiologist can furnish a scan. Eight years after PAMA's enactment, CMS continues to face challenges in completing the rulemaking and implementation of the AUC program, fueling existing concerns about the complexity of the law, associated costs, and regulatory burden sustained by physicians and other health care providers to meet the program requirements.

The AUC program, if ever fully implemented, would impact a substantial number of clinicians, as it would apply to every clinician who orders or furnishes an advanced diagnostic imaging test unless a statutory or hardship exemption applies. Practitioners whose ordering patterns are considered outliers will be subject to prior authorization — at a time when physicians are working to advance policies that reduce the administrative burdens associated with prior authorization. The program will be a financial burden for many practices, as it costs $75,000 or more to implement a CDSM that complies with the AUC Program rules.[6] Furthermore, the law is prescriptive, requiring clinicians to use only CDSMs qualified by CMS and only AUC developed by certain qualified entities — preventing the use of other clinical decision support tools and evidenced-based guidelines for advanced diagnostic imaging developed by medical societies and others. Finally, the AUC program creates a complex exchange of information between clinicians that is not yet entirely supported by interoperable electronic health record systems and relies on claims-based reporting.

Since PAMA's enactment, the AUC program has become obsolete, given the subsequent enactment of MACRA and the rise of new health care payment and delivery models in the QPP and other value-based care programs, which are designed to hold clinicians responsible for health care resource use. Therefore, Congress and CMS must seriously consider the degree to which the AUC program and QPP

[5] More information about neurosurgery-endorsed guidelines is available on the CNS website here.
[6] *See* "Clinical Decision Support (CDS)." Association for Medical Imaging Management. https://ahralink.files.wordpress.com/2017/03/cds-survey-2017.pdf

requirements overlap and create duplicative reporting burdens for physicians already overwhelmed by various other administrative burdens associated with care delivery.

> **Recommendation 9**: Congress should repeal Medicare's Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging and encourage CMS to incorporate AUC into the QPP.

CONCLUDING THOUGHTS

The AANS and the CNS appreciate your engagement on this complex issue. We understand the many challenges in moving forward with comprehensive reforms that will stabilize the Medicare physician payment system and pave the way for meaningful value-based care. We stand ready to assist you in developing legislative solutions to accomplish these goals. If it is helpful, we welcome the opportunity to meet with you in person, including participating in any policy roundtable discussions or Congressional hearings.

In the meantime, thank you all for your hard work on this and other health policy issues facing our country.

Sincerely,

Ann R. Stroink, MD, President
American Association of Neurological Surgeons

Elad I. Levy, MD, President
Congress of Neurological Surgeons

Enclosure: Appendix

Staff Contact:
Katie O. Orrico, Esq., SVP
Health Policy and Advocacy
AANS/CNS Washington Office
25 Massachusetts Avenue, NW, Suite 610
Washington, DC 20001
Office: 202-628-2072
Direct: 202-446-2024
Email: korrico@neurosurgery.org

APPENDIX

NeuroPoint Alliance Overview

The NeuroPoint Alliance (NPA), a not-for-profit 501(c)(6) corporation, was established in 2008 to improve the quality of neurosurgical care through the acquisition, analysis and reporting of clinical data via registries and related studies. The NPA is designed to meet the quality improvement and research needs of physicians, allied health care professionals, health care plans, the biomedical industry, and government agencies. To accomplish this, NPA spearheads and manages various clinical data registries and studies. Clinical data registries are valuable tools to support evidence development, performance assessment, comparative effectiveness studies and adoption of new treatments into routine clinical practice.

NPA's primary objectives include:

- Supporting national quality research efforts, including comparative effectiveness;
- Satisfying public reporting requirements for programs such as MIPS;
- Satisfying practice data collection requirements of the American Board of Neurological Surgery (ABNS) primary certification and continuing certification; and
- Providing robust data, such as the Quality Outcomes Database (QOD), for structured quality improvement studies.

The NeuroPoint Alliance is supported by the AANS, Neurosurgery Research & Education Foundation, CNS, ABNS, Society of Neurological Surgeons and others.

- **QOD**. The Quality Outcomes Database (QOD) Spine and QOD Neurovascular (NV) programs were merged into partnerships with the American Association of Orthopaedic Surgeons (AAOS) and the Society of NeuroInterventional Surgery (SNIS), respectively. However, neurosurgeons and their partners continue to evaluate the legacy QOD data. For example, an alliance of QOD sites forming the SpineCORe Study group continues longitudinal studies from QOD data to demonstrate the efficacy of spinal procedures up to ten years after surgery.

- **Spine Registry**. The American Spine Registry (ASR) is a collaborative effort of the AANS and AAOS on a national quality improvement registry for spine care. The registry has grown quickly, with nearly 300 contracted sites and multiple opportunities for data reuse. As of September 2022, more than 150,000 procedures are represented in the database. Participants have access to analytics resources, including reports and dashboards providing national benchmarks and have added functionality, including filtering capabilities on module, procedure type, approach and revision status. In 2021, the Joint Commission launched its Advanced Certification in Spine Surgery. The only qualifying method to report four required measures for the certification is participation in the ASR. The registry. For more information, visit www.americanspineregistry.org.

American Spine Registry™
A partnership between
American Association of Neurological Surgeons
American Academy of Orthopaedic Surgeons

- **Tumor Registry**. In 2021, the NPA officially launched the QOD Tumor Registry. The registry follows patients receiving surgery for intracranial metastases, primary meningeal, high-grade/malignant, low-grade/benign, pituitary and other intracranial tumors. Patient demographics, ICD-10 and CPT codes, comorbidities, hospital stay, 30-day readmission rates, post-operative complications and recurrent surgery are collected in the registry along with patient-reported outcomes measuring cognition

impairment, physical function, QALY and cognitive function after surgery. The QOD Tumor Registry is housed on the Research Electronic Data Capture (REDCap®) platform, with Mayo Clinic serving as the coordinating center. The registry tracks longitudinal follow-up or patient care following established QOD standards and practices for high-fidelity data capture open to research opportunities for participating sites. The registry just launched and has approximately 11 sites with more than 2,000 patients entered into the database. For more information, visit www.neuropoint.org.

- **Neurovascular Registry**. The NVQI-QOD combines the SNIS' NeuroVascular Quality Initiative (NVQI) registry with the NPA's QOD NV into one unified program focused on quality improvement. As of August 2022, more than 40 centers are now participating in the NVQI-QOD 23 states, with more than 16,000 procedures captured. NVQI-QOD offers modules for acute ischemic stroke, cerebral aneurysms and arteriovenous malformations. NVQI-QOD captures 100% of procedures, including demographic, procedure and post-op data, to provide comprehensive outcome analysis and inform performance improvement, with long-term outcomes of one year or longer. NVQI-QOD has opened to industry projects and is recruiting current registry participants for a project evaluating the efficacy of a new device that came on the market in 2022.

- **Registry for Advancement of DBS Therapy in Parkinson's Disease (RAD-PD)**. The Registry for the Advancement of Deep Brain Stimulation Therapy in Parkinson's Disease (RAD-PD) is a quality improvement effort focused on deep brain stimulation therapy and outcomes for Parkinson's patients. NPA has partnered with the Parkinson Study Group and the Michael J. Fox Foundation. The registry was relaunched on the REDCap® platform in November 2020 and has 20 participating centers with data from more than 310 patients. The registry is currently focused on capturing six, and 12-month follow up.

