AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

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January 17, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

RE: [CMS-1807-F] Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The American College of Rheumatology (ACR), representing over 10,000 rheumatologists and rheumatology interprofessional team members, is writing to respond to the CY 2025 Physician Fee Schedule and Quality Payment Program final rule released on November 1, 2024. Rheumatologists and rheumatology professionals provide ongoing care to Medicare beneficiaries with complex acute and chronic rheumatic diseases that require specialized expertise. This primarily non-procedure-based care impacts patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases that require complex diagnostic and management decisions.

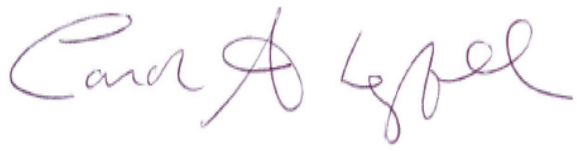
The ACR thanks the Centers for Medicare and Medicaid Services (CMS) for its continued recognition of the value of complex medical decision-making provided by rheumatologists and cognitive care specialists in treating their patients. We particularly thank CMS for listening to and heeding the concerns we raised in response to the proposed rule regarding the use of chemotherapy administration codes when infusing biologics. According to the final rule, codes 96401-96549, which are typically used for chemotherapy administration, can also be used to bill for complex administration of certain drugs and biologics, meaning that if a medication requires complicated handling or monitoring during infusion, it may be appropriately billed using these codes depending on the specific clinical characteristics involved. This clarification will also provide complex clinical characteristics for the Medicare Administrative Contractors (MACs) to consider as criteria when determining payment of claims for these services.

This is highly appreciated because these codes are often utilized by rheumatologists to bill for complex drug administration, particularly for biologic medications such as tumor necrosis factor inhibitors, interleukin inhibitors, monoclonal antibodies, and selective co-stimulation modulators that are used to treat autoimmune or inflammatory diseases. These complex medications have a unique and highly targeted mechanism of action that can also carry a significant risk for adverse events. The elevated level of assessment and monitoring that is required prior to, during, and following the administration of these drugs defines their coding as complex. As such, the ACR is

appreciative of CMS for acknowledging the diverse groups of specialties that use CPT 96401-96549 and for its willingness to listen to the concerns of practicing rheumatologists who have dedicated themselves to providing highly quality care to Medicare beneficiaries with inflammatory diseases.

We look forward to continuing to serve as a resource to you and working with the agency to explore changes and improvements needed to ensure patients with rheumatic diseases have access to quality care. Please contact Colby Tiner, MA, Manager of Regulatory Affairs, at ctiner@rheumatology.org if we can assist or have questions.

Sincerely,



Carol A. Langford, MD, MHS
President, American College of Rheumatology

February 10, 2025

The Honorable Mike Johnson
Speaker
H-232, The Capitol
United States House of Representatives
Washington, DC 20515

The Honorable John Thune
Senate Majority Leader
S-230, The Capitol
United States Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
House Democratic Leader
H-204, The Capitol
United States House of Representatives
Washington, DC, 20510

The Honorable Charles Schumer
Senate Democratic Leader
S-221, The Capitol
United States Senate
Washington, DC 20515

Dear Speaker Johnson, Majority Leader Thune, Leader Schumer, and Leader Jeffries:

The undersigned national medical societies and state medical associations write to collectively urge Congress to include in the forthcoming March 2025 appropriations bill, provisions that both reverse the latest round of Medicare payment cuts and provide physicians with a meaningful payment increase that reflects ongoing inflationary pressures. Our organizations were surprised and deeply disappointed that the final version of the American Relief Act 2025 failed to include *any* financial relief for physicians. America's physicians are united in urging Congress to use the forthcoming March appropriations bill as an opportunity to provide physicians with desperately needed fiscal relief that is imperative to ensuring that seniors retain access to health care services under Medicare.

Following Congressional inaction to stop the cuts finalized by Centers for Medicare and Medicaid Services' (CMS) Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) Final Rule, payments for physicians treating Medicare patients were reduced by an additional 2.83 percent, effective January 1, 2025. The decision to allow previously enacted partial patches to earlier rounds of physician payment reductions to expire without any new relief marks the fifth consecutive year of Medicare physician payment cuts, a truly startling trend that threatens to exacerbate access to care issues throughout the United States. As a result, the unfortunate reality is that physicians' Medicare payments have now been reduced by 33 percent since 2001, when adjusted for inflation in practice costs. In addition, CMS concluded in the CY 2025 MPFS Final Rule that the Medicare Economic Index (MEI), a cumulative measure of the individual costs of running a practice, will increase by 3.5 percent this year. Expecting physicians to provide the same level of care to America's seniors despite being underpaid by over 30 percent and witnessing exponential growth in the cost of providing medical services is simply unsustainable. This cycle threatens to undermine the overarching stability of the Medicare program.

The decision by Congress to extend a variety of other expiring hospital, ambulance, and telehealth provisions in the American Relief Act 2025 without providing physicians any relief was equally troubling. Furthermore, our members understandably think that the federal government has essentially turned its back on physicians following the recent CMS announcement that Medicare Advantage (MA) plans will receive an average payment increase of 4.33 percent from 2025 to 2026. While MA plans receive an increase beyond the expected health care inflation rate, Congress has not acted to incorporate a temporary or permanent inflationary adjustment to the MPFS to ensure adequate access to care.

Thankfully, a bipartisan collection of federal lawmakers has introduced, yet again, another solution to this serious policy issue. Representatives Greg Murphy, MD (R-NC), Jimmy Panetta (D-CA), Mariannette

Miller-Meeks, MD (R-IA), and Kim Schrier, MD (D-WA), along with several other bipartisan House members, have introduced an updated version of the Medicare Patient Access and Practice Stabilization Act, H.R. 879. This bipartisan bill will prospectively, specifically between April 1 and December 31, 2025, stop the latest round of payment cuts in full. The bill also provides physicians with a crucial two percent payment increase, which is about half of the MEI estimate for this year. Therefore, we urge Congressional leadership to adopt the Medicare Patient Access and Practice Stabilization Act as part of the forthcoming legislation to fund the government beyond mid-March.

The time for legislative action is now. America's physicians and the millions of patients we treat can no longer accept any excuses, such as an overcrowded legislative calendar, competing policy priorities, or an inability to achieve bipartisan consensus, as reasons for not including provisions that reverse the latest round of cuts and provide a crucial payment update in next appropriations package. We appreciate the opportunity to outline the many fiscal challenges facing physician practices and stand ready to assist with the overarching effort to expeditiously enact this much needed legislation. Our Medicare beneficiaries and the physicians who treat them deserve the stability that this legislation will provide.

Sincerely,

American Medical Association
Academy of Physicians in Clinical Research
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Emergency Medicine
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology - Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Academy of Sleep Medicine
American Association for Hand Surgery
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Neuromuscular & Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Association of Public Health Physicians
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Lifestyle Medicine
American College of Medical Genetics and Genomics
American College of Mohs Surgery

American College of Physicians
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Epilepsy Society
American Gastroenterological Association
American Geriatrics Society
American Orthopaedic Foot & Ankle Society
American Psychiatric Association
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Gastrointestinal Endoscopy
American Society for Laser Medicine & Surgery, Inc.
American Society for Radiation Oncology
American Society for Surgery of the Hand Professional Organization
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Cataract & Refractive Surgery
American Society of Echocardiography
American Society of Hematology
American Society of Interventional Pain Physicians
American Society of Nephrology
American Society of Neuroradiology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Society of Regional Anesthesia and Pain Medicine
American Society of Retina Specialists
American Society of Transplant Surgeons
American Thoracic Society
American Urogynecologic Society
American Urological Association, Inc.
American Venous Forum
Association for Clinical Oncology
Association of American Medical Colleges
College of American Pathologists
Congress of Neurological Surgeons
Endocrine Society
Heart Rhythm Society
International Pain and Spine Intervention Society
Medical Group Management Association
Outpatient Endovascular and Interventional Society
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery

Society of American Gastrointestinal and Endoscopic Surgeons
Society of Critical Care Medicine
Society of Hospital Medicine
Society of Interventional Radiology
Society of Nuclear Medicine and Molecular Imaging
The American Society of Breast Surgeons
The American Society of Dermatopathology
The Society of Thoracic Surgeons

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association
Medical Association of Georgia
Hawaii Medical Association
Idaho Medical Association
Illinois State Medical Society
Indiana State Medical Association
Iowa Medical Society
Kansas Medical Society
Kentucky Medical Association
Louisiana State Medical Society
Maine Medical Association
MedChi, The Maryland State Medical Society
Massachusetts Medical Society
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
New Mexico Medical Society
North Carolina Medical Society
Medical Society of New Jersey
Medical Society of the State of New York
North Dakota Medical Association
Ohio State Medical Association

Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Utah Medical Association
Vermont Medical Society
The Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wisconsin Medical Society
Wyoming Medical Society

February 28, 2025

The Honorable Mike Johnson
Speaker
H-232, The Capitol
United States House of Representatives
Washington, DC 20515

The Honorable John Thune
Senate Majority Leader
S-230, The Capitol
United States Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
House Democratic Leader
H-204, The Capitol
United States House of Representatives
Washington, DC, 20515

The Honorable Charles Schumer
Senate Democratic Leader
S-221, The Capitol
United States Senate
Washington, DC 20510

Dear Speaker Johnson, Majority Leader Thune, Leader Schumer, and Leader Jeffries:

The undersigned physician and non-physician organizations, representing over one million clinicians, reach out to strongly urge Congress to take action to reverse the current 2.83 percent Medicare Physician Fee Schedule (MFPS) Conversion Factor (CF) reduction and provide clinicians with a positive payment update in the upcoming March 2025 appropriations bill. **Specifically, we ask that you cosponsor and support passage of H.R. 879, the bipartisan Medicare Patient Access and Practice Stabilization Act.**

Our organizations remain united on the need for both long- and short-term Medicare payment reform. Each year since 2020, Congress has acted to mitigate annual reductions in the MPFS CF. However, even with the additional relief from Congress, 2025 now marks the fifth consecutive CF cut.[1]

As the only major provider fee schedule without an annual automatic inflationary update, MPFS reimbursement has failed to keep pace with the actual costs of providing care, leaving our members to navigate financial uncertainty year after year after year. Indeed, when adjusted for inflation, Medicare payments declined by 33 percent since 2001.[2] The cost of running a medical practice continues to rise due to inflation. In fact, the Centers for Medicare & Medicaid Services (CMS) projects a 3.5 percent increase in the Medicare

[1] https://www.ama-assn.org/system/files/cf-history.pdf
[2] https://www.ama-assn.org/system/files/2025-medicare-updates-inflation-chart.pdf

Economic Index (MEI) in 2025.[3] Clearly, this unstable path threatens Medicare beneficiaries' timely access to quality care — in both rural and urban settings. The ongoing downward reimbursement spiral is also contributing to consolidation in the health care system, as more clinicians are no longer able to sustain their practices and are forced to seek alternative business models, such as hospital employment, private equity and other alternatives. Finally, these cuts threaten the ability of our members — who are employers and small business owners — to serve as economic engines of our local communities.

Hospitals enjoy a built-in inflationary update and Medicare Advantage plans receive an update in excess of inflation. Neither can singularly provide the care our patients need. It's the clinicians who are the heroes of patient care, yet our members are constantly being asked to do more with less, which is an extremely dangerous proposition that impacts the lives of millions of Medicare beneficiaries across the country.

Fortunately, a bipartisan group of lawmakers are once again attempting to stop the bleeding— at least for the remainder of 2025. H.R. 879, the Medicare Patient Access and Practice Stabilization Act, recently introduced by Representatives Greg Murphy, MD (R-NC), Jimmy Panetta (D-CA), Mariannette Miller-Meeks, MD (R-IA), and Kim Schrier, MD (D-WA), along with several other bipartisan House members, prospectively stops the entirety of the current reimbursement reduction and helps account for rising inflationary costs with a two percent payment increase, equivalent to roughly half of MEI for 2025**. We urge Congressional leadership to include H.R. 879 in the upcoming government funding legislation.**

We understand that Congress faces many complex issues, competing priorities, and shrinking legislative calendars. However, our members — and, more importantly, our patients — cannot wait any longer. The undersigned organizations, as always, stand ready to help in any way we can to ensure both short- and long-term stability to ensure we can continue to do what we are all called to do — serve our patients.

Thank you for considering our request.

