AMERICAN COLLEGE of CARDIOLOGY

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ACC.org

May 6, 2025

The Honorable Mehmet C. Oz, MD, MBA
Administrator
Centers for Medicare and Medicaid Services
Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Oz:

The American College of Cardiology (ACC) is a global leader dedicated to transforming cardiovascular care and improving heart health for all. For more than 75 years, the ACC has empowered a community of over 60,000 cardiovascular professionals across more than 140 countries with cutting-edge education and advocacy, rigorous professional credentials, and trusted clinical guidance. From its world-class JACC Journals and NCDR registries to its Accreditation Services, global network of Chapters and Sections, and CardioSmart patient initiatives, the College is committed to creating a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at www.ACC.org or connect on social media at @ACCinTouch.

As you begin your tenure as Administrator for the Centers for Medicare and Medicaid Services (CMS), I write to share key policy areas of interest to CMS which ACC believes are important to our members and their patients. As you well know, heart disease is the leading cause of death and chronic disease in the United States. Cardiovascular care, research, and policies that address and prevent both acute and chronic conditions are needed to improve the health of Americans. The College is eager to serve as a resource and collaborator with the agency on these and other areas not raised here.

Payment Reform

ACC members, like all clinicians who care for patients under Part B, are currently operating under payment cuts of 2.8% from 2024 rates. The impact of policies under the sustainable growth rate formula and Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 compounded over time mean Medicare payments to physicians have declined 33% since 2001, in contrast to Medicare payments to hospitals and insurers. Stagnant and declining payment for Medicare services exacerbates financial uncertainty for health systems and

practices and furthers disparities in care delivery, particularly impacting rural, senior and other underserved populations. Congress is considering legislation to address this cut in 2025, but patients' access to care continues to be threatened.

Long-term reform is needed. The physician fee schedule lacks a mechanism for inflationary updates. Restrictive budget neutrality requirements create a zero-sum environment for clinicians. Legislation to address both aspects was introduced in Congress last year. Legislative solutions are required, but **the College urges HHS and CMS to take any possible steps to mitigate the threat posed by stagnant and declining Medicare reimbursement for physician services.**

Separately, as Congress works through budget and appropriations processes for fiscal year 2026, the potential for significant harm to patients exists if beneficiaries lose access to Medicaid and Children's Health Insurance Program (CHIP) services. Both Medicaid and CHIP serve fragile communities and additional funding limitations or reductions will disproportionately hurt this population. Centers that care for the sickest children rely significantly on this funding for their services. Small, rural locations throughout much of the country that fill the critical role of ensuring access to care for complex patients risk becoming larger health care deserts. The ACC supports expanded access to and the prevention of loss of health care coverage through public and private programs, especially access to affordable coverage options for the prevention and treatment of cardiovascular disease. **Careful work by CMS will be needed to ensure efficiency and fraud prevention measures do not create friction or barriers to care for beneficiaries.**

Finally, the College recognizes the importance of CMS's progression of the transition from fee-for-service to value-based care models. To date, significant focus has been placed on models that emphasize initiatives led by primary care that have not produced significant savings. For the progression of this value-based care transition to truly succeed, **it will be vital to support collaboration between primary care and the specialists who care for complex patients. This would enhance patient care as well as emphasize specialty care for chronic conditions like congestive heart failure and atrial fibrillation within these frameworks to be part of value-based program design.**

Practice Expense Concerns

A significant part of physician payment in the Medicare Physician Fee Schedule (MPFS) is reimbursement for practice expenses—supplies, equipment, and staffing that can be directly attributed to services, as well as indirect overhead costs. Rent, utilities, non-clinical staff, etc. are among indirect costs. The AMA recently submitted results from the multi-year effort on a Physician Practice Information Survey (PPIS) to collect data that could inform payment for indirect costs under the MPFS. This information is intended to update indirect payment factors in the payment formula for cardiology and all specialties. **It is imperative that CMS carefully consider data on updated indirect costs and any changes made**

based on it. A key mechanism for doing so will be to share all information about decisions made relying on the data in a transparent, understandable, and reproducible manner in rulemaking so public stakeholders can appropriately respond. Cardiologists were significantly and negatively impacted by the prior PPIS data used in CY 2010 rulemaking, despite demonstrating that the results of the prior survey on which CMS relied to reduce the indirect practice expense factor were flawed. The College believes this new PPIS survey data demonstrate the last survey was flawed and that updates to indirect practice calculations should be thoughtfully considered.