- **Stereotactic Radiosurgery Registry (SRS).** In 2015, the AANS established the Stereotactic Radiosurgery (SRS) Registry in concert with the American Society for Radiation Oncology to collect data on the radiosurgical treatment of brain metastases, primary malignant and benign brain tumors and arteriovenous malformations. The SRS has evolved into a partnership with Brainlab, using Quentry for SRS® technology platform to streamline data collection, integrate workflows and enhance the analyses of information collected throughout the sequence of patients' SRS treatments. In 2021, the registry renewed participants and extended recruitment to new sites. The SRS Registry has more than 20 active participating sites. It has accrued data on nearly 5,000 patients capturing patient characteristics, treatment patterns and outcomes. Patient baseline and follow-up information include lesion volume changes and recurrence, lesion response to treatment, neurological examination findings, patient quality of life, adverse events and survival.

QOD Spine Publications *(through September 2022)*

To demonstrate the impact of the QOD Spine registry, see below summary of studies evaluating the data collected. The information generated from this effort is making a difference in the lives of neurosurgical patients.

Studies evaluating surgical outcomes using the Lumbar module of the QOD:

Title	Year
Inferior Clinical Outcomes for Patients with Medicaid Insurance After Surgery for Degenerative Lumbar Spondylolisthesis: A Prospective Registry Analysis of 608 Patients[1]	2022
Outpatient versus inpatient lumbar decompression surgery: a matched noninferiority study investigating clinical and patient-reported outcomes[2]	2022
Rating Spine Surgeons: Physician Review Websites Versus a Patient-reported Outcomes-derived Ranking	2022
Minimally invasive versus open lumbar spinal fusion: a matched study investigating patient-reported and surgical outcomes[3]	2022
Return to work in patients with lumbar disc herniation undergoing fusion[4]	2021
Impact of surgeon and hospital factors on surgical decision-making for grade 1 degenerative lumbar spondylolisthesis: A Quality Outcomes Database analysis[5]	2021
Impact of dominant symptom on 12-month patient-reported outcomes for patients undergoing lumbar spine surgery[6]	2020
A comparison of minimally invasive and open transforaminal lumbar interbody fusion for grade 1 degenerative lumbar spondylolisthesis: An analysis of the prospective quality outcomes database[7]	2020
Adding 3-month patient data improves prognostic models of 12-month disability, pain, and satisfaction after specific lumbar spine surgical procedures: development and validation of a prediction model[8]	2020
Measuring clinically relevant improvement after lumbar spine surgery: is it time for something new?[9]	2020
Obese Patients Benefit, but do not Fare as Well as Nonobese Patients, Following Lumbar Spondylolisthesis Surgery: An Analysis of the Quality Outcomes Database[10]	2020
Impact of occupational characteristics on return to work for employed patients after elective lumbar spine surgery[11]	2019
Is Length of Stay Influenced by the Weekday on Which Lumbar Surgery is Performed?[12]	2019
Predictive Model for Medical and Surgical Readmissions Following Elective Lumbar Spine Surgery: A National Study of 33,674 Patients[13]	2019
A Strategy for Risk-adjusted Ranking of Surgeons and Practices Based on Patient-reported Outcomes after Elective Lumbar Surgery[14]	2019
Effect of patients' functional status on satisfaction with outcomes 12 months after elective spine surgery for lumbar degenerative disease[15]	2017
Patient characteristics of smokers undergoing lumbar spine surgery: An analysis from the Quality Outcomes Database[16]	2017

Title	Year
An analysis from the Quality Outcomes Database, Part 2. Predictive model for return to work after elective surgery for lumbar degenerative disease[17]	2017
An analysis from the Quality Outcomes Database, Part 1. Disability, quality of life, and pain outcomes following lumbar spine surgery: Predicting likely individual patient outcomes for shared decision-making[18]	2017
Need for Two-Year Patient-Reported Outcomes Score for Lumbar Spine Surgery Is Procedure-Specific[19]	2017
Predictors of Hospital Readmission and Surgical Site Infection in the United States, Denmark, and Japan[20]	2017
Risk factors for 30-day reoperation and 3-month readmission: Analysis from the Quality and Outcomes Database lumbar spine registry[21]	2017
Is the use of minimally invasive fusion technologies associated with improved outcomes after elective interbody lumbar fusion? Analysis of a nationwide prospective patient-reported outcomes registry[22]	2017
Impact of preoperative diagnosis on patient satisfaction following lumbar spine surgery[23]	2017
Impact of obesity on complications and outcomes: A comparison of fusion and nonfusion lumbar spine surgery[24]	2017
Back pain improvement after decompression without fusion or stabilization in patients with lumbar spinal stenosis and clinically significant preoperative back pain[25]	2016
How to predict return to work after lumbar discectomy: Answers from the NeuroPoint-SD registry[26]	2016
Inadequacy of 3-month Oswestry disability index outcome for assessing individual longer-term patient experience after lumbar spine surgery[27]	2016
Modeled cost-effectiveness of transforaminal lumbar interbody fusion compared with posterolateral fusion for spondylolisthesis using N2QOD data[28]	2016
Effect of complications within 90 days on patient-reported outcomes 3 months and 12 months following elective surgery for lumbar degenerative disease[29]	2015
Prediction model for outcome after low-back surgery: individualized likelihood of complication, hospital readmission, return to work, and 12-month improvement in functional disability[30]	2015
Predictive value of 3-month lumbar discectomy outcomes in the NeuroPoint-SD Registry[31]	2015
Lumbar surgery in the elderly provides significant health benefit in the US health care system: Patient-reported outcomes in 4370 patients from the N2QOD registry[32]	2015
Cost-effectiveness of lumbar discectomy and single-level fusion for spondylolisthesis: Experience with the NeuroPoint-SD registry[33]	2014
The efficacy of lumbar discectomy and single-level fusion for spondylolisthesis: Results from the NeuroPoint-SD registry: Clinical article[34]	2013

Summary of studies looking at outcomes of both the Lumbar and the Cervical modules of the QOD:

Title	Year
Complications, Readmissions, Revisions and Patient-Reported Outcomes in Patients with Parkinson's Disease Undergoing Elective Spine Surgery- a Propensity Matched Analysis.[35]	2022
Complications, readmissions, reoperations and patient-reported outcomes in patients with multiple sclerosis undergoing elective spine surgery - a propensity matched analysis[36]	2022
Why are patients dissatisfied after spine surgery when improvements in disability and pain are clinically meaningful?[37]	2020
Prediction of Oswestry Disability Index (ODI) using PROMIS-29 in a national sample of lumbar spine surgery patients[38]	2019
Emergency Department Visits after Elective Spine Surgery[39]	2019
Utility of Anxiety/Depression Domain of EQ-5D to Define Psychological Distress in Spine Surgery[40]	2019
Development and validation of a predictive model for 90-day readmission following elective spine surgery[41]	2018
Causes and Timing of Unplanned 90-day Readmissions Following Spine Surgery[42]	2018

Summary of studies using the QOD Grade I Degenerative Spondylolisthesis database:

Title	Year
Classifying Patients Operated for Spondylolisthesis: A K-Means Clustering Analysis of Clinical Presentation Phenotypes[43]	2021
Does reduction of the Meyerding grade correlate with outcomes in patients undergoing decompression and fusion for grade I degenerative lumbar spondylolisthesis?[44]	2021
Patient-reported outcome improvements at 24-month follow-up after fusion added to decompression for grade I degenerative lumbar spondylolisthesis: A multicenter study using the quality outcomes database[45]	2021
“July Effect” Revisited: July Surgeries at Residency Training Programs are Associated with Equivalent Long-term Clinical Outcomes Following Lumbar Spondylolisthesis Surgery[46]	2021
Is There Additional Value to Flexion-Extension Radiographs for Degenerative Spondylolisthesis?[47]	2021
The Institute for Healthcare Improvement-NeuroPoint Alliance collaboration to decrease length of stay and readmission after lumbar spine fusion: Using national registries to design quality improvement protocols[48]	2020