Sincerely,

Academy of Nutrition and Dietetics

ADVION (formerly National Association for the Support of Long Term Care)

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[3] https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2025-medicare-physician-fee-schedule-final-rule

Alliance for Physical Therapy Quality and Innovation

Alliance of Specialty Medicine

Ambulatory Surgery Center Association

American Academy of Audiology

American Academy of Dermatology Association

American Academy Of Facial Plastic And Reconstructive Surgery

American Academy of Family Physicians

American Academy of Hospice and Palliative Medicine

American Academy of Ophthalmology

American Academy of Oral & Maxillofacial Pathology

American Academy of Otolaryngology — Head and Neck Surgery

American Academy of Physical Medicine and Rehabilitation

American Association of Clinical Urologists

American Association of Hip and Knee Surgeons

American Association of Neurological Surgeons

American Association of Nurse Anesthesiology

American Association of Oral and Maxillofacial Surgeons

American Association of Orthopaedic Surgeons

American Chiropractic Association

American College of Allergy, Asthma and Immunology

American College of Cardiology

American College of Emergency Physicians

American College of Gastroenterology

American College of Mohs Surgery

American College of Obstetricians and Gynecologists

American College of Osteopathic Internists

American College of Physicians

American College of Radiation Oncology

American College of Radiology

American College of Rheumatology

American College of Surgeons

American Gastroenterological Association

American Health Care Association/National Center for Assisted Living

American Medical Association

American Medical Rehabilitation Providers

American Nurses Association

American Occupational Therapy Association

American Optometric Association

American Orthopaedic Foot & Ankle Society

American Physical Therapy Association

American Podiatric Medical Association

American Psychiatric Association

American Psychological Association Services

American Society for Dermatologic Surgery Association

American Society for Gastrointestinal Endoscopy

American Society for Radiation Oncology

American Society for Surgery of the Hand Professional Organization

American Society of Anesthesiologists

American Society of Cataract & Refractive Surgery

American Society of Colon & Rectal Surgeons

American Society of Diagnostic and Interventional Nephrology

American Society of Echocardiography

American Society of Hand Therapists

American Society of Neuroradiology

American Society of Nuclear Cardiology

American Society of Plastic Surgeons

American Society of Retina Specialists

American Society of Transplant Surgeons

American Speech-Language-Hearing Association

American Urological Association

Association for Academic Pathology

Association for Clinical Oncology

Association of Diabetes Care & Education Specialists

Association of Women in Rheumatology

CardioVascular Coalition

Coalition of State Rheumatology Organizations

College of American Pathologists

Congress of Neurological Surgeons

Dialysis Vascular Access Coalition

Emergency Department Practice Management Association

Heart Failure Society of America

Heart Rhythm Advocates

Heart Rhythm Society

Indiana Association of Pathologists

Infectious Diseases Society of America

Large Urology Group Practice Association

Medical Group Management Association

National Association of Rehabilitation Providers and Agencies

National Infusion Center Association

Office-Based Facility Association

Outpatient Endovascular and Interventional Society

Radiology Business Management Association

Renal Physicians Association

Select Medical and the Alliance for Recovery Care

Society for Vascular Surgery

Society of Interventional Radiology

Society of NeuroInterventional Surgery

Society of Nuclear Medicine & Molecular Imaging

The Society of Thoracic Surgeons

US Oncology Network

State Medical Associations

California Medical Association

Florida Medical Association

Kentucky Medical Association

Louisiana State Medical Society

Massachusetts Medical Society

Medical Society of the State of New York

Missouri State Medical Association

Oklahoma State Medical Association

Pennsylvania Medical Society

South Dakota State Medical Association

Texas Medical Association

Washington State Medical Association

March 10, 2025

The undersigned physician organizations urge Members of the House of Representatives to insist to their leadership that language addressing the 2025 Medicare physician payment cut be added to the full year CR before the House votes on the package.

Over 100 Members of the House of Representatives have cosponsored H.R. 879 – *The Medicare Patient Access and Practice Stabilization Act of 2025,* which was introduced by Representative Greg Murphy, MD. This legislation would address the devastating payment cut that doctors faced on January 1st.

Last December, there was a bipartisan funding package that Congress was hours away from passing before it was scuttled. That package addressed the 2025 Medicare physician payment cut.

It is time for Members of the House of Representatives to take a stand to protect Medicare patient access by insisting language addressing the 2025 Medicare physician payment cut be added to the full year CR before the vote.

American College of Surgeons
American Medical Association
Alliance of Specialty Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Academy of Sleep Medicine
American Association of Hip and Knee Surgeons
American Association of Neurological Surgeons
American Association of Neuromuscular and Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Association of Public Health Physicians
American Clinical Neurophysiology Society

American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Lifestyle Medicine
American College of Mohs Surgery
American College of Nuclear Cardiology
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Radiology
American College of Rheumatology
American Gastroenterological Association
American Geriatrics Society
American Medical Group Association
American Orthopaedic Foot & Ankle Society
American Osteopathic Association
American Psychiatric Association
American Rhinologic Society
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Metabolic and Bariatric Surgery
American Society for Surgery of the Hand Professional Organization
American Society for Transplantation and Cellular Therapy
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Breast Surgeons
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of Echocardiography
American Society of Gastrointestinal Endoscopy
American Society of Hematology
American Society of Nephrology
American Society of Neuroradiology
American Society of Plastic Surgeons
American Society of Radiation Oncology
American Society of Regional Anesthesia and Pain Medicine
American Society of Retina Specialists
American Society of Transplant Surgeons

American Thoracic Society
American Urogynecologic Society
American Urological Association
Arkansas Medical Society
Association for Clinical Oncology
Association of American Medical Colleges
Association of Women in Rheumatology
California Medical Association
Coalition of State Rheumatology Organizations
College of American Pathologists
Congress of Neurological Surgeons
Emergency Department Practice Management Association
Endocrine Society
Florida Medical Association
Hawaii Medical Association
Heart Failure Society of America
Heart Rhythm Advocates
Kentucky Medical Association
Louisiana State Medical Society
Maryland State Medical Society
Medical Association of Georgia
Medical Association of the State of Alabama
Medical Group Management Association
Medical Society of New Jersey
Medical Society of Virginia
Medical Society of Washington, DC
Medical Society of the State of New York
Michigan State Medical Society
Missouri State Medical Association
National Infusion Center Association
National Organization of Rheumatology Management
North American Modulation Society
North American Spine Society
North Carolina Medical Society
North Dakota Medical Association
Obesity Medicine Association
Ohio State Medical Association
Oregon Medical Association

Pennsylvania Medical Society
Post-Acute and Long-Term Care Medical Association
Renal Physicians Association
Society for Cardiovascular Magnetic Resonance
Society for Pediatric Dermatology
Society for Vascular Surgery
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Cardiovascular Computed Tomography
Society of Gynecologic Oncology
Society of Hospital Medicine
Society of Interventional Radiology
Society of Nuclear Medicine and Molecular Imaging
South Carolina Medical Association
Tennessee Medical Association
Texas Medical Association
The Society of Thoracic Surgeons
Vermont Medical Society
Washington State Medical Association
Wisconsin Medical Society

P•C•R•C

PHYSICIAN CLINICAL REGISTRY COALITION

May 12, 2025

Submitted Electronically

Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

RE: Physician Clinical Registry Coalition's Comments on Deregulation Initiative

Dear Director Vought:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition") appreciate the opportunity to submit comments in response to the Office of Management and Budget's ("OMB's") request for information ("RFI") on deregulation. 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.

In response to the Trump Administration's deregulation initiative, the Coalition respectfully urges the Centers for Medicare and Medicaid Services ("CMS") to consider rescinding Merit-based Incentive Payment System ("MIPS") policies that impose significant financial and administrative burden on clinician-led clinical data registries. This includes policies concerning data validation, measure testing, harmonization, scoring, and the MIPS Value Pathways. To improve access to data, we also request that CMS waive the data request fees associated with the Virtual Research Data Center ("VRDC"). The current fee structure is a barrier to most registries requesting data from the VRDC.

Clinician-Led Clinical Data Registries

Clinical data registries are organized data collection and analysis systems operated by or affiliated with a national medical society, hospital association, or other health care association. These 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. 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. Medical societies have invested millions of dollars in a system of quality performance evaluation through Qualified Clinical Data Registries ("QCDRs") and other clinician-led clinical data registries. Clinical data registries are major sources of real-world evidence, including patient-reported outcomes data. The comprehensive and valuable measures developed by clinical data registries are meaningful and relevant to participating providers and their patient populations.

Clinical data registries improve quality of healthcare by providing timely and actionable feedback to practitioners on their performance. This quality improvement effort is typically achieved by developing benchmarks on performance/treatment outcomes from data submitted by all registry participants and sharing those benchmarks with each registry participant. Registry data helps identify best clinical practices, determine the relative value of physician services, and identify deficiencies or disparities in care that require corrective action.

The federal government, health care products manufacturers, accreditors, and state and local governments have increasingly come to rely on clinical data registries for a wide variety of purposes. Clinical data registries report medical and clinical data to the CMS on behalf of their participating health care providers for purposes of the MIPS and for more general patient and disease tracking. In fact, CMS relies on QCDRs and other registries as a way to extend federal resources and enhance the efficiency and impact of the MIPS program. For instance, QCDRs and registries take over a major chunk of the data collection and quality reporting work, which would otherwise require substantial CMS resources. Further, QCDRs often develop custom quality measures that are more relevant and clinically meaningful for specialists than CMS-developed measures. Congress recognized the importance of QCDRs when it passed the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). MACRA requires the Secretary of Health and Human Services to encourage the use of QCDRs for reporting measures under the quality performance category of the MIPS program. MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 87 (2015).

Elimination of Burdensome MIPS Policies

Over recent years, however, CMS has established policies that contravene the language and intent of MACRA, including policies that disincentivize the development of meaningful specialty measures and impose financial and administrative burdens on registry operations. The Coalition has serious concerns regarding the agency's complex and cumbersome MIPS policies that have created obstacles for clinician-led clinical data registries to successfully accomplish their goals in supporting physicians in delivering high-quality, safe, and patient-centered care. To ease regulatory burdens, we urge CMS to consider eliminating the following MIPS policies:

1. **Data Validation Requirements**

QCDRs and qualified registries ("QRs") must conduct annual data validation audits. 42 C.F.R. § 414.1400(b)(3)(v). If a data validation audit identifies one or more deficiencies or data errors, the QCDR or QR 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. *Id*. § 414.1400(b)(3)(vi)(A). 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. CMS's policies regarding data validation and targeted audits are unnecessarily complicated, costly, and burdensome for QCDRs, QRs, and clinicians. These policies also fail to recognize that QCDRs and QRs employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data.

To reiterate, Coalition supports the idea of reporting true, accurate, and complete data. However, CMS's implementation of this goal disproportionally burdens QCDRs and QRs compared to other reporting mechanisms (e.g., direct reporting). Moreover, the audits that QCDRs and QRs are required to conduct are duplicative of independent audits that CMS conducts on clinicians. CMS should not shift the burden of auditing onto registries.

Therefore, we request that CMS rescind 42 C.F.R. § 414.1400(b)(3)(v) and (vi) and consider data validation options that are less burdensome on QCDRs, QRs, and clinicians.

2. Measure Testing

CMS may approve a QCDR measure only if the QCDR measure meets face validity. *Id*. § 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.' It is a subjective assessment by experts about whether the measure reflects its intended assessment." *Measures Testing*, CMS Measures Management System (Mar. 2025), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity. However, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination. 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).

We understand and agree with CMS's desire that all QCDR measures be appropriate, reliable, and valid. The key to "appropriate measures" is the development of measures by medical specialty societies. Medical specialty societies play a major role in supporting the quality performance category by developing, testing, and maintaining a majority of the current MIPS quality measure inventory. Quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, thus providing implicit face validity for each measure.

However, CMS's specific testing requirements are unnecessarily excessive for 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 (approximately $500,000 per measure and sometimes more) and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. The unfunded mandate to test measures imposes 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. **The Coalition believes that 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3) should be rescinded and a more strategic and flexible approach to**

measure testing is warranted. CMS should engage with registries to develop more appropriate measure testing requirements.

3. Harmonization

CMS may provisionally approve the individual QCDR measures for one year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. *Id*. § 414.1400(b)(4)(iii)(A)(5). If such areas of duplication are not addressed, CMS may reject the QCDR measure. *Id*.

