AMERICAN COLLEGE of CARDIOLOGY

Heart House
2400 N St. NW, Washington, DC 20037
1-202-375-6000 | 1-800-253-4636 | Fax: 1-202-375-6842
ACC.org

March 24, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

The American College of Cardiology (ACC) is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, ACC credentials cardiovascular professionals in over 140 countries who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. Through its world-renowned family of *JACC* Journals, NCDR registries, ACC Accreditation Services, global network of Member Sections, CardioSmart patient resources and more, the College is committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes.

As you begin your tenure as the 26th Secretary of Health and Human Services (HHS), I write to share key policy areas which ACC believes are important to our members and their patients. Heart disease is the leading cause of death and chronic disease in the U.S. Cardiovascular care, research, and policies that address both acute and chronic conditions are needed to improve the health of Americans. A small number of key topics of interest at HHS and related agencies under the HHS umbrella are noted below. The College is prepared 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 have declined 33% since 2001. 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.**

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. 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 treatment of cardiovascular disease. **Careful work by HHS and CMS will be needed to ensure efficiencies and fraud prevention measures do not create friction that creates barriers to care for beneficiaries.**

Telehealth, Digital Health, and Artificial Intelligence

The provision of services via telehealth and remote technologies and platforms can improve the 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 within 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, 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 HHS and key agencies it oversees, such as the Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) 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 valid concerns about the payment differentials that exist between different sites of service. 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.**

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. 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, to name a few. The FDA has utilized NCDR data in collaboration with industry to conduct post-approval studies and to consider clinical indications. NCDR has also been a participant in the FDA's Sentinel Initiative, looking at methods of drawing on registry data as a mechanism of providing safety signals to the FDA. We look forward to continuing to work collaboratively on these initiatives.

CMS has also 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. It increases the collaboration between industry and professional societies, providing 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 HHS, CMS, FDA, and the Centers for Medicare and Medicaid Innovation (CMMI), among others. 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 head count. The ACC urges caution to avoid harm to essential programs that ultimately advance patient care.

The ACC has long supported robust research funding for NIH, recognizing the significant role the agency plays in sustaining investment in medical research and maintaining the infrastructure that supports scientific discovery and lifesaving breakthroughs. A large and abrupt reduction of payments from the National Institutes of Health (NIH) for facility and administrative costs in grantmaking is

also concerning. Reassessment of these payments could well identify opportunities for savings, but precipitous reductions without a phase-in or notice will likely mean that planned and ongoing projects will be abandoned and that researchers will lose their positions. Reconsidering this change regardless of the outcome of pending legal cases—and proceeding in a manner that achieves savings and efficiencies—can avoid immediately throttling necessary research initiatives.

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,

Cathleen Biga, MSN, FACC
President