Title	Year
Predictors of the best outcomes following minimally invasive surgery for grade 1 degenerative lumbar spondylolisthesis[49]	2020
Effects of preoperative obesity and psychiatric comorbidities on minimum clinically important differences for lumbar fusion in grade 1 degenerative spondylolisthesis: Analysis from the prospective Quality Outcomes Database registry[50]	2020
Assessing the differences in characteristics of patients lost to follow-up at 2 years: Results from the Quality Outcomes Database study on outcomes of surgery for grade I spondylolisthesis[51]	2020
Patients with a depressive and/or anxiety disorder can achieve optimum Long term outcomes after surgery for grade 1 spondylolisthesis: Analysis from the quality outcomes database (QOD)[52]	2020
Open versus minimally invasive decompression for low-grade spondylolisthesis: analysis from the Quality Outcomes Database[53]	2020
Sexual dysfunction: Prevalence and prognosis in patients operated for degenerative lumbar spondylolisthesis[54]	2020
Outcomes and Complications with Age in Spondylolisthesis: An Evaluation of the Elderly from the Quality Outcomes Database[55]	2020
Regional Variance in Disability and Quality-of-Life Outcomes After Surgery for Grade I Degenerative Lumbar Spondylolisthesis: A Quality Outcomes Database Analysis[56]	2020
Predictors of nonroutine discharge among patients undergoing surgery for grade I spondylolisthesis: Insights from the Quality Outcomes Database[57]	2020
Laminectomy alone versus fusion for grade 1 lumbar spondylolisthesis in 426 patients from the prospective Quality Outcomes Database[58]	2019
Predictive model for long-term patient satisfaction after surgery for grade I degenerative lumbar spondylolisthesis: Insights from the Quality Outcomes Database[59]	2019
A comparison of minimally invasive transforaminal lumbar interbody fusion and decompression alone for degenerative lumbar spondylolisthesis[60]	2019
Women fare best following surgery for degenerative lumbar spondylolisthesis: A comparison of the most and least satisfied patients utilizing data from the Quality Outcomes Database[61]	2018
Defining the minimum clinically important difference for grade I degenerative lumbar spondylolisthesis: Insights from the Quality Outcomes Database[62]	2018
Minimally invasive versus open fusion for Grade I degenerative lumbar spondylolisthesis: Analysis of the Quality Outcomes Database[3]	2017

Summary of studies looking at outcomes of cervical spine surgery using the Cervical module of the QOD:

Title	Year
Impact of predominant symptom location among patients undergoing cervical spine surgery on 12-month outcomes: An analysis from the quality outcomes database[63]	2021
Clinically Meaningful Improvement Following Cervical Spine Surgery: 30% Reduction Versus Absolute Point-change MCID Values[64]	2021
Development and Validation of Cervical Prediction Models for Patient-Reported Outcomes at 1 Year After Cervical Spine Surgery for Radiculopathy and Myelopathy[65]	2020
Trajectory of Improvement in Myelopathic Symptoms from 3 to 12 Months Following Surgery for Degenerative Cervical Myelopathy[66]	2020
Applicability of cervical sagittal vertical axis, cervical lordosis, and T1 slope on pain and disability outcomes after anterior cervical discectomy and fusion in patients without deformity[67]	2020
Effect of Modified Japanese Orthopedic Association Severity Classifications on Satisfaction with Outcomes 12 Months after Elective Surgery for Cervical Spine Myelopathy[68]	2019
Comparison of outcomes following anterior vs posterior fusion surgery for patients with degenerative cervical myelopathy: an analysis from quality outcomes database[69]	2019
Predictors of patient satisfaction following 1- or 2-level anterior cervical discectomy and fusion: Insights from the Quality Outcomes Database[70]	2019
A predictive model and nomogram for predicting return to work at 3 months after cervical spine surgery: An analysis from the Quality Outcomes Database[71]	2018

Summary of studies using the QOD CSM database:

Title	Year
Social risk factors predicting outcomes of cervical myelopathy surgery[72]	2022
Cervical spondylotic myelopathy with severe axial neck pain: is anterior or posterior approach better?[73]	2022
Determining the time frame of maximum clinical improvement in surgical decompression for cervical spondylotic myelopathy when stratified by preoperative myelopathy severity: a cervical Quality Outcomes Database study[74]	2022
Association of ≥ 12 months of delayed surgical treatment for cervical myelopathy with worsened post-operative outcomes: a multicenter analysis of the Quality Outcomes Database[75]	2022
Differences in Patient-Reported Outcomes Between Anterior and Posterior Approaches for Treatment of Cervical Spondylotic Myelopathy: A Quality Outcomes Database Analysis[76]	2022
Identifying patients at risk for nonroutine discharge after surgery for cervical myelopathy: An analysis from the Quality Outcomes Database[77]	2021

Title	Year
Using PROMIS-29 to predict Neck Disability Index (NDI) scores using a national sample of cervical spine surgery patients[78]	2020
Does Neck Disability Index Correlate with 12-Month Satisfaction after Elective Surgery for Cervical Radiculopathy? Results from a National Spine Registry[79]	2020

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Alliance of Specialty Medicine

Sound Policy. Quality Care.

October 28, 2022

The Honorable Ami Bera
U.S. House of Representatives
172 Cannon House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Kim Schrier
U.S. House of Representatives
1123 Longworth House Office Building
Washington, DC 20515

The Honorable Michael Burgess
U.S. House of Representatives
2161 Rayburn House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
U.S. House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup
U.S. House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

The Honorable Bradley Schneider
U.S. House of Representatives
300 Cannon House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks
U.S. House of Representatives
1716 Longworth House Office Building
Washington, DC 20515

RE: Request for Information on the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015

Dear Representatives Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider, and Miller-Meeks:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians and is deeply committed to improving access to specialty medical care through the advancement of sound health policy. Today, we write to suggest actions Congress should take to stabilize the Medicare payment system while ensuring successful value-based care incentives are available for specialty physicians. Like you, we have serious concerns about structural and mounting instability in Medicare payments to physicians and request your assistance in urging the committees of jurisdiction to hold hearings to begin the process of stabilizing and improving Medicare physician reimbursement and performance programs.

Our comments below discuss the major pain points our specialty organizations and their members have been facing under the current Medicare physician payment system and quality improvement programs.

We urge Congress to take the following actions to address many of the challenges we face, and our recommendations include:

- Replace flat base payment updates with a payment mechanism that includes an appropriate inflationary index to the Medicare conversion factor that reflects rising practice costs, such as the Medicare Economic Index (MEI).
- Exempt the following from budget-neutrality adjustments:
    - Newly-covered or expanded Medicare benefits, items and services, such as preventative services and new technologies,
    - Items and services that are delivered in response to a public health emergency (PHE); and
    - Changes in relative values due to increased practice costs (e.g., clinical labor, professional liability insurance).
- Authorize the Secretary of Health and Human Services (HHS) the flexibility to waive or modify budget neutrality requirements in other circumstances, as appropriate.
- Require ongoing and consistent updates of key data inputs used to set Medicare payments to physicians, including practice expense costs.
- Evaluate the impact of the Quality Payment Program (QPP) and Physician-Focused Payment Model Technical Advisory Committee (PTAC) on health care quality and value, as well as access to care — particularly as it relates to specialty care.
- Make technical improvements to MACRA to strengthen the QPP, including:
    - Provide the Centers for Medicare & Medicaid Services (CMS) with the authority to make Merit-based Incentive Payment System (MIPS) more streamlined and flexible, including allowing physicians to earn credit across the four performance categories of MIPS for certain robust activities, such as reporting to and using data from a clinical data registry to improve care, rather than having to check the boxes of all four categories. Congress must provide CMS with the authority to truly dismantle the silos that currently prevent more accurate and efficient assessments of value.
    - Provide CMS with the authority to move away from the current one-size-fits-all approach to measurement and permit more flexibility regarding measure adoption, participation pathways, scoring, and performance thresholds to reflect better the diversity of clinical practice in terms of settings, specialties and/or patient populations. This should include:
        - Providing CMS with the flexibility to adjust the weights of the MIPS performance categories over time to reflect the current state of the healthcare landscape, shifting gaps in care, and the current state of available measures. This is particularly important with the Cost category. While CMS continues to develop more focused episode-based cost measures, there are still many specialists and patient populations that are not yet captured by these measures, as well as many specialists who do not benefit from the remaining total per capita cost measures. CMS should be able to account for extenuating circumstances, such

as the ongoing lack of relevant cost measures for many specialists, when setting the weights of MIPS performance categories. Similarly, CMS should have the authority to adjust the weight of the Promoting Interoperability category — which has remained stagnant since the start of the program despite evolving industry standards and practices.

- Allowing CMS to set the MIPS performance threshold (i.e., the minimum points needed to avoid a penalty) at an appropriate level each year based on performance trends and stakeholder input, rather than setting it at the mean or median score of all MIPS eligible clinicians during a previous performance period, as mandated by MACRA. This current mandate does not account for unforeseen circumstances, such as a pandemic, which could minimize the appropriateness of relying on historical performance trends for future payment years. CMS should also be able to set multiple performance thresholds, such as a separate threshold for small and rural practices.

- Put pressure on CMS to better incentivize the use of Qualified Clinical Data Registries (QCDRs), specialty-specific measures, and participation pathways that are more meaningful to specialists. This includes adopting minimum standards of reliability and validity that ensure high-quality data without discouraging specialty society engagement. This also means enforcing MACRA's requirement that CMS provide access to Medicare claims data to assist specialties and their registries with a better understanding of existing gaps in care and supporting the development of quality and cost measures.
- Allow CMS to modify the MIPS Cost category by removing the 1) primary care-based total per capita costs measure mandate that could hold physicians responsible for costs outside of their control; and 2) requirement that episode-based cost measures account for at least one-half of Part A and B expenditures to ensure prioritization of episodes with high variability and that specialists can directly impact. The total cost measures do not help specialists better manage resource use since they focus on treatment decisions over which specialists have little direct control. They may also result in double-counting the same patient costs across multiple measures. Regarding prioritizing episodes, the current statutory target is arbitrary and may result in measures that are not necessarily valid and actionable.
- Require that CMS may only measure cost in the context of quality. Cost measure assessments must ensure that efforts to lower costs do not result in poorer quality care or negatively impact access to care.
- Extend the MIPS Exceptional Performance Bonus, which has funded the bulk of MIPS incentive payments to date, but expires under MACRA after the 2022 performance year/2024 payment year.
- Improve the alternative payment model (APM) pipeline to provide specialists with more opportunities to participate meaningfully in APMs and qualify for the APM track of the QPP.
- Extend the 5% APM incentive payments and maintain current Advanced APM (A-APM) Qualifying Participant (QP) thresholds for an additional six years, which would help

facilitate specialty physician movement toward new and innovative models that have not yet materialized. The 5% incentive payment has been a critical source of financial support for physicians investing in APMs. If new specialty models are implemented, the financial risk and additional administrative costs of implementing the models will need to be offset by the incentive payment. Therefore, we encourage Congress to extend the expiring A-APM incentive payment.

- Require CMS to release more granular data regarding physician participation in MIPS, APMs, and QP eligibility, by specialty.

Key Challenges with MACRA and the Medicare Physician Payment System

In 2015, MACRA was enacted — replacing the flawed sustainable growth rate physician payment formula with a payment system that sought to reward physicians based on quality, efficiency, and outcomes. Thus far, ***the implementation of MACRA's two-track value-based payment system has been ineffective and, arguably, detrimental to the delivery of most specialty medical care***.

Payments to physicians

MACRA aimed to improve Medicare payments to physicians, yet physicians are still grossly under-reimbursed for delivering care to Medicare beneficiaries. This is particularly true when comparing Medicare payment updates across various providers. For example, physicians are slated to receive a 4.42% reduction in calendar year (CY) 2023 payment under the Medicare Physician Fee Schedule (MPFS), whereas other providers will realize sizeable increases (e.g., inpatient hospitals (4.3%); inpatient rehabilitation facilities (3.9%); hospices (3.8%); and hospital outpatient departments (2.7%)). In fact, Medicare Advantage plans expect an overall increase in payments of 8.5%. This payment disparity between Medicare providers is unconscionable and indefensible and must be addressed.

As we have shared for many years — even before MACRA was enacted — the costs associated with running a physician practice have increased considerably. The prices of medical supplies, equipment, and clinical and administrative labor have risen dramatically — particularly during this period of extremely high inflation, as demonstrated by the Consumer Price Index (CPI) and MEI (*see* American Medical Association (AMA) Medicare Updates Compared to Inflation (2001-2022)). Unlike other Medicare providers that receive annual payment updates based on an inflation proxy, such as the CPI, MACRA established physician payment updates without a yearly automatic inflation adjustment. Congress anticipated that physicians would receive value-based incentives and differential payment updates based on their participation in either the MIPS or the APM tracks. However, for multiple reasons (including the budget-neutral nature of MIPS and the ongoing lack of meaningful APM participation pathways for specialists), these QPP programs have failed to produce sufficient payment updates, particularly when compared to the effort and resources physicians must devote to participate.

Instead, most specialty physicians have received flat or reduced payment updates (*see* AMA History of Medicare Conversion Factors), along with minuscule incentives for MIPS participation (with +2.33% being the highest incentive payment to date). Further, the bulk of incentives under MIPS have stemmed from the Exceptional Performance Bonus pool, which is set to expire after the 2022 performance year/2024 payment year under MACRA.

In addition, and as discussed below, most specialty physicians have struggled to engage in the APM track. According to recent statistics released in the Medicare Payment Advisory Commission (MedPAC) July 2022 Data Book, approximately 90,060 specialists reached Qualifying APM Participant status and earned an incentive.[1] However, remember that most specialists in an APM — primarily Accountable Care Organizations (ACOs) — are participating through their employment in a hospital or health system; thus, incentive payments are made to that billing entity. Additionally, the APM incentive is set to expire in CY 2024 (based on CY 2022 participation). Legislation introduced in the 117th Congress, the *Value in Health Care Act of 2021 (H.R.4587)*, would extend the APM incentive through 2030 and address other challenges that might assist specialists with their participation in ACOs. However, this legislation does not address the MIPS exceptional performance bonus that will soon expire.

Beyond the challenges in physician payment created under MACRA, the MPFS is plagued by other challenges: requirements to maintain budget neutrality and slow, irregular updates to practice expense data used to set payments. As a reminder, the CY 2021 MPFS final rule prompted a significant budget neutrality adjustment by way of CMS' implementation of increased relative values for office and outpatient evaluation and management (E/M) services, which resulted in a 10.2 percent reduction in the conversion factor. In the CY 2022 MPFS, CMS updated clinical labor prices — an exercise it had not done in 20 years — and resulted in a drastic redistribution of Medicare funds across services due to the budget neutrality adjustments within the practice expense pool. In the recent CY 2023 MPFS proposed rule, relative values for inpatient and certain other E/M services are set to increase, prompting yet another budget neutrality adjustment. Congress has intervened to temporarily mitigate the impact of these conversion factor reductions, and we look to Congress again to avert the 4.42 percent cut expected on January 1, 2023. However, we believe it would be prudent to provide additional direction and authority to the Secretary to address these issues, for example, requiring the agency to make consistent, ongoing updates to practice expense inputs and authorizing the Secretary to, in certain circumstances, waive or modify budget neutrality requirements.