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, ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report. In addition, asking measure developers to combine measures may result in unnecessarily complex measures that increase burden on clinicians and confusion in the program. **Therefore, we request that CMS rescind the measure harmonization requirement at 42 C.F.R. § 414.1400(b)(4)(iii)(A)(5).**

4. Flawed Scoring Policies: Topped Out Measures and Benchmarks

CMS should eliminate its flawed MIPS scoring policies and work with registries to craft a more appropriate solution to scoring measures. For instance, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out—a measure with a median performance rate of 95% or higher. *Id*. §§ 414.1305, 414.1400(b)(4)(iv)(D). This regulation fails to recognize that 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. **Therefore, we urge CMS to rescind 42 C.F.R. §§ 414.1305, 414.1400(b)(4)(iv)(D).**

Additionally, CMS has a policy of generally assigning clinicians zero points for reporting on a measure that lacks a benchmark, which provides little incentive for clinicians to report on these measures. *Id.* § 414.1380(b)(1)(i)(A)(1). To encourage measure development and clinician use of meaningful specialty measures, we request that CMS rescind this policy at 42 C.F.R. § 414.1380(b)(1)(i)(A)(1) and work with stakeholders to develop a more appropriate scoring policy.

5. Mandating MIPS Value Pathways ("MVPs")

CMS has expressed a desire to replace the traditional MIPS program with its new MVPs framework by the 2029 performance period. Traditional MIPS is a deeply flawed program that requires significant reform. Unfortunately, the implementation of MVPs only exacerbates these problems. The MVP framework fails to resolve foundational issues in the MIPS program, including problematic MIPS scoring rules and other policies that often disincentivize the development and use of more clinically focused measures and participation pathways that better align with clinical practice. In addition, medical societies have expressed serious concerns regarding the development of MVPs applicable to their specialties. Specifically, medical societies are concerned that measures included in MVPs are not meaningful to providers and that MVP reporting will necessitate costly IT support. Some barriers to MVP development include lack of applicable MIPS measures that apply to the specialty, lack of benchmarks for existing QCDR measures, measure testing requirements that will limit the number of QCDR measures eligible for inclusion in MVPs, and lack of relevant cost measures. We have serious concerns that CMS is developing the MVP framework contrary to the language and spirit of MACRA. CMS appears to be limiting the number of QCDR measures in MVPs by excluding QCDR measures or asking QCDR measures to be harmonized with existing measures. During the MVP development process, CMS has declined, on numerous occasions, to adopt QCDR measures recommended by medical societies. In doing so, the agency failed to provide a sufficient rationale for refusing to include measures that were deemed by providers to be clinically meaningful.

CMS should continue to recognize MVP participation as voluntary and work with stakeholders to craft a solution that better responds to concerns regarding the traditional MIPS program.

6. Mandatory Subgroup Reporting Requirement

Beginning in the 2023 performance period, clinicians can choose to form a subgroup, comprised of clinicians with similar scopes of care, to report an MVP. *Id*. § 414.1400(b)(1)(iii). CMS has previously finalized that such subgroups will become mandatory for multispecialty groups choosing to report MVPs beginning in the 2026 performance period, and that multispecialty groups will no longer be able to submit data at the group level. *Id.* § 414.1305. The Coalition believes that defining the specifics of mandatory subgroups for multispecialty practices is premature. Requiring mandatory subgroup reporting would be logistically challenging for many practices. Doing so during the transition process from MIPS to MVPs increases the administrative burden of practices attempting to switch to MVP reporting. **Therefore, we request that CMS rescind the requirement that multispecialty groups must report via subgroups at 42 C.F.R. § 414.1305.**

Virtual Research Data Center

The VRDC is a virtual research environment under which registries can—in theory—access Medicare claims data for research purposes. Registries' use of the VRDC process is often

limited because the process is slow, cumbersome, and expensive. The VRDC process provides for the release of a defined set of data only for discrete research projects, and data requests can take months and sometimes years to process with no guarantee of approval. The costs associated with requesting data is so great that it acts as a barrier to most registries requesting data from the VRDC. **To improve access to claims data, we request that CMS remove the assessment of VRDC fees and work with stakeholders to allow for access to data in a manner that is more cost-effective.**

Addressing these challenges is critical to ensuring that clinician-led registries can continue to play an essential role in improving clinical outcomes and advancing quality care. Therefore, we respectfully urge CMS to consider repealing these overbearing and burdensome MIPS policies and VRDC fees.

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The Coalition appreciates the Trump Administration's consideration of our concerns and recommendations. If you have any questions, please contact Leela Baggett at Powers Pyles Sutter & Verville, PC (Leela.Baggett@PowersLaw.com).

Respectfully submitted,

American Academy of Dermatology Association
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 Radiology
American College of Rheumatology
American Society of Plastic Surgeons
Association for Clinical Oncology
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society of Neurointerventional Surgery
The Society of Thoracic Surgeons

June 23, 2025

VIA ELECTRONIC TRANSMISSION

The Honorable John Thune
Majority Leader
U.S. Senate
Room S-309, The Capitol
Washington, D.C. 20515

The Honorable John Barrasso, MD
Majority Whip
U.S. Senate
Room S-208, The Capitol
Washington, D.C. 20515

Dear Leader Thune and Majority Whip Barrasso:

On behalf of the undersigned clinician and other professional organizations, we respectfully urge the Senate to include the Medicare payment provision in the House-passed One Big Beautiful Bill Act (H.R. 1) in the legislative package currently under consideration in the Senate. This provision represents a critical step toward stabilizing the Medicare Physician Fee Schedule (MPFS) and protecting access to care for seniors and individuals with disabilities who rely on trusted clinicians in their communities. It also helps promote competition by supporting community-based small businesses.

House leadership recognized the urgent need to rectify the failures of previous Congresses by prioritizing a significant first step towards long-term reform in its first major legislative package. Section 44304 of H.R. 1 ties the MPFS to inflation by establishing a permanent, annual update based on the Medicare Economic Index, beginning in the next plan year. The provision reflects policy principles that physician and other clinician stakeholders have long advocated for.[1, 2] Moreover, it reflects many members across both chambers, who have long asked for prior Senate leaders to prioritize their communities.[3, 4, 5]

Under the Medicare program, the MPFS sustains access to entire care teams, including physicians, dentists, physician assistants, nurse practitioners, nurses, occupational and physical therapists, audiologists, and professional staff who work together to deliver coordinated, high-quality care to your communities. This access is at risk. While Congress has intervened in prior years to soften the impact of some reductions, it failed to prevent the 2025 payment reduction, further compounding the persistent undervaluation of clinician services. When adjusted for inflation, for example, Medicare physician payments have already declined by 33 percent since 2001, and the consequences are painfully visible.[6]

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[1] American Medical Association, Characteristics of a Rational Medicare Payment System, 2022, https://www.ama-assn.org/system/files/characteristics-rational-medicare-payment-principles-signatories.pdf.
[2] Congress of Neurological Surgeons, AANS and CNS Join Groups Urging Congress to Provide Physicians with Inflation-Based Medicare Payment Update, September 10, 2024, https://www.cns.org/advocacy/legislative-affairs-detail/new-powerpoint-201.
[3] U.S. Senator John Boozman, Press Release: Boozman, Welch Lead Letter Calling for Legislative Solution to Protect Access to Medicare Services, February 23, 2024, https://www.boozman.senate.gov/press-releases?ID=38E4F449-331B-4C57-BDCA-934B1D7010C7.
[4] U.S. Senator Roger Marshall, MD, Press Release: Senators Introduce Bipartisan Legislation to Protect Seniors' Access to Healthcare, August 1, 2024, https://www.marshall.senate.gov/newsroom/press-releases/senators-introduce-bipartisan-legislation-to-protect-seniors-access-to-healthcare/.
[5] U.S. Senator John Boozman, Press Release: Boozman, Welch Lead Push to Protect Access to Medicare Services, November 26, 2024, https://www.boozman.senate.gov/press-releases?ID=3E2D8327-0D91-4531-8D21-6009BAE94971.
[6] American Medical Association, Chart: Medicare Updates Compared to Inflation in Practice Costs (2001 – 2025), https://www.ama-assn.org/system/files/2025-medicare-updates-inflation-chart.pdf.

Clinician-led practices care for around 33.9 million Americans enrolled in Original Medicare, nearly half of all Medicare beneficiaries.[7] More than 3.3 million individuals are under age 65 and qualify for Medicare due to disabling conditions and end-stage renal disease.[8] In the most rural areas, nearly 58 percent of Medicare beneficiaries are covered by traditional Medicare, where access to reliable care remains essential and increasingly fragile.[9] Between 2019 and 2024, rural areas lost nearly 9,500 independent physicians and experienced a 42 percent reduction in independent rural medical practices.[10] As a result, fewer than 12,500 independent physicians currently serve these communities. If Congress continues to delay action, access to primary and specialty care will continue to erode, forcing patients to travel long distances, leave their communities, or wait until their health deteriorates into an emergency that's harder and more expensive to recover from.

At the same time, congressional inaction has fueled ongoing consolidation and market distortions that affect patients nationwide. Today, the largest employer of physicians is Optum, a subsidiary of the UnitedHealth Group and an entity currently the subject of lawsuits and federal investigations. Congress can act to rein in further concentration of market power and address the threats to the viability of local community-based practices.

We strongly urge you to reinsert the House-passed provision in the Senate package. Allowing another year to pass without action will only accelerate the very consolidation and access challenges that Congress has consistently said it aims to prevent – issues that have been the focus of bipartisan concern and multiple legislative efforts. Following the conclusion of this budget reconciliation process, we hope you will support the re-launch of the bipartisan Medicare payment reform working group.[11] As members of that group, you and the Senate Finance Committee leaders explored reforms to payment adequacy, alternative payment models, chronic care management, telehealth, and workforce shortages, as well as other strong policies.[12] We believe this renewed effort will enhance Section 44304 into meaningful, long-term stability.

Thank you for your leadership and for considering this request. We stand ready to work with you to protect Medicare access, support clinicians, and ensure that rural and underserved communities are not left behind.

Sincerely,

American Association of Neurological Surgeons

Congress of Neurological Surgeons

American Society of Anesthesiologists

American Association of Orthopaedic Surgeons

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[7] U.S. Centers for Medicare and Medicaid Services (CMS), Medicare Monthly Enrollment, https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.
[8] CMS, Medicare Monthly Enrollment Data Dictionary, https://data.cms.gov/resources/medicare-monthly-enrollment-data-dictionary.
[9] Freed, M., Biniek, J. F., Sroczynski, N., & Neuman, T. (2025, April 10). Most people in the most rural counties get Medicare coverage from traditional Medicare. Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/most-people-in-rural-areas-get-medicare-coverage-from-traditional-medicare/.
[10] Physicians Advocacy Institute, PAI-Avalere Report: Rural Areas Face Steep Decline in Independent Physicians and Practices, https://www.physiciansadvocacyinstitute.org/PAI-Research/Rural-Physician-Employment-and-Acquisition-Trends-2019-2024.
[11] U.S. Senator Catherine Cortez Masto, Press Release: Cortez Masto, Blackburn, Thune, Barrasso, Stabenow, Warner Announce Formation Of Medicare Payment Reform Working Group, February 9, 2024, https://www.cortezmasto.senate.gov/news/press-releases/cortez-masto-blackburn-thune-barrasso-stabenow-warner-announce-formation-of-medicare-payment-reform-working-group/.
[12] U.S. Senate Committee on Finance, Press Release: Wyden and Crapo Release White Paper for Medicare Doctor Pay Reform, May 17, 2024, https://www.finance.senate.gov/chairmans-news/wyden-and-crapo-release-white-paper-for-medicare-doctor-pay-reform.