The growing cost of some direct practice expense inputs and the resulting impact on the fee schedule is another significant concern for clinicians. **The ACC has long supported making a change to the fee schedule so that CMS separately identifies and pays for high-cost supplies using appropriate Healthcare Common Procedure Coding System (HCPCS) supply codes. ACC again urges the Agency to adopt that approach.** As services with high-cost supplies are increasingly performed in the physician office setting, the pool of resources available to pay physicians for their work is increasingly being diluted. Clinicians caring for beneficiaries should not be harmed through budget neutrality in the fee schedule to offset the adoption of new technologies, such as AI analysis of imaging studies or performance of procedures with high-cost supplies in the lower-cost office setting. The fee schedule was designed in the 1980s without envisioning a mechanism to reimburse for high-cost equipment or AI analyses that increasingly drain the pool of money for physician services. Further attention to this problem is needed.

Telehealth, Digital Health, and Artificial Intelligence

The provision of services via telehealth and remote technologies and platforms can improve patient experience and support clinicians. Patient access to these services during and after the COVID-19 public health emergency demonstrated this utility. **As Congress continues to wrestle with how to codify these changes, continued support from agencies through regulations will be helpful.**

Digital health encompasses a broad scope of tools that engage patients for clinical purposes; collect, organize, interpret and use clinical data; and manage outcomes and other measures of care quality. The ACC is an advocate for the responsible development of innovative digital health tools that enable patient engagement in their care and improve quality, safety, and outcomes without hampering clinical workflow.

Artificial intelligence (AI) has the potential to transform U.S. health care by analyzing large data sets to drive innovation, reduce clinicians' administrative burdens, and accelerate the development of new therapeutics and personalized medicine. However, despite the promise of AI, it is essential that government agencies and stakeholders appropriately monitor and balance the potential risks AI presents. These include but are not limited to

impeding the clinicians' expertise and nuance essential to treating patients, unfair reviews for prior authorization, deploying unproven technologies that can harm patients with incorrect outputs intended to guide decision-making, and burdening health systems and clinicians with increasingly expensive systems without adequate reimbursement. **It is imperative that CMS and related agencies embrace solutions that ensure clinician autonomy, establish public trust in AI, and incorporate a consistent and unified approach to governance across agencies.**

Site of Service Policies

Policymakers continue to entertain site-neutral payments as a solution to restrain costs and encourage competition in the health care marketplace. The ACC recognizes there are concerns about the payment differentials that exist between different sites of service. However, the College also believes payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities, higher need populations, or other factors relevant to a site of service. **The College urges HHS and agencies within its purview to consider the financial impact of payment changes to the stability of the health care system, particularly those providing care to underserved populations.**

Similarly, the movement of services from higher to lower acuity settings warrants careful consideration. Provision of care in different sites of service that match the acuity of the procedure with that of the patient represents an opportunity for innovation and improved patient care. CMS evaluates the ambulatory surgery center (ASC) covered procedures list (CPL) each year to determine whether procedures should be added to or removed from the list. Changes are often made in response to specific feedback shared by stakeholders. Surgical procedures that meet general standards and are not excluded under general exclusion criteria may be placed on the CPL.