In addition, we are concerned that newly-covered and expanded Medicare benefits, items and services add more pressure to the already strained Medicare physician payment system. When CMS encourages or incentivizes beneficiaries and clinicians to deliver certain health care services, such as preventative care, those services should be excluded from budget-neutrality adjustments. This would include care that is necessary to address a public health emergency (PHE).

Finally, increases in practice expenses, such as clinical labor wages and professional liability insurance premiums, fall outside the control of physicians, and they should not be penalized for these increased costs. Congress should authorize the Secretary of HHS to waive budget neutrality when relative values change due to increased practice costs.

As we have shared previously, the increasing downward financial pressure on physicians is forcing many to sell or merge their practices with hospitals, health systems, and private equity groups, which is reflected in an April 2022 report prepared by Avalere. According to the report, nearly 70% of all physicians are now employed — a figure that spiked 19% in 2021 alone. In addition, a 2020 AMA survey found that less than half of physicians are working in physician-owned practices. The consequence of

[1] According to MedPAC, nearly 237,000 clinicians nationwide qualified for the A–APM bonus. Among clinicians who qualified for an A-APM bonus in 2022, 38 percent were specialists. This means approximately 90,060 specialists qualified for incentive payments that would have been sent directly to their employer.

increasing market consolidation is rising health care costs for payers, patients and the federal and state governments. Indeed, as part of its March 2020 Report to the Congress, MedPAC explained that:

> [G]overnment policies have played a role in encouraging hospital acquisition of physician practices. For example, when hospitals acquire physician practices, Medicare payments increase due to facility fees that Medicare pays for physician services when they are integrated into a hospital's outpatient department. The potential for facility fees from Medicare and higher commercial prices encourages hospitals to acquire physician practices and have physicians become hospital employees. (p. 458)
>
> Physician–hospital integration, specifically hospital acquisition of physician practices, has caused an increase in Medicare spending and beneficiary cost sharing due to the introduction of hospital facility fees for physician office services that are provided in hospital outpatient departments. Taxpayer and beneficiary costs can double when certain services are provided in a physician office that is deemed part of a hospital outpatient department. (p. 460)

To what extent the MPFS contributes to rising health care costs because it encourages consolidation is something that warrants thorough examination and correction by Congress.

Driving value

Most specialists perceive the QPP as an enormous administrative hassle that diverts critical resources away from more meaningful activities that could directly impact the quality and value of specialty care. Under MIPS, in particular, most specialty physicians often have no choice but to report on marginally relevant measures that result in data that is of little use to physicians or their patients. Further, CMS has not produced any evidence to suggest that quality, efficiency, and outcomes for Medicare's seniors, the disabled, and underserved populations has demonstrably improved as a result of the MACRA-established quality programs.

In contrast to the promises of MACRA, for most specialists, MIPS has evolved into an unnecessarily complex, disjointed, burdensome, and clinically irrelevant program. Even the U.S. Government Accountability Office (GAO), in an October 2021 report, expressed concern 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. The Alliance requests that Congress consider the following fundamental flaws that continue to plague MIPS:

- **Siloed Performance Categories**. CMS has failed to produce a more unified quality reporting structure, as promised under MACRA. MIPS continues to rely on four separate performance categories, each with distinct reporting requirements and scoring rules. Additionally, what is being measured on the quality side rarely aligns with what is being measured on the cost side, resulting in a flawed value equation. The Alliance has repeatedly asked CMS to provide cross-category credit for more robust value-based activities, such as reporting to a clinical data registry, which would minimize duplicative reporting and reward more innovative improvement activities. However, CMS continues to cite statutory constraints, including the mandate to measure clinicians on each of the four MIPS performance categories as dictated by MACRA. As a

result, the program is not only challenging to navigate and comply with, but it does not accurately reflect the overall value of care.

- **Constantly Shifting Goalposts**. Each year, CMS changes not only the MIPS eligibility rules and reporting requirements but also the performance thresholds. As a result, it is challenging for physicians to keep up with the program and make year-to-year comparisons regarding their performance. It is equally challenging for CMS to accurately analyze the overall impact of the program over time.

- **Lack of Incentives for Specialty Measures**. Generally, MIPS also disincentivizes the development and use of specialty-specific quality measures that are more meaningful to patients and clinicians. Whether in regards to the development of clinically relevant MIPS measures or maintaining a QCDR, CMS has made the process extremely expensive and labor-intensive for specialty societies to participate. This is unfortunate because it has had a chilling effect on the development of tools that will allow patients to make more informed decisions on the specific care they are receiving and physicians to receive actionable feedback on the services they are providing. Instead, specialists are forced to report on less relevant primary care-focused measures because they do not have any alternatives.

- **Flawed Cost Measures**. Cost measures adopted for MIPS are also extremely difficult to interpret and take meaningful action. They often reflect care decisions and costs (e.g., Part B/D drugs) that are outside of a specialist's direct control and rarely align with quality measures. Measuring the cost of care in isolation is dangerous as it fails to account for the impact that changes in spending have on care quality and access.

- **Lack of Flexibility to Promote Interoperability**. The MIPS Promoting Interoperability category continues to take a one-size-fits-all approach to care that fails to appreciate the diversity and readiness of practices across the nation. The category also continues to focus on very specific EHR functionalities rather than promote innovative use cases of health information technology, such as clinical data registries, clinical decision supports tools, and tracking data from wearables and other digital devices that are more common among specialty patients.

- **Lack of Alignment Across CMS Programs**. MIPS physician-level reporting requirements and measures largely fail to align with other CMS value-based incentive programs that apply to other providers and settings of care. This results in administrative redundancy, duplicative accountability, and conflicting incentives — particularly regarding team-based care coordination. This misalignment is costly for taxpayers and continues to make it challenging for Medicare to move the needle on the overall value of care for its beneficiaries.

- **Failure to Provide a Glidepath to APM Participation**. The intent of MIPS, as envisioned by MACRA, was to prepare physicians to move into APMs. However, the current program fails to align with APMs and does little to ready specialists to move into APMs. Further, there are ongoing barriers to APM participation among specialists, as explained below.

- **Misguided Efforts to Improve MIPS**. Although CMS' recently introduced MIPS Value Pathways (MVP) framework was intended to address many of the problems outlined above, it simply reshuffles the deck while doing very little to address the program's fundamental flaws, which increases frustration and disillusionment among physicians at a time when worker burnout is historically high.

Unfortunately, the APM track of the QPP is no less challenging. Only a few specialty models exist for a limited set of conditions. As a result, specialists either do not have access to an APM or participate passively in existing models, such as Accountable Care Organizations (ACOs), which were developed with primary care in mind and provide specialists with no direct control over measured quality or value. Specialty physicians have attempted to address these challenges, urging the Centers 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 the PTAC. Although PTAC has reviewed over 35 models to date and recommended several for implementation, CMS has yet to advance *any* of these models in their original form. This has been frustrating for several Alliance members who have invested significant resources in developing more impactful models and provided 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. Furthermore, even in situations where specialists participate in existing APMs, such as ACOs, the models do little to meaningfully capture or incentivize the quality and overall value of their participation compared to their primary care colleagues. In fact, physician-led ACOs have limited or excluded specialists from participation, a trend that CMS publicly recognized in the CY 2023 MPFS proposed rule. Despite multiple requests, CMS and other federal agencies have refused to provide data on the number and type of specialists in APMs to help us better understand and overcome these challenges.