Academy of Doctors of Audiology

Academy of Medical-Surgical Nurses

ADVION (formerly National Association for the Support of Long Term Care)

Alliance for Physical Therapy Quality and Innovation

American Academy of Allergy, Asthma & Immunology

American Academy of Anesthesiologist Assistants

American Academy of Audiology

American Academy of Dermatology Association

American Academy of Emergency Medicine

American Academy of Ophthalmology

American Academy of Otolaryngology–Head and Neck Surgery

American Academy of Pain Medicine

American Academy of Sleep Medicine

American Association of Clinical Urologists

American Association of Hip and Knee Surgeons

American Association of Neuromuscular & Electrodiagnostic Medicine

American Association of Nurse Anesthesiology

American Association of Oral and Maxillofacial Surgeons

American Association of Psychiatric Pharmacists

American College of Allergy, Asthma and Immunology

American College of Gastroenterology

American College of Medical Genetics and Genomics

American College of Osteopathic Family Physicians

American College of Osteopathic Internists

American College of Rheumatology

American Epilepsy Society

American Gastroenterological Association

American Medical Society for Sports Medicine

American Medical Women's Association

American Occupational Therapy Association

American Optometric Association

American Orthopaedic Foot and Ankle Society

American Physical Therapy Association

American Physical Therapy Association Academy of Hand and Upper Extremity

American Podiatric Medical Association

American Society for Clinical Pathology

American Society for Dermatologic Surgery Association

American Society for Gastrointestinal Endoscopy

American Society of Colon & Rectal Surgeons

American Society of Dermatopathology

American Society of Nuclear Cardiology

American Society of Ophthalmic Plastic and Reconstructive Surgery

American Society of Regional Anesthesia and Pain Medicine

American Society of Shoulder and Elbow Surgeons

American Society of the Hand Professional Organization

American Society of Transplant Surgeons

American Speech-Language-Hearing Association

American Urogynecologic Society

American Urological Association

APTA Private Practice

Association for Clinical Oncology

Association of University Professors of Ophthalmology

Association of Women in Rheumatology

Community Oncology Alliance

Digestive Health Physicians Association

Free2Care

Infectious Diseases Society of America

International Pain and Spine Intervention Society

J. Robert Gladden Orthopaedic Society

National Association of Spine Specialists

North American Neuromodulation Society

North American Spine Society

Orthoforum

Renal Physicians Association

Society for Cardiovascular Angiography and Interventions

Society of Critical Care Medicine

Society of Gastroenterology Nurses and Associates, Inc.

Society of Neurological Surgeons

Society of Nuclear Medicine and Molecular Imaging

The Society of Thoracic Surgeons

United Physical Therapy Association

P•C•R•C

PHYSICIAN CLINICAL REGISTRY COALITION

July 9, 2025

Hearing of the United States House Committee on Ways and Means
Subcommittee on Health
on
"Health at Your Fingertips: Harnessing the Power of Digital Health Data"

Statement for the Record by the Physician Clinical Registry Coalition

Chairman Buchanan, Ranking Member Doggett, and Members of the Subcommittee:

The undersigned members of the Physician Clinical Registry Coalition (the "Coalition"), appreciate the opportunity to submit this statement for the record with respect to the hearing entitled, "Health at Your Fingertips: Harnessing the Power of Digital Health Data," held by the Committee on June 25, 2025. 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.

Clinician-led clinical data registries use digital health data to enhance quality reporting, promote value-based care, and augment valuable research efforts. As Congress evaluates pathways to utilize and improve digital health data, we respectfully call on the Subcommittee on Health and the full Ways and Means Committee to direct the Department of Health and Human Services ("HHS") to (1) integrate clinician-led clinical data registries into value-based care models, (2) remove regulatory barriers that hinder the operation and effectiveness of registries, (3) improve access to claims data, and (4) strengthen enforcement against information blocking. Our recommendations aim to preserve and expand the role of registries in value-based care, improving provider experience and ensuring that quality programs remain meaningful and actionable for clinicians.

Harnessing Clinician-Led Clinical Data Registries to Strengthen Value-Based Care

Under the 21st Century Cures Act, clinician-led clinical data registries must meet high standards that demonstrate their rigor and reliability. Clinician-led clinical data registries must be clinician-led or controlled, operate as tax-exempt entities, and be devoted to the care of a population defined by a specific disease, condition, exposure, or therapy.[1] Additionally, clinician-led clinical data registries must conduct core activities such as collecting detailed, standardized data on an ongoing basis, providing feedback to participants, meeting standards for

[1] 42 U.S.C. § 300jj-14(b)(1).

data quality, and providing ongoing training and support for participants.[2] To ensure accuracy and integrity, clinician-led clinical data registries also are required to systematically collect data, use standardized data elements, verify data completeness and validity, and ensure regular data audits.[3]

Given these requirements, clinician-led clinical data registries are uniquely positioned to advance the healthcare system's transformation toward value-based care. Their infrastructure enables timely and actionable feedback to providers, as well as sophisticated data aggregation and benchmarking analyses in support of a wide range of scientific, clinical, and policy objectives. By using registry data to benchmark provider performance against peers, registries can help identify variation in care delivery, which can highlight opportunities for improvement or reveal best practices to emulate. These registries generate real-world evidence critical to evaluating the cost-effectiveness of treatments and informing whether services are reasonable and necessary. These registries also contribute vital data to public health efforts. Many registries collect patient-reported outcomes measures, which provide additional insights for clinicians and health officials.

Moreover, the measures developed by Qualified Clinical Data Registries ("QCDRs") are deeply relevant to providers and reflect clinical priorities. These measures are often more clinically relevant than other traditional CMS data sources. QCDR quality measures are developed by subject matter experts, thoroughly reviewed by professionals, and backed by literature, clinical guidelines, and initial data. Congress recognized the value of QCDR measures when it enacted the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). Under MACRA, the Secretary of Health and Human Services is directed to encourage the use of QCDRs for reporting quality measures within the Merit-Based Incentive Payment System ("MIPS").[4] Further, Congress explicitly recognized the role of QCDRs in "linking [claims] data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety."[5]

In addition, registries are a source of real-world evidence to support clinical research and innovation and inform the development of clinical practice guidelines. Registries and their robust data sets enable quicker and less expensive randomized clinical trials, longitudinal studies, and other observational studies. In contrast, electronic health records ("EHRs") are not designed to support longitudinal quality measurement, benchmarking, or population-level improvement, nor can they the offer the same specialty-focused expertise. EHR systems are primarily built to serve billing, documentation, and internal clinical workflow needs. Clinician-led clinical data registries also are designed by clinical experts within a specific medical specialty, ensuring that the data is clinically accurate, relevant, and meaningful to specific patient populations. In contrast, EHRs are administrative tools not developed by clinical specialists and may lack the clinical nuance required for specialty-specific insights. Simply put, registries are far better suited for evaluating care coordination, disease progression, and outcomes over time. Although EHRs are a necessary component of modern clinical practice, they are not a substitute for the robust, purpose-driven infrastructure that registries provide. Therefore, clinician-led clinical data

[2] *Id*. § 300jj-14(b)(2)-(5).
[3] *Id*. § 300jj-14(b)(4).
[4] MACRA, Pub. L. No. 114-10, § 101(c), 129 Stat. 92 (2015).
[5] *Id*. § 105(b)(1)(A), 129 Stat. 136 (2015).

registries should be prioritized for quality measurement and value-based care initiatives, as they offer the clinical insight, analytical rigor, and longitudinal perspective that EHRs alone cannot deliver.

Eliminating Regulatory Barriers that Hinder the Operation and Effectiveness of Registries

When registries are weighed down by overly burdensome regulatory obligations, including requirements that contravene the language and intent of MACRA, their capacity to serve both providers and CMS diminishes. CMS derives substantial value from the critical services provided by registries through the extension of federal resources and enhancement of the efficiency and overall impact of the MIPS program. Registries assume significant responsibilities in data collection and quality reporting—functions that would otherwise demand considerable investment from CMS. Registries take on much of the work of interpreting and submitting quality measures, and they offer tailored dashboards and benchmark comparisons that would be burdensome or impossible for individual providers to create themselves. Moreover, QCDRs develop specialized, clinically meaningful quality measures that are better tailored to the needs of specific specialties than other measures. QCDRs often standardize or normalize data before calculating quality measures, offering practices and providers with more reliable data for reporting and quality improvement efforts. QCDRs also create quality improvement opportunity for practices by giving them actionable quality scores throughout the year, not just annual reporting options. For instance, a radiology practice can rely on a registry to track multiple performance measures and benchmark against peers—far easier and more clinically useful than navigating generalized EHR reports. In contrast, providers often cannot extract usable data from their EHRs without significant customization, IT support, or fees.

Over recent years, CMS has established policies that disincentivize the development of meaningful specialty measures and impose financial and administrative burdens on registry operations. Removing these burdens would allow registries to operate more efficiently. To that end, we recommend that Congress direct HHS to reconsider the following policies:

- **Data Validation Requirements**: QCDRs and qualified registries ("QRs") must conduct annual data validation audits.[6] If a data validation audit identifies one or more deficiencies or data errors, the QCDR or QR 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] 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. CMS's policies regarding data validation and targeted audits are unnecessarily complicated, costly, and burdensome for QCDRs, QRs, and clinicians. These policies also fail to recognize that QCDRs and QRs employ rigorous internal quality data controls and conduct external audits to ensure the accuracy of data. Moreover, the audits that QCDRs and QRs are required to conduct are duplicative of independent audits that CMS conducts on clinicians. CMS should not shift the burden of

[6] *Id.* § 414.1400(b)(3)(v).
[7] *Id.* § 414.1400(b)(3)(vi)(A).

auditing onto registries. Therefore, Congress should direct HHS to rescind 42 C.F.R. § 414.1400(b)(3)(v) and (vi) and consider data validation options that are less burdensome on QCDRs, QRs, and clinicians.

- **Measure Testing**: CMS may approve a QCDR measure only if the QCDR measure meets face validity.[8] "Face validity" is the "extent to which a measure appears to reflect what it is supposed to measure 'at face value.' It is a subjective assessment by experts about whether the measure reflects its intended assessment."[9] However, a QCDR measure approved for a previous performance year must be fully developed and tested, with complete testing results at the clinician level, prior to self-nomination.[10] We understand and agree with CMS's desire that all QCDR measures be appropriate, feasible, reliable, and valid. The key to "appropriate measures" is the development of measures by medical specialty societies. Medical specialty societies play a major role in supporting the quality performance category by developing, testing, and maintaining a majority of the current MIPS quality measure inventory. Quality measures submitted by QCDRs are created by subject matter experts, undergo significant expert vetting, and are supported by literature, guidelines, and preliminary data, thus providing implicit face validity for each measure. However, CMS's specific testing requirements are unnecessarily excessive for 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 (approximately $500,000 per measure and sometimes more) and is an expense that nonprofit medical societies, particularly small specialties, cannot bear. The unfunded mandate to test measures imposes 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. Moreover, approval is not guaranteed for the following year, making it an annual uncertainty. The Coalition believes that 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3) should be rescinded and a more strategic and flexible approach to measure testing is warranted.

- **Harmonization**: CMS may provisionally approve the individual QCDR measures for one year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years.[11] If such areas of duplication are not addressed, CMS may reject the QCDR measure.[12] 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, ultimately at the disadvantage of specialists who are left with fewer meaningful measures to report. In addition, asking measure developers to combine measures may result in unnecessarily complex measures that increase burden on clinicians and confusion in the program. Therefore, we request that CMS rescind the measure harmonization requirement at 42 C.F.R. § 414.1400(b)(4)(iii)(A)(5).

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[8] Id. § 414.1400(b)(4)(iii)(A)(3).
[9] *Measures Testing, CMS Measures Management System* (Mar. 2025), https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/scientific-acceptability/validity.
[10] 42 C.F.R. § 414.1400(b)(4)(iii)(A)(3).
[11] *Id*. § 414.1400(b)(4)(iii)(A)(5).
[12] *Id*.

- **Flawed Scoring Policies: Topped Out Measures and Benchmarks**: Congress should direct HHS to eliminate its flawed MIPS scoring policies and work with registries to craft a more appropriate solution to scoring measures. For instance, considerations for whether to remove a QCDR measure from the program include whether the QCDR measure is topped out—a measure with a median performance rate of 95% or higher.[13] This regulation fails to recognize that 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. Therefore, 42 C.F.R. §§ 414.1305, 414.1400(b)(4)(iv)(D) should be rescinded. Additionally, CMS has a policy of generally assigning clinicians zero points for reporting on a measure that lacks a benchmark, which provides little incentive for clinicians to report on these measures.[14] To encourage measure development and clinician use of meaningful specialty measures, CMS should work with stakeholders to develop a more appropriate scoring policy.

  Further, even when quality measures have established benchmarks, these benchmarks often fall short as reliable indicators of performance across the healthcare system due to the flawed structure of this program that forces practices to focus on a narrow set of conditions and procedures not necessarily representative of the scope of their work. The aforementioned scoring policies incentivize clinicians to report on measures they will perform well on, even if they are not truly relevant to their patients, simply to comply with the program and avoid a penalty. As a result, the benchmarks are inherently biased—skewed upward and unrepresentative of the broader clinical landscape. Consequently, a clinician's quality score is often less a reflection of actual care quality and more a function of measure availability, EHR system capabilities, and access to a knowledgeable registry.

  We strongly recommend against mandating that clinicians report on a standard set of measures given the diversity of patient populations seen by clinicians across specialties and even within the same specialty. One of the main purposes of the QCDR pathway is to move away from a one-size-fits-all approach to quality measurement and towards a program that recognizes varied clinical relevance, practice patterns, and patient populations across and within disciplines. It is critical that CMS preserve this flexibility to ensure MIPS performance assessments are fair, accurate, and meaningful to both clinicians and patients.

- **MVPs**: CMS has expressed a desire to replace the traditional MIPS program with its new MVPs framework by the 2029 performance period. Traditional MIPS is a deeply flawed program that requires significant reform. Unfortunately, the implementation of MVPs only exacerbates these problems. The MVP framework fails to resolve foundational issues in the MIPS program, including problematic MIPS scoring rules and other policies that often

[13] *Id*. §§ 414.1305, 414.1400(b)(4)(iv)(D).
[14] *Id*. § 414.1380(b)(1)(i)(A)(1).

> disincentivize the development and use of more clinically focused measures and participation pathways that better align with clinical practice. In addition, medical societies have expressed serious concerns regarding the development of MVPs applicable to their specialties. Specifically, medical societies are concerned that measures included in MVPs are not meaningful to providers and that MVP reporting will necessitate costly IT support. Some barriers to MVP development include lack of applicable MIPS measures that apply to the specialty, lack of benchmarks for existing QCDR measures, measure testing requirements that will limit the number of QCDR measures eligible for inclusion in MVPs, and lack of relevant cost measures. We have serious concerns that CMS is developing the MVP framework contrary to the language and spirit of MACRA. CMS appears to be limiting the number of QCDR measures in MVPs by excluding QCDR measures or asking QCDR measures to be harmonized with existing measures. During the MVP development process, CMS has declined, on numerous occasions, to adopt QCDR measures recommended by medical societies. In doing so, the agency failed to provide a sufficient rationale for refusing to include measures that were deemed by providers to be clinically meaningful.

Congress should reform the MIPS program by simplifying and streamlining requirements for both providers and registries. Easing regulatory burdens on clinical data registries is not about relaxing oversight—it strategically empowers registries to better serve providers. When registries can focus on their core functions, everyone benefits.

Improving Access to Claims Data

Section 105(b) of MACRA directs CMS 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." Despite this mandate, the agency has not provided the 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. This failure to comply with the clear statutory mandate in MACRA limits QCDRs' ability to perform longitudinal and other data analyses for quality improvement, patient safety, cost-effectiveness, and research purposes.

Currently, QCDRs have two options for accessing Medicare claims data—the Qualified Entity ("QE") Program and the Virtual Research Data Center ("VRDC"). The VRDC is a virtual research environment under which QCDRs can—in theory—access Medicare claims data. However, the VRDC program only allows the use of claims data for very specific research purposes. The VRDC application and data request process also is slow, cumbersome, and expensive.

The QE Program enables organizations approved as "qualified entities" to receive Medicare claims data for use in evaluating provider performance for quality improvement purposes. CMS offers QCDRs the option of becoming "quasi-qualified entities" under this program. However, quasi-qualified entity status only provides QCDRs access to provider-wide and state-specific data. QCDRs generally need data on a provider-specialty specific and nationwide basis. Thus, qualified entity status would provide QCDRs with both more and less data than they need to link Medicare Claims data with provider-level clinical outcomes data. In addition, the application

process and associated fees imposed by this program is too costly and cumbersome to provide registries with timely and meaningful access to claims data. Neither the VRDC process nor QE Program provide QCDRs with the type of access to Medicare claims data that satisfies the requirements of Section 105(b).

Therefore, we urge Congress to direct CMS to establish a dedicated program or revisit its existing programs to truly satisfy the requirements of Section 105(b). CMS should accommodate a range of data query options, including provider-specific, state-level, and national datasets. In order to link claims data with patient-level clinical outcomes, registries must be permitted to use either direct patient identifiers or validated probabilistic matching methodologies. Moreover, the cost structure for data access should be reasonable, and the application process should be streamlined. Once appropriate data use agreements are in place, registries should be granted automatic eligibility to request and query datasets that enable timely linkage between clinical outcomes and claims data. CMS could further enhance usability by developing a secure dashboard or portal system that allows authorized registries to access and analyze Medicare claims data—mirroring the access registries already provide to their participating clinicians. Such a system would meaningfully support quality measurement, care coordination, and innovation in value-based care.

Strengthening Enforcement Against Information Blocking

It is critical to foster an ecosystem where data flows securely, efficiently, and meaningfully—from EHRs/hospital systems to registries and back to providers. In response to concerns that EHR vendors, along with large hospitals and health systems, were knowingly impeding the exchange of electronic health information ("EHI")—by charging excessive fees, imposing onerous contract terms, or simply refusing to respond to requests—Congress enacted the 21st Century Cures Act. This legislation and its implementing regulations prohibit health care providers, as well as health information technology developers, exchanges, or networks (including EHR vendors), from engaging in "information blocking," defined as any practice that is likely to interfere with, prevent, or materially discourage access to, exchange of, or use of EHI. A practice is not considered information blocking if it meets one or more of the exceptions outlined by the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology ("ASTP/ONC").

Despite this directive in the 21st Century Cures Act, our registries continue to be harmed by information blocking practices which inhibit the free-flow of digital health data. We urge Congress to direct ASTP/ONC to reexamine the current exceptions, particularly the "fees exception." This exception is increasingly being invoked by EHR vendors and large health systems to block access to data requested by clinician-led clinical data registries. EHR vendors frequently decline to engage in good-faith negotiations to enable the transfer of clinical data to registries, effectively denying registries any access to such data. Others impose prohibitively high and often unjustified fees for data transfers, placing significant financial burdens on providers and undermining the registries' ability to function. For example, we are aware of at least one EHR vendor charging over $20,000 to solo practitioners for data access.

Another example involves a cloud-based EHR system that explicitly informed a registry that it "doesn't integrate with any systems to extract data for MIPS reporting." This blanket refusal to enable data access for a federally supported quality reporting program poses a serious problem. It not only impedes provider participation in MIPS, but also obstructs the registry's role in aggregating, analyzing, and reporting data critical to improving patient outcomes. Even if a specific refusal technically does not satisfy the current definition of information blocking, a categorical denial of integration with any system—without justification or a path forward—violates the spirit of the law by materially discouraging the use and exchange of EHI.

The current restrictions on data flow stifle progress in quality measurement, evidence-based care, and innovation. Tackling information blocking practices head-on is essential to realizing a truly interoperable healthcare system. Therefore, ASTP/ONC should reevaluate the effectiveness of the existing information blocking rules and narrow exceptions that are being misused to impede data sharing with registries. ASTP/ONC could consider limiting an actor's ability to charge fees to the recovery of costs reasonably incurred to provide access, exchange, or use of EHI, based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. Additionally, in the interest of transparency, actors should be required to disclose the methodology behind their fees.

In parallel, the Office of Inspector General ("OIG") and CMS should utilize their existing authority to enforce existing regulations against EHR vendors and hospital systems that continue to obstruct data exchange to clinical data registries. The OIG should closely examine these kinds of systemic refusals/fees as potential forms of information blocking and take timely enforcement action where appropriate. Additionally, the OIG should respond to complaints of information blocking within a reasonable timeframe.

If ASTP/ONC are unable to curtail these harmful practices, Congress should direct CMS to establish a hardship exemption under the MIPS program. Information blocking practices may adversely affect performance scores under the MIPS program. When EHR vendors categorically deny access to data or impose prohibitively high fees, providers are placed in an untenable position. As with current exceptions, the inability to report would stem from circumstances beyond the provider's control. Clinicians should not be penalized for the bad-faith actions of EHR vendors that obstruct access to essential data.

* * * * *

The Coalition appreciates your consideration of our concerns and recommendations.

Respectfully submitted,

American Academy of Ophthalmology
American Academy of Otolaryngology–Head and Neck Surgery
American Association of Neurological Surgeons
American College of Rheumatology
American Society of Plastic Surgeons
American Urological Association
Congress of Neurological Surgeons
Outpatient Endovascular and Interventional Society
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Association for Clinical Oncology
The Society of Thoracic Surgeons

August 4, 2025

The Honorable John Joyce, MD
United States House of Representatives
2102 Rayburn House Office Building
Washington, DC 20515

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

Dear Representatives Joyce and Schrier,

The undersigned organizations would like to thank you for your leadership in reintroducing the Access to Claims Data Act. This bipartisan bill would create a process enabling clinician-led clinical data registries to obtain timely, comprehensive, and ongoing access to federal claims data. Advancing quality improvement, innovation, transparency, accountability, and value in health care are at the core of our organizations' missions. By granting access to this critical data, this legislation would help us move closer to a safer, more efficient, and patient-centered health care system.

Clinician-led registries, such as those managed by our specialty societies, are invaluable sources of real-world evidence that can significantly enhance quality and effectiveness research. However, they currently face considerable regulatory obstacles in accessing federal claims data. Linking clinical registry data with Medicare, Medicaid, and State Children's Health Insurance Program (CHIP) data opens the door to much-needed quality improvement and long-term studies. This work provides essential insights for improving health care quality and efficiency.

Section 105(b) of the Medicare Access and CHIP Reauthorization Act (MACRA) instructed the Secretary to give Qualified Clinical Data Registries (QCDRs) access to Medicare claims data for the purpose of linking it with clinical outcomes and conducting scientifically valid, risk-adjusted analyses to support quality improvement and patient safety. Unfortunately, regulatory barriers have largely prevented registries from obtaining meaningful access to federal health plan data. While the Centers for Medicare and Medicaid Services (CMS) technically provides access through the Virtual Research Data Center (VRDC), the system is limited to narrow research questions and is often slow, expensive, and difficult to use.

The current process falls short because clinician-led registries need continuous, long-term access to comprehensive Medicare data to accurately track patient outcomes. CMS's failure to effectively implement Section 105(b) of MACRA has hindered these registries' ability to perform the detailed analyses necessary to improve quality, safety, cost-effectiveness, and research.

The Access to Claims Data Act directly addresses this ongoing issue by allowing registries to connect their provider-level outcome data with Medicare, Medicaid, and CHIP claims data. This would unlock critical insights into long-term patient outcomes and device performance. With access to data from the time of intervention through the end of life, we can further our mission of ongoing learning and continuous improvement in health care.

Once again, thank you for your support and leadership on these important issues. We look forward to working with you to see this legislation passed into law.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons (AANS)
American Association of Orthopaedic Surgeons
American Board of Family Medicine
American College of Cardiology
American College of Gastroenterology
American College of Rheumatology
American Orthopaedic Foot & Ankle Society
American Society for Surgery of the Hand Professional Organization
American Society of Anesthesiologists
American Society of Cataract & Refractive Surgery
American Society of Plastic Surgeons
American Urological Association
Association for Clinical Oncology
College of American Pathologists
Congress of Neurological Surgeons (CNS)
Outpatient Endovascular and Interventional Society
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncology
Society of Interventional Radiology
Society of NeuroInterventional Surgery
The Society of Thoracic Surgeons

August 22, 2025

The Honorable Greg Murphy, M.D.
407 Cannon House Office Building
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Neal Dunn, M.D.
466 Cannon House Office Building
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Adam Gray
1230 Longworth House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressmen Murphy, Gray, and Dunn:

The Part B Access for Seniors and Physicians (ASP) Coalition, representing over 300 patient and provider organizations across the country, applauds the introduction of H.R. 4299, the *Protecting Patient Access to Cancer and Complex Therapies Act of 2025*, which, if enacted, will address the untenable Part B payment cuts to healthcare providers included in the Inflation Reduction Act (IRA), and protect Medicare beneficiaries' access to lifesaving therapies. Physicians have seen a ratcheting down of reimbursements over the years, which has made it extremely difficult for them to continue providing high-quality, accessible, and affordable medical care to Medicare seniors; the additional Part B payment cuts through the IRA further threatens care delivery to Medicare beneficiaries. Your legislation would correctly hold physicians harmless from IRA "drug price negotiation." A recent independent study found that your legislation would save the Medicare program $3.3 billion over 10 years while maintaining the IRA's $93.3 billion in savings for patients over 10 years[1].

Medicare Part B provides drugs to close to 60 million seniors and disabled Americans, including those with cancer and other serious and complex conditions such as rheumatologic, autoimmune, and inflammatory conditions; those living with blinding eye diseases, Crohn's disease and ulcerative colitis, and other rare diseases; as well as those living with serious mental illness. Given the often life-threatening complexity of their health conditions, these patients require personalized and accessible medical care from their providers. Through Part B, physicians have access to a variety of treatment options for a wide range of health conditions, enabling them to provide the appropriate, life-saving care that their patients need.

Medicare beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program. Physicians caring for these patients face an increasingly challenging reimbursement environment that, without intervention, will be made worse by the IRA by putting providers and their patients in the middle of "drug price negotiations" between the government and drug companies. Under the IRA, reimbursement for negotiated Part B drugs will no longer be based on "Average Sales Price" (ASP) but rather a new rate called the "Maximum Fair Price" (MFP). A 2024 study analyzing the potential range of reimbursement reductions in Part B found that add-

[1] Robb; Holcomb; Ulin. "Impact of Inflation Reduction Act on Part B Provider Payment and Patient Access to Care." *Milliman,* May 2025, https://www.milliman.com/en/insight/ira-impact-on-part-b-provider-payments

on reimbursements could fall by as much as 61 percent.[2] A recent study found that this will reduce physician reimbursement in Medicare by $56.3B over ten years[3]. These figures do not account for the overhead costs associated with acquiring and administering drugs, placing all the financial risk on physicians. Additionally, it will be an administrative nightmare for medical practices to have two different reimbursement rates – ASP and MFP – that will also affect their commercial insurance contracts.

Prior to the passage of the IRA, the healthcare provider community warned that the cuts to add-on payments for Part B drugs included in the bill would place extreme pressure on practice viability. Nevertheless, lawmakers moved forward with the provision, knowing they would further exacerbate the reimbursement cuts that the Centers for Medicare & Medicaid Services (CMS) has been implementing for years now. Practices are closing, especially in rural areas, and consolidating into the more expensive hospital setting. This new round of IRA-induced reimbursement cuts will make a terrible situation even worse.

Our coalition is extremely grateful for your leadership in keeping providers whole throughout Medicare's "drug price negotiation" process and removing them from this draconian outcome. We look forward to working with you on passage of the *Protecting Patient Access to Cancer and Complex Therapies Act of 2025* to protect patient access and quality care for Medicare beneficiaries.

Sincerely,

1in9/Hewlett House
ADAP Advocacy Association (aaa+)
Advanced Rheumatology and Arthritis Research Center (ARARC)
Advocates for Responsible Care/Rx in Reach Coalition
Alabama Society for the Rheumatic Diseases
Alliance for Patient Access
American Academy of Allergy, Asthma & Immunology
American Academy of Ophthalmology
American College of Rheumatology
American Society for Gastrointestinal Endoscopy
American Society of Ophthalmic Plastic and Reconstructive Surgery
Arizona Bioindustry Association, Inc. (AZBio)
Arizona Myeloma Network
Association for Clinical Oncology
Association of Northern California Oncologists
Association of Women in Rheumatology

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[2] Sullivan; Dilmanian; Frazier, Krupp, et al. "Commercial Spillover Impact on Part B Negotiations on Physicians." *Avalere Health*, 16 Sept. 2024, https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.

[3] Robb; Holcomb; Ulin.

BioNJ
California Rheumatology Alliance
Caregiver Action Network
Carson Valley Health
Charleston (WV) Parkinson's Support Group
Chicago Rheumatism Society
Christian Coalition of Delmarva
Coalition of Hematology and Oncology Practices
Coalition of State Rheumatology Organizations
Community Oncology Alliance (COA)
Connecticut Rheumatology Association
Easter Seals North Georgia, Inc.
Florida Society of Rheumatology
Free ME from Lung Cancer
Georgia Society of Clinical Oncology
HealthCare Institute of New Jersey (HINJ)
HealthyWomen
Hereditary Angioedema Association
ICAN, International Cancer Advocacy Network
Infusion Providers Alliance (IPA)
Large Urology Group Practice Association (LUGPA)
Let's Talk About Change, LLC
Liver Coalition of San Diego
Living Hope for Mental Health
Looms For Lupus
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Maryland Society for Rheumatic Diseases
Medical Oncology Association of Southern California (MOASC)
MidWest Rheumatology Association
Mississippi Oncology Society
Multiple Sclerosis Foundation
Multiple Sclerosis Resources of CNY, Inc.
National Infusion Center Association (NICA)
Nebraska Rheumatology Society
Nevada Chronic Care Collaborative
New Jersey Association of Mental Health and Addiction Agencies, Inc.
New Mexico Biotechnology & Biomedical Association (NMBio)
North Carolina Rheumatology Association
North Dakota Medical Association
Oncology Managers of Florida
Pennsylvania Rheumatology Society
Pennsylvania Society of Oncology and Hematology

Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa (RAI)
State of West Virginia Rheumatology Society
Tennessee Association of Adult Day Services
The Rheumatism Society of the District of Columbia
The US Oncology Network
Vets Place Northwest
ZERO Prostate Cancer

CC: Speaker Mike Johnson
Leader Hakeem Jeffries

AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Empowering rheumatology professionals to excel in their specialty

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September 10, 2025

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Submitted electronically via regulations.gov

RE: [CMS-1832-P] Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz:

The American College of Rheumatology (ACR), representing over 10,400 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the CY 2026 Physician Fee Schedule and Quality Payment Program proposed rule published in the Federal Register on July 16, 2025. We welcome the chance to share our comments regarding the impact of these policies on rheumatologists' ability to provide quality care to the 53.2 million Americans living with rheumatic diseases.

Rheumatologists and rheumatology professionals provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. They provide primarily non-procedure-based care to patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases that entail complex diagnoses and treatments. Rheumatologists and rheumatology professionals also work closely with physical and occupational therapists to maximize the ability of patients to achieve and maintain independence outside of healthcare settings. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly surgical or interventional procedures. These improved outcomes enable our patients to be more productive than they would have been without timely, effective, specialized treatment.

The ACR thanks the Centers for Medicare and Medicaid Services (CMS) for its continued recognition of the value of complex medical decision-making provided by rheumatologists and other cognitive specialties in treating their patients. We appreciate the policies set forth by CMS to help alleviate these challenges amid challenging environments for providing high quality healthcare. The ACR offers the following comments on policies regarding physician reimbursement for Part B services and drugs, telehealth flexibilities, code valuations, and the Quality Payment Program (QPP).

Proposed Provisions in the CY26 Physician Fee Schedule

Conversion Factor

The ACR appreciates CMS's proposed increase to the conversion factor from $32.35 to $33.42 (non-Alternative Payment Model (APM) participants) and $33.59 (qualifying APM participants). However, while this represents a nominal increase, it is insufficient to address decades of Medicare reimbursement erosion for cognitive, chronic-care specialties like rheumatology. According to the American Medical Association (AMA), Medicare physician payments declined 33% from 2001 to 2024 when adjusted for inflation in practice costs.[1]

On top of this, the U.S. inflation rate has risen nearly 25% since 2020. This has had grave effects on consumer prices, healthcare labor costs, prescription drug costs, supply procurement, and other healthcare practice expenses.[2] In particular, the cost of practicing medicine has risen by nearly an estimated 25% over the past two decades with CMS estimating that the Medicare Economic Index (MEI) increased by 3.5% in 2025 alone.

While the increase to the conversion factor is certainly a positive step, it is largely due to the 2.5% increase signed into law in early July. This increase is a temporary measure, only affecting reimbursements from January 1, 2026, through December 31, 2026. Without further congressional action, the conversion factor for 2027 will drop to the previous rate. Further, this underwhelming increase from CMS comes despite predictions that the MEI will increase by 2.3% percent in 2026, thus confirming that inflationary costs associated with running a practice will continue to rise and increase the divide between expense and income for Medicare providers.

The lack of an inflationary update continues to threaten the viability of physician practices, adds considerable burden to the practice of medicine, and stifles innovation. Rheumatology practices face disproportionately high overhead due to the need for specialized staff, infusion services, costly drugs, and monitoring equipment. As financial strain increases, some rheumatologists are forced to limit the number of Medicare patients they see, consolidate with larger systems, or in some cases close their practices. This further limits access for patients with chronic rheumatic diseases, particularly in rural and underserved areas where there is already a severe shortage of practicing rheumatologists.

In addition to limiting the number of Medicare patients, practices are increasing the total volume of patients they see to compensate for decreasing reimbursement. Many commercial insurers follow Medicare rates, so a decrease in Medicare reimbursement translates to a decrease from all payers. Overextending physicians' patient volumes is a driver of burnout that leads to physicians

[1] https://www.ama-assn.org/practice-management/medicare-medicaid/medicare-physician-pay-has-plummeted-2001-find-out-why?utm_source=chatgpt.com

[2] https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector

choosing to leave their practice.[3] This trend is particularly concerning for rheumatology, which is already facing a workforce shortage.[4]

Additionally, rheumatologists are being asked to invest in care coordination, quality reporting, and practice modernization. However, with stagnant reimbursements eroded by inflation, practices lack the resources to invest in practice updates, undermining CMS's own goals for value-based care. With the number of Medicare beneficiaries expected to increase to over 80 million patients by 2030, coupled with a corresponding increase in the frequency of rheumatic disease in this patient population, many beneficiaries will be unable to access the specialized care they need.

In short, failure to provide an appropriate inflationary update results in cumulative pay cuts for rheumatologists, threatens practice sustainability, and worsens patient access to timely, specialized care. **The ACR urges CMS to increase the conversion factor beyond the proposed amount to at least keep pace with the MEI and to collaborate with Congress to enact a permanent inflationary update for physician payments.**

Efficiency Adjustment

CMS is proposing a -2.5% efficiency adjustment to the Medicare Physician Fee Schedule (MPFS) for CY 2026. This adjustment aims to account for productivity gains over time that are not reflected in current reimbursement rates. While the adjustment is intended to apply to non-time-based services, the ACR has significant concerns regarding its potential impact.

CMS's proposal to decrease the work Relative Value Units (RVU) and physician intraservice time for approximately 7,000 physician services due to efficiencies is arbitrary and does not justify a decrease in payment every three years. This adjustment will likely nullify the small increase in the conversion factor and aggravate the payment reductions physicians endured for over 20 years, thus adding to the financial pressure on practices that are already coping with increasing costs and stagnant payments. It will also threaten beneficiary access to care and jeopardize our healthcare system's sustainability.

Secondly, the proposed across-the-board adjustment is not being appropriately applied and does not reflect the time and effort physicians use in providing thousands of services. The ACR agrees with CMS that "accruing efficiencies does not apply to all services equally" and we believe the agency should not apply this adjustment arbitrarily. CMS should instead work with us to address the impact on Medicare beneficiaries living with complex, chronic autoimmune and inflammatory diseases.

CMS has taken important steps in recent years to strengthen access to cognitive specialists, including improvements to office and outpatient E/M codes, creation of new codes for prolonged and chronic care management, and expanded use of telehealth. These actions have supported specialties such as rheumatology, which play a vital role in treating patients with conditions that require ongoing, comprehensive management. However, the proposed efficiency adjustment

[3] https://www.mgma.com/mgma-stat/physician-burnout-still-major-factor-even-as-unexpected-turnover-eases
[4] https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/art.42833

would significantly erode these gains. **The ACR strongly urges CMS to rescind this proposal and explore alternatives to blunt, across-the-board efficiency adjustments that unintentionally penalize cognitive specialties. We also welcome the opportunity to contribute clinical expertise to help shape an alternative solution that will be fair to both physicians and their patients.**

Practice Expense Methodology

CMS proposes revising the methodology for allocating indirect practice expense (PE) costs for facility-based services. Beginning in CY 2026, CMS proposes to reduce the portion of PE RVU allocated based on work RVU in the facility setting to half the amount used in the non-facility setting. CMS's proposed shift in reimbursement away from services provided in the facility setting will create a redistribution of value for facility-based services and reduce the indirect PE RVU component formula. This will be a substantial change and will significantly lower reimbursement for practices in the facility setting.

The ACR is concerned that the proposed revision to the practice expense methodology will exacerbate already insufficient Medicare reimbursement for rheumatology services. Insufficient reimbursement across the board has led many independent practices to sell to hospital systems to remain financially viable. Under the proposed methodology, payments would be cut even further, which will have the opposite effect and will create higher costs, new cuts, and fewer options for patient access to care. The ACR strongly encourages CMS to rescind this proposal and instead work on a methodology that accounts for the real costs associated with providing care, so the growing number of patients with rheumatic diseases can access affordable, high-quality care that they need.

Prevention and Management of Chronic Disease – Request for information (RFI)

The ACR commends CMS for seeking a better understanding of how it could enhance its support management for prevention and management of chronic disease. We have the following feedback:

1. *How could we better support prevention and management, including self-management, of chronic disease?*

   Rheumatology patients often present with complex, multi-system autoimmune conditions requiring ongoing medication monitoring, comorbidity management, and frequent coordination between specialists, primary care, and ancillary services. Although CMS currently reimburses Chronic Care Management (CCM), Principal Care Management (PCM), and Complex CCM codes, uptake among specialists remains limited due to complicated billing requirements, prohibitions on concurrent billing with certain services, and administrative burden that disproportionately affects small and rural practices.

   Proactive care coordination for rheumatologic disease patients is associated with a reduction in emergency room visits. However, the current CCM/PCM payment structure does not reflect the intensity of coordination required in subspecialty care. CMS should streamline

documentation and reporting requirements for these codes, permit shared management arrangements between rheumatologists and primary care providers, and provide targeted education to specialty practices on billing and compliance. This approach would ensure that beneficiaries with rheumatic diseases can benefit from timely, coordinated care that prevents costly disease exacerbations.

Additionally, CMS must increase reimbursement for evaluation and management (E/M) visits. Medicare payment policies have long undervalued these visits relative to procedural services. Rheumatology is a largely cognitive specialty, relying heavily on E/M services rather than procedural revenue. When Medicare reimbursement for E/M visits does not keep pace with inflation or practice costs, rheumatology practices, especially small or independent ones, face increased financial strain. This makes it more difficult to sustain operations, retain staff, and invest in infrastructure such as infusion suites or electronic health record (EHR) systems that optimize patient care and provide interoperability.

If E/M reimbursement rates continue to decline, some rheumatologists may limit the number of Medicare patients they accept, shorten visit lengths, or in some cases withdraw from Medicare entirely. This is particularly concerning because rheumatology already faces a significant workforce shortage, and reduced participation could worsen wait times and access barriers for older adults with arthritis, lupus, and other rheumatic diseases

2. *Are there certain services that address the root causes of disease, chronic disease management, or prevention, where the time and resources to perform the services are not adequately captured by the current physician fee schedule code set?*

   There are a few notable examples of rheumatology services that are not adequately captured by the current fee schedule code set. First, teaching patients self-injection techniques and safe medication use are bundled by current E/M codes into counseling time, but do not reflect the structured, team-based education needed for effective self-administered treatments and medication adherence. No specific code covers self-injection training or medication device education.

   Second, existing infusion administration codes (96365+) only capture the technical infusion service, not the cognitive/coordination work of therapy management, patient safety protocols, and adherence follow-up. This negatively impacts risk assessment before infusion, infusion reaction management, and coordination with specialty pharmacies.

   Lastly, CMS must remove the restriction on reporting modifier –25 when G2211 is billed. Rheumatology patients often require comprehensive management of chronic, systemic diseases alongside medication safety monitoring and comorbidity management. G2211 was intended to account for this added complexity. By restricting its use when modifier -25 is applied (i.e., when an E/M visit occurs on the same day as a procedure, such as a joint injection or infusion service), CMS is essentially removing payment for the longitudinal complexity of the encounter, even though that complexity still exists.

Telehealth

The ACR appreciates CMS's proposals in the CY 2026 PFS to expand and improve telehealth, including:

- Permanent removal of frequency limits for inpatient, Skilled Nursing Facilities, and critical care telehealth visits;
- Streamlined addition of services to the telehealth list; and
- Permanent allowance for real-time virtual direct supervision.

These changes will directly benefit patients with complex rheumatic diseases by enabling timely follow-up, continuity of care, and practice efficiency.

However, we are deeply concerned about the impending expiration of the originating site and geographic restrictions on October 1, 2025. Many rheumatologic patients, particularly those who are immunocompromised, mobility-impaired, or living in rural areas, depend on the flexibility to connect with their providers from home. Reinstating location limits will create significant access barriers, delay care, and undermine the very intent of telehealth expansion. By preserving broad telehealth access and adapting services to specialty needs, CMS can strengthen equitable care delivery for Medicare beneficiaries with rheumatic diseases. **The ACR encourages CMS to work with Congress to permanently extend all regulatory flexibilities on telehealth reimbursement. We also call for CMS to remove all restrictions on payment parity and remove any barriers to interstate licensure that bar providers from treating beneficiaries across state lines.**

Average Sales Price: Price Concessions and Bona Fide Service Fees

The December 2022 Office of Inspector General (OIG) report titled, "Manufacturers May Need Additional Guidance to Ensure Consistent Calculations of Average Sales Prices," recommended that CMS determine whether additional guidance would ensure more accurate and consistent Average Sales Price (ASP) calculations. CMS is thus proposing new regulatory text and definitions related to price concessions and bona fide service fees intended to provide further clarification to manufacturers and improve the accuracy of ASP, which is used to determine Medicare Part B drug payment limits. The ACR applauds CMS's efforts to "reduce the opportunity for improper manipulation of the ASP calculation," and increase certainty in the "integrity of the submitted ASP." Ensuring integrity of the ASP calculation is key to better aligning reimbursement for Part B drugs with the actual prices paid by rheumatology practices.

However, the ACR remains concerned about rebates between manufacturers and pharmacy benefit managers (PBM) that are reflected in manufacturers' quarterly ASP reporting. These rebates have artificially lowered the ASP for certain biosimilar drugs to the point that many providers' acquisition costs substantially exceed Medicare and other private health plan reimbursement. This scenario puts rheumatology practices in an untenable position and threatens patients' access to critical treatments which may lead to suboptimal outcomes including disease worsening.

The ACR encourages CMS to work with Congress to pursue the following legislative updates to the Social Security Act (SSA) to help ensure appropriate reimbursement and access to biosimilar drugs:

- **Amend Section 1847A(b) of the SSA to temporarily provide an 8% add-on to the providers' acquisition cost of all biosimilar products.**
- **Amend Section 1847A(c)(4) of the SSA to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% until ASP reaches sustainable levels, as determined by the Secretary; or**
- **Amend Section 1847A(c)(3) of the SSA to permanently remove manufacturer rebates from the ASP methodology for biosimilars.**

Average Sales Price: Units Sold at Maximum Fair Price

The Inflation Reduction Act (IRA) empowers Medicare to negotiate maximum fair prices (MFPs) for high-cost prescription drugs under Part D, beginning in 2026. These MFPs establish price ceilings below traditional list prices. Starting January 1, 2026, CMS is proposing that units of selected drugs sold at the MFPs—as negotiated under the IRA—will be included in the calculation of the manufacturer's ASP. As CMS knows, Part B drugs will be included in the Medicare Drug Price Negotiation Program's third round of negotiations, with prices taking effect in 2028. As such, this proposal will have several negative implications for rheumatologists.

First, MFPs are likely to be lower than current ASPs for Part B drugs, which are currently calculated as a manufacturer's ASP across a number of eligible entities, including providers, commercial insurers, and Medicare Advantage plans. Inclusion of MFPs in the calculation of ASP is likely to pull ASPs downward. Currently, a significant share of provider reimbursement by commercial insurers for medicines is based on ASP. A recent survey of commercial insurers showed that over 60% of commercial and Medicare Advantage insurers reference ASP for reimbursing Part B drugs.[5] If CMS moves forward with including MFPs in the calculation of ASP for selected drugs, research suggests providers could face add-on payment decreases of up to $37 billion across Medicare and the commercial market. [6] CMS's decision comes at a time when providers, particularly independent, community-based providers, are already feeling significant financial pressure from historical Medicare payment cuts.

Second, CMS' decision is likely to cause patient access issues, and lead to practice closures and consolidation. The increased financial pressure on rheumatologists that often accompanies rising infusion costs frequently requires them to make difficult decisions when it comes to patient care. This is particularly the case for small and rural rheumatology practices, which typically operate on slim margins and would be least able to absorb the reimbursement cuts triggered by the inclusion of MFPs in the calculation of ASP. If reimbursement does not cover acquisition and

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[5] Avalere Health. (January 2025). Estimating the Spillover Impact of IRA Part B Negotiation. Available at: https://advisory.avalerehealth.com/insights/estimating-the-spillover-impact-of-ira-part-b-negotiation

[6] Avalere Health. (September 2024). Commercial Spillover Impact of Part B Negotiations on Physicians. Available at: https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.

administration costs, some rheumatologists might limit offering certain therapies or shift prescribing patterns. They may also decide to refer patients to an offsite infusion center, which tends to be more costly for the patient, or switch the patient to a less expensive but potentially less effective treatment. These cost necessities would disrupt the continuity of patient care and could negatively impact patient outcome. CMS should also note that many of these practices are already underwater in prescribing a number of biologic medications – meaning acquisition costs are greater than reimbursement due to PBM/manufacturer rebates.

The ACR strongly encourages CMS to not move forward with this provision. If CMS chooses to move forward with it, the ACR recommends that CMS create a reimbursement floor so that ASP reductions from MFPs do not push reimbursement below drug acquisition and administration costs. We also request monitoring and reporting requirements from CMS on whether access disruptions (i.e., site-of-care shifts, drug shortages) occur after the ASP declines.

MVP Group Reporting

The ACR is deeply engaged in helping our members with quality reporting and improvement through our own Qualified Clinical Data Registry (QCDR). As such, we would like to express our concerns regarding the proposed requirement that, beginning with the CY 2026 Merit-based Incentive Payment System (MIPS) performance period (2028 payment year), multispecialty groups must report MIPS Value Pathways (MVPs) either as subgroups or as individuals, rather than as a single group entity.

While we understand CMS's intent to align reporting more closely with specialty-specific care, this proposal introduces significant operational and technical burdens for multispecialty practices, particularly those leveraging QCDRs for MIPS reporting. Our concerns are as follows:

1. **Increased Administrative Burden**
   Subgroup formation, registration, and management introduces new layers of complexity. Practices will need to invest in additional resources to manage subgroup configurations, ensure accurate attribution, and maintain compliance with evolving MVPs requirements. This is particularly burdensome for large multispecialty groups with diverse clinical services that would be required to report through multiple MVPs.

2. **Disruption to Established Reporting Workflows**
   Many multispecialty practices have invested heavily in QCDR-based workflows that are optimized for group-level reporting. The proposed change would necessitate significant reengineering of these workflows, potentially disrupting data integrity and continuity in performance measurement.

3. **Limited Practice and QCDR Support for Multiple MVPs**
   Not all QCDRs are equipped to support multiple MVPs simultaneously. This limitation means that multispecialty practices may be forced to engage with multiple QCDRs or alternative reporting mechanisms to accommodate the diverse specialties within their group.

This fragmentation increases administrative complexity and costs and may lead to inconsistent data capture and reporting.

4. **Loss of Aggregated Quality Insights**
   One of the key advantages of group-level reporting is the ability to aggregate data across specialties for comprehensive quality improvement initiatives. Requiring subgroup or individual reporting undermines this capability, making it difficult for organizations to identify system-wide trends, benchmark performance, and implement coordinated quality improvement strategies.

The ACR urges CMS to reconsider this proposal. Additionally, maintaining the option for group-level MVP reporting, particularly for practices that can demonstrate meaningful quality improvement through aggregated data, would preserve flexibility and reduce unnecessary burden.

Core Elements RFI

While the ACR supports CMS's goal of simplifying measure selection and enhancing the relevance of quality reporting, we have several concerns and recommendations regarding the current proposal.

1. **Patient Understanding and Transparency**
   If one of the primary goals of Core Elements is to provide patients with meaningful information to compare clinician performance, the current approach may fall short. Patients generally do not understand the technical nuances of quality measures. To truly empower patients, CMS must simplify and translate these measures into language and concepts that are accessible and relevant to the public. Without this, CMS's goal for transparency will not be achieved.

2. **Core Elements Do Not Reduce Complexity as Proposed**
   As written, the Core Elements policy and mandating of a core element could risk inadvertently penalizing clinicians whose patient populations or practice settings do not align with the selected metric. Such misalignment may result in inaccurate performance evaluations and negative payment adjustments, especially for smaller or subspecialized practices. Additionally, if a Core Element is a QCDR measure that requires licensing it could place significant burden on Qualified Registries (QRs) and QCDRs. If only QPP measures are included as Core Elements, it may negatively impact the specialty nature of the MVP.

3. **Need for Stakeholder Collaboration**
   We strongly recommend that CMS convene working groups with stakeholders from all areas of the QPP program—including clinicians, registry staff, specialty societies and informatics experts—to collaboratively define the "core concepts" that should underpin MVPs. From there, CMS can develop Core Elements that are both clinically meaningful and understandable to patients. This collaborative approach will ensure that Core Elements reflect real-world practice and support both quality improvement and transparency.

4. **Timeline Concerns**
   Implementing a Core Elements policy by the 2027 MIPS payment year is premature if CMS intends to make a meaningful and lasting impact. Developing truly representative, actionable, and patient-friendly Core Elements will require thoughtful design, stakeholder engagement, and system-wide readiness. We urge CMS to take the necessary time to do this right, rather than rushing implementation on an aggressive timeline that could compromise effectiveness and increase burden.

5. **Requirement to Tying MVPs to Procedural Billing**
   While we recognize potential positives to this proposal, we have two concerns with the concept of requiring clinicians to report a specific MVP based on the procedural codes that they bill.
   - This requirement may limit a clinician's ability to select the most appropriate MVP for the scope of their practice.
   - While using Medicare Part B claims data is a useful starting point, it may not fully capture the complexity of a clinician's practice.
   - As an alternative, the ACR recommends that CMS use clinical support tools within the QPP portal that guide MVP selection based on billing codes and show how similar clinicians/peers report data.

Well-being and Nutrition Measures RFI

The ACR commends CMS for recognizing the importance of a comprehensive approach to disease prevention and health promotion. We offer the following comments and recommendations.

First, we strongly support the inclusion of validated patient-reported outcome measures (PROMs). Patient-Reported Outcome (PRO) assessments are rigorously developed and widely used to assess physical, mental, and social health across a variety of conditions and populations offer a standardized way to capture the patient's voice and provide actionable insights into overall well-being. However, CMS should be aware that PROs are typically not captured as structured data elements in the EHR and are difficult to collect. If CMS moves forward with this policy, it needs to address implementation concerns such as:

- Identifying which PROs are relevant for each specific quality measure.
- Access to licensed PRO instruments.
- Ensuring PRO access to clinicians, hospitals, patients, and that surveys are available in multiple languages.
- Patient education.
- Provider education.
- Ensuring results are in a structured data field or results are interoperable.

Secondly, if CMS intends to use well-being measures to inform patient choice and transparency, it is critical that these measures be presented in a way that is understandable to the public. Concepts like "emotional well-being" or "life satisfaction" must be translated into plain language and supported by clear, relatable examples. Without simplification, patients may struggle to interpret the data meaningfully, undermining the goal of informed decision-making.

The ACR recommends that CMS convene expert panels knowledgeable about PROMs to collaboratively define the core concepts of well-being and nutrition measures and implement a robust framework that will ensure long-term success and adoption.

Third Party Intermediaries Support of MVPs

We thank CMS for the proposed modification that QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data no later than one year after finalization of the MVP in accordance with the current requirement. The ACR agrees with this modification.

Toward Digital Quality Measurement in CMS Quality Programs – Request for Information

While the ACR supports the long-term vision of interoperability and real-time data exchange to improve care quality and outcomes, we would like to highlight several concerns regarding the practical implications of this transition—particularly for clinicians with limited EHR capabilities.

1. **Small and Rural Practices Face Infrastructure Gaps**
   Many small and rural practices operate with limited EHR systems that lack the advanced functionality required to support structured data capture or Fast Healthcare Interoperability Resources (FHIR)-based interoperability. These practices may not have the financial or technical resources to upgrade their systems in the near term, making it difficult for them to comply with new digital reporting requirements without significant support.

2. **Widespread Use of Unstructured Documentation**
   Even in larger or more technologically advanced settings, many clinicians continue to document key clinical information in unstructured notes fields. These data are often not captured in discrete, reportable formats, which poses a major challenge for automated digital quality measurement. Without robust natural language processing or manual abstraction, critical information may be excluded from quality reporting, leading to incomplete or inaccurate performance assessments.

3. **Data Blocking**
   Despite ongoing efforts to improve interoperability, EHRs continue to pose significant challenges for providers participating in the QPP particularly due to data blocking practices. Although the 21st Century Cures Act and subsequent regulations have aimed to curb information blocking, many EHR vendors and health systems still engage in behaviors that restrict the access, exchange, or use of electronic health information. These practices can include excessive fees for data sharing, technical limitations, or refusal to integrate with other systems. This not only jeopardizes performance scores but also undermines the broader goals of care coordination and patient-centered care. The lack of seamless data exchange continues to frustrate providers, hinder quality reporting, and ultimately impact reimbursement and patient outcomes.

4. **Need for Technical and Financial Support**
   To ensure equitable adoption of Digital Quality Measures (dQMs), CMS should consider providing technical assistance, financial incentives, and phased implementation timelines for practices with limited infrastructure. This support could include grants for EHR upgrades, training on structured documentation, and access to centralized tools for FHIR conversion.

5. **Impact on QCDRs and Specialty Reporting**
   QCDRs play a vital role in supporting specialty-specific quality measurement. Requiring all QCDR-developed measures to be specified in FHIR may limit innovation and create barriers for registries that serve niche clinical areas. CMS should consider allowing flexibility in existing measure formats during the transition period to avoid significant burden and use of resources. The ACR urges CMS to work closely with QCDRs and other stakeholders to ensure alignment with specialty needs.

Proposal to Adopt a Two Year Informational Only Feedback Period for New MIPS Cost Measures

The ACR fully supports this approach and commends CMS for taking a thoughtful and measured step toward improving cost measure implementation. A two-year feedback period will provide clinicians and groups with the necessary time to evaluate their performance without the pressure of financial implications, identify data or attribution issues and provide meaningful feedback to CMS for refinement or improvement. This approach promotes transparency, encourages engagement, and supports a more accurate and equitable rollout of cost measures. It also aligns with the broader goals of value-based care by ensuring that cost measures are both clinically relevant and methodologically sound before they impact payment.

Promoting Interoperability

The ACR acknowledges CMS's proposal to modify the Security Risk Analysis measure under the Promoting Interoperability performance category to include a second component: an affirmative attestation of having conducted security risk management in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule.

This enhancement reinforces the importance of safeguarding electronic protected health information (ePHI) and aligns with existing HIPAA requirements. By requiring clinicians to affirm that they have conducted a security risk analysis and implemented necessary updates, CMS is promoting accountability and strengthening data protection practices.

While the measure remains a "Yes/No" attestation, it is critical that CMS provide clear guidance and accessible tools—such as the Security Risk Assessment Tool developed by ONC and OCR—to support clinicians in meeting this requirement. **The ACR strongly urges CMS to ensure that the programmatic requirements of the QPP do not become burdensome for clinicians and practices.**

RFI Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure

The ACR appreciates CMS's efforts to enhance the Promoting Interoperability performance category through the PDMP measure that tracks controlled substance prescriptions. However, we continue to ask that CMS consider the burden new requirements will put on clinicians and practices as the QPP program continues to evolve. We believe adopting a performance-based approach could improve accountability and data quality, however the measure must be carefully designed to reflect clinical relevance and workflow feasibility. PDMP queries can be time-consuming, especially when systems are not integrated into the EHR. This can cause workflow disruptions for busy clinicians.

We urge CMS to consider the following regarding this proposed measure:

- Allow flexible implementation timelines.
- Provide technical assistance and funding for Certified EHR Technology (CEHRT) upgrades.
- Offer hardship exemptions for providers lacking PDMP integration or facing state level access restrictions.
- Allow group reporting to reduce burden.
- Exclude providers who do not prescribe controlled substances.

RFI on the Modification of the Query of PDMP Measure to Include All Schedule II Drugs

The ACR supports the proposed expansion of the Query of PDMP measure to include all Schedule II drugs. This broader scope will enhance patient safety and improve monitoring of controlled substance prescribing.

RFI Regarding Data Quality

The ACR appreciates CMS's focus on improving data quality across the healthcare continuum. High-quality data is essential for accurate performance measurement, care coordination, and patient safety. Below are responses to the specific questions posed in the RFI:

1. What data quality challenges does your organization experience? How are you addressing them? What challenges persist longitudinally?

QCDRs encounter several data quality challenges:

- Inconsistent data capture across EMR systems - Variability in how clinical concepts are documented (e.g., disease activity scores, medication adherence) leading to gaps in completeness and reliability.
- Missing or incomplete data fields - Key data elements such as lab results, imaging, or patient-reported outcomes are often absent, inconsistently structured, or captured outside of the EMR.
- Lack of standardization - Differences in coding practices. For example, medication data may be recorded using different formats—some systems use National Drug Codes (NDC), others use RxNorm, and some rely on free-text entries. This inconsistency complicates efforts to aggregate and analyze data across practices.

To address these issues, we urge CMS to do the following:

- **Work closely with EMR vendors to improve structured data capture and improve the capture of specialty-specific and disease-specific data elements in structured data fields.**
- **Provide data validation tools and dashboards to help clinicians identify and correct gaps.**
- **Promote use of standardized terminologies and templates.**
- **Encourage practices to integrate patient-reported outcomes and longitudinal tracking tools.**

2. What are the primary barriers to collecting high-quality data? What resources could help?

Key barriers include:

- EMR limitations - Many systems lack the flexibility to capture specialty-specific data in structured formats.
- Workflow burden - Clinicians face time constraints that limit detailed documentation.
- Lack of interoperability - Data exchange between systems is often fragmented or delayed.
- Limited technical support - Smaller practices may lack IT resources to optimize data capture and reporting.

The ACR recommends that CMS create the following resources:

- **Funding for EMR enhancements and integration.**
- **Technical assistance programs for small and rural practices.**
- **Incentives for adopting standardized data models and Application Programming Interfaces (APIs).**
- **Continued support for QCDRs to serve as intermediaries in data quality improvement.**

3. What solutions have MIPS eligible clinicians found most effective to address data quality?

Clinicians have found success with:

- Using QCDR dashboards to monitor data completeness and performance.
- Implementing structured templates for documentation of disease activity and treatment plans.
- Participating in peer benchmarking to identify and address data gaps.
- Engaging in quality improvement collaboratives that focus on data-driven care.

These strategies improve both clinical outcomes and reporting accuracy.

4. What steps should CMS consider to drive further improvement in data quality and usability?

CMS can support data quality improvement by:

- Promoting interoperability standards such as Fast Healthcare Interoperability Resources (FHIR) and United States Core Data for Interoperability (USCDI).
- Expanding support and funding for QCDRs to develop and validate specialty-specific measures and define specialty-specific data elements to be implemented in EMR systems.

- Encouraging alignment across federal programs to reduce duplication and streamline data requirements.
- Facilitating partnerships between clinicians, vendors, measure developers and agencies to co-develop solutions.

5. What methods should CMS and partners explore to rectify data quality issues?

The ACR recommends:
- Real-time data validation tools embedded in CEHRT.
- Standardized data dictionaries/templates for specialty care.
- Pilot programs to test innovative data capture and exchange models.
- Public-private partnerships to advance data quality research and implementation.

Conclusion

The ACR is dedicated to working with CMS to ensure rheumatologists and rheumatology interprofessional team members are equipped to provide patients with quality care. As costs for providing high quality care continue to increase, we urge CMS to ensure reimbursement policies reflect the complexity and longitudinal value of rheumatologic care and to consider workforce shortages in rheumatology and the impact of reimbursement on patient access.

Rheumatologists are vital to the health and independence of Medicare beneficiaries living with chronic rheumatic diseases. Continued support from CMS will help sustain access to these highly specialized services, prevent avoidable complications, and improve the quality of life for millions of patients. We look forward to serving as a resource to you and working with the agency to explore changes and improvements needed to ensure patients with rheumatic diseases have access to quality care. Please contact Colby Tiner, MA, Manager of Regulatory Affairs, at ctiner@rheumatology.org if the ACR can be of assistance or if you have questions.

Sincerely,

Carol A. Langford, MD, MHS
President, American College of Rheumatology