Several cardiovascular interventions performed by cardiologists were added to the CPL in recent years, facilitating patient access and easing the burden on busy hospital departments. Cardiac diagnostic catheterizations were added for 2019, and some elective percutaneous coronary interventions were added for 2020. With the evolution of technology and patient care, the ACC has been working to place cardiac electrophysiology ablation services on the CPL. The process for making that addition includes formal nomination through the CMS portal—which has been completed—consideration of the services and nominating materials, and proposal for inclusion in rulemaking for 2026. **The ACC believes that cardiac catheter ablations can be safely performed in the ASC setting in appropriately selected patients as adjudicated by physician judgment (with case selection determined by physician factors, facility considerations, and patient social-support factors/co-existing clinical conditions), and these services**

should be included in upcoming rulemaking. The ACC is working with the Heart Rhythm Society on a document to provide guidance on these issues.

Real World Evidence

Critical to learning about outcomes and patient safety is a mechanism for collecting data on patients who undergo treatments. Clinical trials can provide information on immediate outcomes and even short-term or intermediate follow-up in a selected patient population using a particular device in a procedure performed by a specific pool of physicians at specific facilities. While these trials provide invaluable efficacy information, they are expensive to conduct and do not necessarily provide the full gamut of information needed.

Existing clinical data repositories can be leveraged to evaluate patient selection, procedure indications, peri-procedural outcomes and longitudinal safety surveillance and patient outcomes for patients' benefit. ACC's National Cardiovascular Data Registry® (NCDR) is one example of such an existing clinical data infrastructure. In 1997 the ACC launched the NCDR to advance its exploration of various strategies for collecting and implementing clinical data to improve cardiovascular care. The outgrowth of that effort focused on quality patient care through standardized measurement of clinical practice and patient outcomes, including through collaboration with the Society of Thoracic Surgeons (STS) National Database on the STS/ACC Transcatheter Valve Therapy Registry. Then, as now, NCDR is committed to including clinicians and care providers in its leadership and to using standardized, clinically relevant data elements and scientifically appropriate methods to collect, analyze and report clinical outcomes.

Today, more than 2,200 hospitals nationwide participate in the NCDR. As the US' preeminent cardiovascular data repository, the NCDR provides evidence-based quality improvement solutions for cardiologists and other medical professionals who are committed to measurement, improvement and excellence in cardiovascular care. As a trusted, patient-centered resource, the NCDR has developed clinical modules, programs and information solutions that support the areas of cardiovascular care where quality can be measured, benchmarked, and improved to make a difference in patients' lives.

NCDR data has been studied for a variety of purposes, including consistency with guidelines, appropriateness, and comparative effectiveness,. CMS has relied upon NCDR data to evaluate promising therapies under the Coverage with Evidence Development program utilized for some National Coverage Determinations. There are certain efficiencies to be gained from using registries, such as NCDR, for post-market research and surveillance. This collaboration between industry and professional societies provides an increased level of credibility to the data and findings. NCDR has the ability to conduct site recruitment, patient randomization and data audits. Additionally, because of the existing registry structure, there are a large number of pre-defined data elements and procedures

already available to those interested in using NCDR for new services in a transcatheter valve therapy registry for therapies emerging in this area. Patients can be helped by relying on physician-led clinical data registries to advance knowledge, and we urge HHS to continue utilizing them.

Disruption to the Healthcare Ecosystem

The ACC has a long and successful history of partnering with and relying on staff at CMS and federal agencies. Like all stakeholders in the medical and scientific field, the College has taken note of the large-scale staff dismissals across agencies. The ACC expresses its hope that any reductions in the agencies that power our nation's health care and scientific excellence are conducted to create efficiencies through thoughtful and targeted reassessment and redirection of resources and not merely intended to reduce the number of government employees. The ACC urges caution to avoid harm to essential programs that ultimately advance patient care.

Thank you for considering the ACC's perspective on these topics. These are just a few examples of key areas of interest to cardiovascular care professionals, and we stand ready to engage on these or other areas to improve patient care. We look forward to making similar outreach as leadership is confirmed at umbrella agencies. Please contact James Vavricek, Director of Regulatory Affairs, at jvavricek@acc.org or 202-375-6421 for any follow-up.

Sincerely,

Christopher Kramer, MD, FACC
President