Making matters worse is that under MACRA, the 5% Medicare incentive payment offered since 2019 (based on 2017 APM participation) to clinicians who are QPs expires next year. Instead, those who are QPs in 2023 will receive a zero percent base conversion factor update in 2025 and then will be eligible for a slightly higher base conversion factor update (0.75 percent vs. 0.25 percent for non-QPs) going forward. MACRA also prescribes specific payment and patient thresholds that clinicians must meet to become a QP. Beginning with the 2023 performance year, the Medicare QP Thresholds will increase to 75% (from 50%) for the payment amount method and 50% (from 35%) for the patient count method, making it more challenging for physicians to meet the definition of a QP.

The Alliance is very concerned about the negative impact these shifting policies will have on the already slow movement of specialists into APMs. As mentioned earlier, there have been very limited opportunities for specialists to participate meaningfully in APMs and qualify as QPs. With the expiring 5% incentive payment, most specialists will never even have had the opportunity to qualify for this critical source of funding, which has been immensely helpful to physicians who must invest in infrastructure and analytics to participate meaningfully in an APM. Similarly, the shifting QP thresholds will result in even fewer specialists qualifying for this track.

Finally, as mentioned earlier in the context of MIPS, CMS suffers from internal disorganization regarding its Medicare value-based initiatives. Multiple offices within CMS are responsible for managing 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 administering APMs, despite the intrinsic link between the two. Additionally, to carry out these initiatives, CMS relies on numerous contractors who are not aligned or coordinated with one another, which leads to confusion, inefficiencies, and situations where individuals with no institutional history

and very little understanding of the clinical implications of their recommendations and actions are making important decisions.

Recommendations to Improve MACRA

Congress sought to provide flexible options for clinicians to engage in meaningful quality improvement and value-based care in the Medicare program. However, the implementation of these statutory quality programs has resulted in a rigid system that penalizes most physicians based on metrics and models that do not apply to them. We contend that MACRA must be overhauled and replaced with a payment system that:

- Ensures financial stability and predictability in the Medicare physician fee schedule;
- Promotes and rewards value-based care innovation that meaningfully improves patient care and outcomes, particularly within specialty care; and
- Safeguards timely access to high-quality care by advancing health equity and reducing disparities.

As stated above, to achieve this, we urge Congress to:

- Replace flat base payment updates with a payment mechanism that includes an appropriate inflationary index to the Medicare conversion factor that reflects rising practice costs, such as the MEI.
- Exempt the following from budget-neutrality adjustments:
    - Newly-covered or expanded Medicare benefits, items and services, such as preventative services and new technologies,
    - Items and services that are delivered in response to a PHE; and
    - Changes in relative values due to increased practice costs (e.g., clinical labor, professional liability insurance).
- Authorize the Secretary of HHS the flexibility to waive or modify budget neutrality requirements in other circumstances, as appropriate.
- Require ongoing and consistent updates of key data inputs used to set Medicare payments to physicians, including practice expense costs.
- Evaluate the impact of the QPP and PTAC on health care quality and value, as well as access to care — particularly as it relates to specialty care.
- Make technical improvements to MACRA to strengthen the QPP, including:
    - Provide CMS with the authority to make MIPS more streamlined and flexible.
    - Provide CMS with the authority to move away from the current one-size-fits-all approach to measurement and permit more flexibility regarding measure adoption, participation pathways, scoring, and performance thresholds to reflect better the diversity of clinical practice in terms of settings, specialties and/or patient populations.
    - Put pressure on CMS to better incentivize the use of QCDRs, specialty-specific measures, and participation pathways that are more meaningful to specialists.

  - Allow CMS to modify the MIPS Cost category by removing the 1) primary care-based total per capita costs measure mandate that could hold physicians responsible for costs outside of their control; and 2) requirement that episode-based cost measures account for at least one-half of Part A and B expenditures to ensure prioritization of episodes with high variability and that specialists can directly impact.
  - Require that CMS may only measure cost in the context of quality.
  - Extend the MIPS Exceptional Performance Bonus.
  - Improve the APM pipeline to provide specialists with more opportunities to participate meaningfully in APMs and qualify for the APM track of the QPP.
  - Extend the 5% APM incentive payments and maintain current QP thresholds for an additional six years, which would help facilitate specialty physician movement toward new and innovative models that have not yet materialized.

- Require CMS to release more granular data regarding physician participation in MIPS, APMs, and QP eligibility, by specialty.

In addition, members of the Alliance participated in efforts by the AMA to develop its "Characteristics of a Rational Medicare Payment System" and urge you to incorporate these principles in any physician payment reform solution.

***

The Alliance appreciates the opportunity to share its concerns and hopes that Congress will consider holding hearings and/or a series of roundtable discussions to examine the implementation and impact of MACRA policies related to physician reimbursement and value-driven performance. At the same time, Congress must take immediate steps to stabilize Medicare physician payments while it explores more permanent solutions.

Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

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

P•C•R•C

PHYSICIAN CLINICAL REGISTRY COALITION

October 31, 2022

VIA ELECTRONIC MAIL (MACRA.RFI@MAIL.HOUSE.GOV)

The Honorable Ami Bera, MD
U.S. House of Representatives
172 Cannon House Office Building
Washington, DC 20515

The Honorable Larry Bucshon, MD
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Kim Schrier, M.D.
United States House of Representatives
1123 Longworth House Office Building
Washington, DC 20515

The Honorable Michael C. Burgess, M.D.
United States House of Representatives
2161 Rayburn House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
United States House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

The Honorable Brad R. Wenstrup, D.P.M.
United States House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

The Honorable Bradley Schneider
United States House of Representatives
300 Cannon House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks
United States House of Representatives
1716 Longworth House Office Building
Washington, DC 20515

Re: Physician Clinical Registry Coalition Comments on Medicare Access and CHIP Reauthorization Act of 2015

Dear Representatives Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider, and Miller-Meeks:

The undersigned members of the Physician Clinical Registry Coalition ("Coalition") appreciate the opportunity to provide comments regarding the Centers for Medicare and Medicaid Services' ("CMS") implementation of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") as it relates to Qualified Clinical Data Registries ("QCDRs") and clinician-led clinical data registries. The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes.

Registries collect and analyze data on specified outcomes submitted by physicians, hospitals, and other types of health care providers related to a wide variety of medical procedures, diagnostic tests, and/or clinical conditions. Registries play an essential role in promoting quality of care. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. QCDRs and clinician-led clinical data registries provide timely and actionable feedback to providers on their performance, speeding and enhancing quality improvement opportunities. They perform data aggregation and related benchmarking analyses that support one or more predetermined scientific, clinical, or policy purposes, including, but not limited to, describing the natural history of disease, determining the effectiveness (including the comparative effectiveness) of therapeutic modalities, and measuring quality of care to identify best practices.

Medical societies have invested millions of dollars in a system of quality performance evaluation through QCDRs because QCDRs are effective in improving quality in specialty areas. The measures developed by QCDRs and clinician-led clinical data registries are comprehensive, meaningful, and relevant to participating providers and their patient populations. They also provide important information that is not available from claims data alone.

As you are aware, MACRA requires the Secretary of Health and Human Services ("Secretary") to encourage the use of QCDRs and certified electronic health record technology for reporting measures under the quality performance category of the Merit-Based Incentive Payment System ("MIPS") program.[1] In addition, 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."[2]

Given these statutory mandates, it is important that CMS adopt policies that provide clinical data registries with meaningful access to Medicare claims data, encourage QCDR participation in the MIPS program, and promote the development of strong QCDR measures and a framework that support accurate quality data measurement. Over recent years, however, CMS has established policies that contravene the language and intent of MACRA, including policies that deter registry access to Medicare claims data and disincentivize development of meaningful specialty measures. These increasingly burdensome and often extraneous requirements have resulted in a significant decline in the number of QCDRs participating in MIPS.

Therefore, we respectfully urge Congress to critically review CMS policies and reforms discussed below; and consider standalone credit for participation in a QCDR. Although most of these reforms can be accomplished through regulation, we believe that legislative intervention is necessary to ensure that CMS is properly implementing the plain language and intent of MACRA.

In addition, we greatly appreciate the inclusion of language in the bipartisan legislation—H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act—introduced by Dr.

[1] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).
[2] *Id*. § 105(b)(1)(A).

Bucshon and Dr. Schrier. As discussed below, this legislation would help address CMS's failure to provide QCDR's and clinician-led clinical data registries with meaningful access to Medicare claims data for research and quality improvement purposes.

Measure Testing

To be approved for the 2023 performance year/2025 MIPS payment year, all QCDR measures must meet "face validity" for the initial MIPS payment year for which the measure is approved.[3] For subsequent years after being initially approved, all QCDR measures must be fully developed and tested, with complete testing results *at the clinician level*, prior to submitting the QCDR measure at the time of self-nomination.[4] To be included in a MIPS Value Pathway ("MVP") for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.[5]

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. However, these specific testing requirements are unnecessarily excessive for some QCDRs and/or measures, and contrary to the MACRA's requirement to encourage the use of QCDRs for reporting measures. The cost of full measure testing is significant and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. These requirements impose unreasonable cost and other burdens on QCDRs, and such costs are already causing many QCDRs to reduce or cease measure development or to leave the program. These requirements are further complicated by the COVID-19 extreme and uncontrollable circumstances exception policy, which decreased the number of clinicians and groups reporting to MIPS via QCDRs.

To encourage the use of QCDRs, the policy should:

- Require face validity for the first two MIPS payment years for which the measures are approved.
- Support the decision of QCDR statisticians familiar with sample sizes and populations relative to the level of testing (clinician, facility, or group) required.
- Provide funding to assist measure stewards in testing their measures, such as offering financial incentives or improvement activity credit for practices to choose to submit data on new QCDR measures.
- Exempt measures targeted by CMS for harmonization with other QCDR measures from satisfying the measure testing requirement prior to self-nomination.

CMS should delay the requirement that QCDR measures must be fully tested prior to their inclusion in an MVP. This would simplify the program's rules by maintaining consistency between traditional MIPS and MVPs.

[3] 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3). "Face validity" is the "extent to which a measure appears to reflect what it is supposed to measure 'at face value.'
[4] *Id*.
[5] *Id*. § 414.1400(b)(4)(iii)(A)(3)(i).

Data Validation Requirements

The Coalition appreciates the importance of reporting true, accurate, and complete data; however, we are concerned that the data validation and targeted audit requirements contravene MACRA's directive to encourage the use of QCDRs for reporting measures. Beginning with the 2021 performance year, QCDRs and qualified registries must conduct annual data validation audits for the payment year before submitting any data for that payment year to CMS for purposes of the MIPS program.[6] If a data validation audit identifies one or more deficiencies or data errors, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each deficiency or data error and correct such deficiencies or data errors prior to the submission of data for that MIPS payment year.[7]

CMS's policies regarding data validation and targeted audits—particularly now that they apply to not only the quality category, but also the Promoting Interoperability ("PI") and Improvement Activities ("IA") performance categories—are unnecessarily complicated, costly, and burdensome for QCDRs, qualified registries, and clinicians. These policies also fail to recognize that QCDRs and qualified registries employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data. CMS's policies impose considerable burden on clinicians given that the agency has not provided adequate guidance on validating PI and IAs, that not all IAs are reported electronically, and that PI is largely out of the control of registries.

Therefore, we request that Congress direct CMS, not QCDRs, to conduct data validation audits of participating providers. It is inappropriate for the agency to shift its program integrity responsibility to QCDRs. At the very least, Congress should require CMS to work with QCDRs to establish more reasonable data validation requirements that align with MACRA's directive to encourage the use of QCDRs.

Harmonization

Congress should direct CMS to implement appropriate safeguards to ensure that measure harmonization occurs only when doing so is clinically appropriate. Beginning with the 2022 MIPS payment year, in circumstances where multiple, similar QCDR measures exist, CMS may provisionally approve the QCDR measure for one year with the condition that the QCDR must address certain areas of duplication with other approved QCDR measures or MIPS quality measures for subsequent years.[8] If QCDRs cannot collaborate to harmonize their measures, CMS may reject the duplicative QCDR measure.[9]

CMS has failed to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so. This has resulted in specialty societies being forced to "harmonize" their QCDR measure with other distinct and non-risk stratified measures,

[6] *Id*. § 414.1400(b)(3)(v).
[7] *Id*. § 414.1400(b)(3)(vi).
[8] *Id*. § 414.1400(b)(4)(iii)(5).
[9] *Id*.

ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report.

In addition, CMS has not implemented a formal process for appealing decisions regarding measure harmonization. An appeal process would give QCDRs an opportunity to provide CMS with additional information, including if there is a clinical rationale for why measures should not be harmonized or if a measure is an appropriate derivative work of another existing measure. If the measure owner can provide a documented clinical rationale for keeping the measures separate, then CMS should not require measure harmonization. Therefore, Congress should direct CMS to ensure that measure harmonization occurs only when doing so is clinically appropriate.

Topped Out Measures

The Coalition has concerns regarding the effect of topped out measures—a measure with a median performance rate of 95% or higher.[10] Beginning with the 2020 performance period, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out.[11] In addition, beginning with the 2023 MIPS payment year, QCDR measures may be approved for two years, at CMS discretion, by attaining approval status by meeting QCDR measure considerations and requirements.[12] CMS, however, may revoke a QCDR measure's second year approval upon annual review if the QCDR measure is found to be topped out.[13]

The public health emergency, and the corresponding extreme and uncontrollable circumstances exception policy, dramatically reduced the number of providers reporting within the program in the 2020 and 2021 performance years. For instance, the GIQuIC QCDR experienced a 44% drop in QCDR reporters for the 2020 performance year compared to the 2019 performance year and then a drop of 48% in QCDR reporters for the 2021 performance year compared to the 2020 performance year. CMS should allow QCDR measures to remain in the MIPS program for at least two full performance years in which there is no disruption in public quality reporting. This is necessary to meaningfully assess the performance of the measures and their continuation in the program.

If CMS determines that many of a subspecialty's MIPS measures are topped out, it may not be possible for a subspecialty to maintain a QCDR due to the lack of measures. Moreover, measures are expensive to develop, test, and submit to CMS. Congress created the QCDR mechanism to fill critical gaps in the traditional quality measure sets and to ensure that clinicians have access to measures that are more meaningful and relevant to their specialty. CMS's policy concerning topped out measures creates an effect that is counter to the statutory purpose of QCDRs being innovative and targeted to the needs of different specialties. In addition, CMS's policy fails to reward physicians' sustained excellence in providing care.

[10] *Id.* § 414.1305.
[11] *Id.* § 414.1400(b)(4)(iv)(D).
[12] *Id.* § 414.1400(b)(4)(iii)(C).
[13] *Id.*

Once a topped out measure is removed from the program, it is challenging to monitor for new performance gaps over time. Measures play a key role in identifying disparities in care, particularly with respect to race, gender, ethnicity, and age. Removing "topped out" measures may hinder efforts to monitor and rectify health equity and disparities. Rather than removing topped-out measures, or even imposing scoring caps on such measures, CMS should consider a more appropriate transition period to extend the utility of "topped-out" measures.

MVP Program

CMS has expressed a desire to replace the traditional MIPS program with its new MVP framework at the end of a transition period. The Coalition strongly believes that CMS should maintain the current process of MIPS reporting for all eligible clinicians and groups and continue to recognize MVP participation as voluntary. Instead of CMS requiring MVP participation, Congress should increase funding and payment for those participants opting to report MVPs. Assigning bonus points for MVP participation would encourages more participants to transition from traditional MIPS reporting to MVP reporting.

CMS's efforts to design, evaluate, and implement the MVP framework must comply with the language and spirit of MACRA. The agency should work collaboratively with stakeholders to develop an MVP framework that results in more clinically relevant and meaningful performance data for specialties and subspecialties, as well as patients. This includes finding solutions to aspects of MIPS that are fundamentally flawed, which are described in this letter and unfortunately are not addressed by the current MVP framework. To ensure that resources are appropriately invested, CMS also should provide greater transparency during the MVP development and approval process. For instance, if CMS receives two MVP candidates that concern the same specialty, CMS should inform both MVP developers of this information prior to the commencement of the notice-and-comment rulemaking process to give the developers of the MVP candidates time to coordinate their efforts.

CMS could encourage participation in value-based models through MVPs. We believe specialties should not be siloed within the MVP framework. CMS should develop multispecialty MVPs to ensure that the full perioperative team has a common interest to perform well as a group. Developing MVPs specifically designed to capture the individual members of a multispecialty case would help clear up existing ambiguities in attribution and strengthen the relationship between specialties in delivering patient-centered care. Individual specialists would still report their specialty-specific measure to their specialty-specific registries in the process. But in working through these attribution issues, multispecialty MVPs may also help CMS identify additional delivery of care models and future Alternative Payment Models.

Cost Measures

The lack of relevant cost measures for certain specialties is an ongoing challenge for traditional MIPS, which the new MVP framework fails to address. CMS currently employs a single contractor, Acumen, LLC, to develop new episode-based cost measures. Although this process

is comprehensive, it is lengthy, relies strictly on claims data, and does not simultaneously account for quality, which results in a flawed assessment of overall healthcare value. The Coalition urges Congress to put pressure on CMS to accommodate more innovative, out-of-the-box solutions related to cost measurement, such as the integration of clinical registry data with claims data to most accurately evaluate value and the use of appropriateness measures to assess cost. As noted above, CMS should provide QCDRs with better access to claims data so that they can help develop a broader inventory of specialty-specific cost measures. If changes that make cost measures more relevant and fair cannot be implemented, Congress must release/reduce the emphasis on this flawed approach.

The budget neutrality requirement of the MIPS program already poses a significant challenge for many clinicians, particularly those in smaller independent practices. Being assessed for value on measures using a narrow set of retrospective claims data adds to the pressures MIPS exerts on physicians and unlike quality measures, registries are largely unable to assist clinicians in interpreting and improving performance.

Additional Funding to Registries

Over the years, CMS has imposed a significant number of QCDR requirements to shift the cost and burden of administering the MIPS program onto specialty societies and other entities that operate QCDRs and develop QCDR measures. In addition, registries have been adversely affected by the COVID-19 pandemic, resulting in a significant decline in provider participation. Congress should authorize and appropriate federal funding and/or grants to clinical data registries to maintain operations and offset these burdens.

CMS Cooperative Agreements with QCDRs

Congress should encourage the use of cooperative agreements between CMS and QCDRs for the development, improvement, and expansion of quality measures for MIPS. CMS currently relies heavily on contractors to develop specialty-specific MIPS quality measures without specialty organizations' active input. For measures that have been developed by specialty organizations, CMS has required changes that are not clinically appropriate for the specialty. It would make more sense, where appropriate, for CMS to use those same resources to instead collaborate directly with specialty society QCDRs that already have the clinical expertise and infrastructure in place to assist with new measure development.

Access to Medicare Claims Data

We respectfully urge the House of Representatives to swiftly pass bipartisan legislation—H.R. 5394, the Meaningful Access to Federal Health Plan Claims Data Act—introduced by Dr. Bucshon and Dr. Schrier. This legislation would provide clinician-led clinical data registries with an essential tool to play a pivotal role in creating a safer, more efficient, and patient-centered health care delivery system.

Contrary to Section 105(b) of MACRA, CMS has not provided clinician-led clinical data registries with a meaningful way to gain continuous access to Medicare claims data. CMS initially refused to implement Section 105(b), stating that QCDRs could access Medicare claims data through the Research Data Assistance Center ("ResDAC") process.[14] After the Coalition and other stakeholders expressed concerns regarding the ResDAC process, CMS provided QCDRs with an alternative mechanism for accessing Medicare claims data, by permitting QCDRs to serve as quasi-qualified entities under the Qualified Entity Program.[15] Neither option, however, provides QCDRs with the type of timely, broad, and continuous access to Medicare claims data contemplated by Section 105(b) and necessary for QCDRs to effectively link their outcomes data with Medicare claims data

The ResDAC process does not provide sufficient access to Medicare claims data for quality improvement purposes. The ResDAC process is also slow, costly, and cumbersome. Moreover, CMS' decision to treat QCDRs as quasi-qualified entities for purposes of obtaining access to Medicare claims data does not provide QCDRs (or other clinician-led clinical data registries) with the long-term, continuous, and timely access to Medicare claims data required under Section 105(b). Quasi-qualified entities cannot use Medicare data for research purposes without submitting a separate research protocol to ResDAC for review and approval. QCDRs and other clinician-led clinical data registries generally need data on a provider-specialty specific and nationwide basis; however, quasi-qualified entity status only provides registries access to provider-wide and state-specific data. In addition, the Qualified Entity Program requirements on eligibility, operations, and governance are extremely lengthy and burdensome. Quasi-qualified entity status only lasts for three years and continued participation in the program requires re-application. Therefore, it does not allow for the continuous access needed for monitoring quality improvement over time. CMS' failure to properly implement Section 105(b) hinders clinician-led clinical data registries' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes.

The Meaningful Access to Federal Health Plan Claims Data Act would allow QCDRs and clinician-led clinical data registries to gain more meaningful access to Medicare, Medicaid, and State Children's Health Insurance Program for quality improvement, patient safety, and research purposes. It also would permit more comprehensive use of the data—including research, quality of care measurement, and reporting—while at the same time ensuring that the data is protected and used appropriately through data use agreements. Tying Medicare claims data to clinical outcome information would enable clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide them with the information necessary to assess the cost-effectiveness of alternative therapies. Therefore, we respectfully urge the House of Representatives to pass this bipartisan legislation.

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[14] *See* Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 5,397, 5,408 (Feb. 2, 2016) (proposed rule).
[15] Medicare Program: Expanding Uses of Medicare Data by Qualified Entities, 81 Fed. Reg. 44,456 (July 7, 2016).

The Coalition appreciates your consideration of our request. If you have any questions, please contact Rob Portman or Leela Baggett at Powers Pyles Sutter & Verville, PC (Rob.Portman@PowersLaw.com or Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Emergency Physicians
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Anesthesiologists/Anesthesia Quality Institute
American Urological Association
Association for Clinical Oncology
Center for Professionalism and Value in Health Care
College of American Pathologists
Congress of Neurological Surgeons
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons