AMERICAN
COLLEGE of
CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org

November 29, 2019

The Honorable Richard Neal
Chairman
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

Dear Chairman Neal and Ranking Member Brady,

The American College of Cardiology (ACC) is pleased to respond to your Request for Information and thanks you for seeking stakeholder comments and recommendations to enhance your bipartisan efforts to improve care and expand access to rural and underserved communities.

ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

The College commends you for your commitment to improving patient access to care. As the organization leading the fight against the #1 cause of death in the United States – heart disease – the College encourages a comprehensive, top-to-bottom examination of our nation's healthcare system. We believe that innovative technologies such as telehealth are essential parts of the solution to improving outcomes and reducing costs.

Cardiovascular disease touches the lives of millions of Americans and is the #1 cost to Medicare and private payors. As the leading cardiovascular organization and the managers of cardiovascular care, the College is committed to exploring and providing solutions to optimize management of cardiovascular disease.

We are pleased to offer several concepts for discussion, including:

- Expanding Access to Cardiovascular Rehab Services
- Improving Telehealth Availability and Functionality
- Reducing Administrative Barriers to Patient Care
- Transitioning to Improved Care Models
- Expanding Access and Hospital Competition
- Enhancing the Graduate Medical Education System

Expanding Access to Cardiovascular Rehabilitation Services to Address Chronic Heart Disease

Cardiac rehabilitation (CR) is a medically supervised program that includes exercise training, education on heart healthy living, and counseling. For patients with cardiovascular disease, these programs are proven to reduce the risk of a future cardiac event, reduce all-cause mortality by 25 percent, decrease hospitalizations and the use of medical resources, and improve health-related quality of life.

Coronary heart disease patients who enroll in CR have a 26 percent lower risk of CVD-related death and an 18 percent lower risk of readmission at 1-year follow-up compared to those who don't enroll[1].

Last year, Congress recognized the importance of CR programs by passing the *Improving Access to Cardiac and Pulmonary Rehabilitation Act* as part of the *Bipartisan Budget Act of 2018* (P.L. 115-123). This legislation authorized physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs), collectively referred to as advanced practice providers (APPs), to conduct and supervise CR beginning in 2024.

However, participation in CR remains low. Only a third of patients referred to CR attend at least one session[2] and rates are 30 percent lower for individuals who live outside of metropolitan areas and 42 percent lower for those who live in economically-deprived urban communities[3]. Research found that women were 12 percent less likely to be

[1] Anderson L, Thompson DR, Oldridge N, Zwisler A, Rees K, Martin N, Taylor RS. Exercise-based cardiac rehabilitation for coronary heart disease. Cochrane Database of Systematic Reviews 2016, Issue 1. Art. No.: CD001800. DOI: 10.1002/14651858.CD001800.pub3

[2] Doll JA, Hellkamp A, Ho PM, et al. Participation in Cardiac Rehabilitation Programs Among Older Patients After Acute Myocardial Infarction. JAMA Intern Med. 2015;175(10):1700–1702. doi:10.1001/jamainternmed.2015.3819

[3] M. Bachmann, Justin & Huang, Shi & K. Gupta, Deepak & Lipworth, Loren & T. Mumma, Michael & Blot, William & Akwo, Elvis & Kripalani, Sunil & A. Whooley, Mary & J. Wang, Thomas & S. Freiberg, Matthew. (2017). Association of Neighborhood Socioeconomic Context With Participation in Cardiac Rehabilitation. Journal of the American Heart Association. 6. e006260. 10.1161/JAHA.117.006260.

referred than men, and Blacks, Hispanics, and Asian patients were 20 percent, 36 percent and 50 percent less likely to be referred than White patients[4].

Under current Medicare law, only physicians are authorized to order CR for Medicare patients. The ACC supports policy changes to authorize APPs to order and refer patients for CR. APPs are well qualified to refer patients to CR, and as noted above, they already have authority to conduct the actual services. The *Increasing Access to Quality Cardiac Rehabilitation Care Act of 2019,* H.R. 3911 and S. 2842, is bipartisan legislation that would address this issue, and is supported by numerous public health advocacy organizations.

Improving Telehealth Availability and Functionality

The prospect of telehealth services holds immense promise in providing care to rural and underserved patients. However, several barriers exist that prevent providers from fully utilizing these services to reach patients sooner and avoid unnecessary in person visits

Telehealth Payment and Value Generation

The formal Medicare telehealth program requires providers to meet several requirements for payment for a specific and limited set of designated telehealth services. In addition to originating site requirements (described in detail below), providers must use an interactive audio and video telecommunications system that permits real-time communication between a provider and the beneficiary. Currently, "store and forward" technology is only allowed in federal telemedicine demonstration programs in Alaska and Hawaii. As technology rapidly advances, **Congress should encourage development of reimbursement structures which account for and encourage innovative and secure communication techniques.** Reimbursement structures should also involve continuous evaluation to ensure there is ample room for innovation and adequate payment for services and technology. This includes allowing technology where a patient can send information, including images, to a provider to determine the medically appropriate course of action.

Originating Site Requirements

By statute, Medicare can only cover designated telehealth services when the patient is in a location that is presumed to have limited access to providers—a county outside a Metropolitan Statistical Area (MSA) or a rural Health Professional Shortage Area (HPSA) that is located in a rural census tract. As Congress considers activity in this space, it may prove useful to revisit these standards. Telehealth services have evolved from a way to obtain relatively minor access for rural patients to a mechanism by which

[4] Li, S., Fonarow, G.C., Mukamal, K., Xu, H., Matsouaka, R.A., Devore, A.D., & Bhatt, D.L. (2018). Sex and racial disparities in cardiac rehabilitation referral at hospital discharge and gaps in long-term mortality. Journal of the American Heart Association. 7(8). Doi: 10.1161/JAHA.117.008088

any patient can readily interact with their health care provider, and one that can eliminate office visits and hospitalizations, increase access, and improve outcomes.

Consider an example commonly seen by cardiologists—a nursing home patient with chronic heart failure. If these patients could have a telehealth visit from the facility instead of an office visit, a feeble, elderly patient would avoid the disruption and cost of transport—often by ambulance—to a cardiologist's office. Payment for a telehealth visit would be a net savings to the system. Building on that example, this patient may also be able to avoid unnecessary hospitalizations. Commonly a decompensating heart failure patient will be transported to the emergency department. The emergency physician evaluates the patient with heart failure and calls a hospitalist. The hospitalist often admits the patient. The patient is seen by a consulting cardiologist, medications are adjusted, the patent stabilizes and improves, and returns to the nursing facility. That entire chain of events and associated costs may have been prevented were incentives and requirements correctly aligned such that the cardiologist could have cared for the patient remotely in the first place.

Necessary Infrastructure

As Congress continues to explore methods to expand access to telehealth and remote monitoring systems across the country, it is important to continue efforts to expand access to infrastructure necessary for utilization of these services. This includes continued development of broadband access to rural or otherwise underserviced communities. The Federal Communications Commission (FCC) estimates nearly 30 million Americans lack access to high-speed fixed services, with only 65 percent of rural areas having access to broadband services[5]. Without access to broadband, providers and patients will not be able to take advantage of telehealth and remote monitoring services. To expand the use of services in rural or otherwise underserved communities, it is vital for Congress to make the necessary investments to develop the infrastructure necessary to support access to high-speed fixed broadband services.

Reducing Prior Authorization Barriers to Patient Care

Unnecessary prior authorization barriers to care disrupt the patient-physician relationship, divert physician attention to administrative tasks, lead to care delays, and in some cases, adverse medical events.

Over the past 10 years, insurers have substantially increased the use of prior authorization. Within cardiology, prior authorization rules may require a patient's initial diagnostic test, therapeutic procedure and medication all to be authorized by the insurer making a same day appointment nearly impossible. In any given week, most physicians must contend with between 11 and 40 prior authorizations. Ultimately, our members state that the majority of services are approved but require extensive time and effort from physicians or support staff to ensure all paperwork and follow up is

[5] https://www.fcc.gov/about-fcc/fcc-initiatives/bridging-digital-divide-all-americans

conducted. The wait time for prior authorization can be lengthy. For most physicians it takes between 2 to 14 days to obtain prior authorization, but for some, this process can take from 15 to more than 31 days. These delays in care lead to treatment abandonment, contribute to a lack of access, and have a negative impact on clinical outcomes.

Patients in rural and underserved communities need and deserve efficient and effective health care. Prior authorization barriers are only exacerbated in these communities where patients may be subject to long wait times or face significant travel challenges to see specialty physicians with limited office hours and in-person availability. For many patients, returning to a physician office several days in a row to receive medically necessary treatment that is delayed by insurance paperwork is a significant burden that may include taking additional time away from work, arranging childcare, and finding transportation.

The College believes reducing the numerous insurance-related burdens and requirements is vital to promoting efficient care for these communities. **Congress should consider legislation to address and streamline the prior authorization process and reduce barriers to care.** Specifically, the *Improving Seniors' Timely Access to Care Act* (H.R. 3107) will improve the prior authorization process for items and services within Medicare Advantage plans. This legislation was introduced in June of 2019 and has received significant bipartisan support.

Transitioning to Improved Care Models

The College remains committed to leading the transition to improved care models that strengthen value patient outcomes. Such initiatives are all the more important in underserved areas, where improved efficiency is particularly needed in order to deliver appropriate care with the limited resources available. As part of that effort, we recognize that the Stark Law presents a major impediment to the modernization of care delivery.

Gainsharing Arrangements

Like the physician self-referral (Stark) law, the Anti-Kickback Statute (AKS) and the beneficiary inducement provisions of the Civil Monetary Penalties (CMP) Law predate the interest in shifting from a fee-for-service based system to one that rewards clinicians based on the value of the care furnished. As such, many of the existing laws are predicated on old notions of healthcare and either prevent or disincentivize clinicians from developing novel methods of delivering care. Care coordination is prioritized in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); yet, the regulatory schema implementing the AKS, Stark law and beneficiary inducements CMP are all fashioned for a fee-for-service based system. In some cases, these actively prevent the coordination of care across settings and/or specialties.

In order to best serve patients within a risk-bearing structure and drive value for patients and the healthcare system, there must be mechanisms that allow for some degree of financial alignment between hospitals/health systems and clinicians. Under these circumstances, such incentives encourage clinicians toward practices that improve patient outcomes while reducing total medical costs. In 2008, the Centers for Medicare and Medicaid Services (CMS) took steps towards issuing a gainsharing exception to the Stark rule by including a discussion of one in the proposed CY 2009 Medicare Physician Fee Schedule. Unfortunately, that effort stalled for a variety of reasons. That should not prevent the Office of Inspector General (OIG) from undertaking such an effort. Both independent and integrated cardiovascular groups have explored options for assisting hospitals and health systems in addressing workflow inefficiencies and operating expense reductions. However, these efforts have floundered as a result of interpretations of the AKS and gainsharing provisions of the CMP. Even in situations involving cardiologists working as employees of hospitals and/or health systems, the compliance regulations inhibit a direct approach.

To its credit, the OIG has issued several Advisory Opinions permitting gainsharing in certain limited situations. However, given the limitations regarding the broad applicability of Advisory Opinions and the narrow nature of the fact patterns described in existing Advisory Opinions, it is difficult for clinicians or hospitals to have any degree of comfort when entering into gainsharing arrangements without asking for their own Advisory Opinion.

The College recognizes that CMS and OIG have proposed rules to revise the Stark Law and Anti-Kickback Statute regulations and will be submitting comments. While these proposed rules offer welcome improvements to encourage care coordination, the College remains concerned that the overall complexity of the rules surrounding these two laws may discourage clinicians, hospitals, and health systems from taking advantage of the proposed new exceptions. **To that end, the College urges Congress and the Administration to continue working toward a comprehensive legislative overhaul to address the Stark law, anti-kickback statute, and civil monetary penalties that inhibit the ability of clinicians, hospitals, and health systems from working together to control costs and collaborate on patient care.**

Medicare Care Coordination Improvement Act

The College encourages Congress to pass *The Medicare Care Coordination Improvement Act* (H.R. 2282 and S. 966). This bipartisan legislation would modernize the self-referral law that was enacted nearly 30 years ago, which now serves as a barrier to care coordination.

The Stark Law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the parties. These prohibitions stifle innovation by inhibiting practices from incentivizing their physicians to deliver patient care more effectively and efficiently because the practices cannot use resources from designated health services in rewarding or penalizing adherence to clinical guidelines and treatment pathways."

The Medicare Care Coordination Improvement Act provides CMS with the regulatory authority to create exceptions under the Stark Law for alternative payment models and to remove barriers in the current law to the development and operation of such arrangements. This legislation provides the Department of Health and Human Services (HHS) the same authority to waive Stark and associated prohibitions for physicians seeking to develop and operate APMs as was provided to Accountable Care Organizations in the Affordable Care Act.

As we continue the transition to a value-based payment system, care coordination and efficiency are essential. As referenced above, a complete overhaul of the Stark law, anti-kickback statute, and civil monetary penalties is most ideal. We acknowledge, however, that while fee-for-service continues to exist, there must be laws that protect patient choice and abusive self-referral practices. The College encourages Congress to continue to revisit these laws even after CMS and OIG have completed their rulemaking process to ensure that they support rather than hinder ongoing innovation in care delivery.

Supporting the Transition to Value

In addition to addressing the Stark Law and Anti-Kickback Statute, Congress must support the transition to value-based payment in other ways. This can include incentivizing participation in risk-based Advanced APMs. To be a Qualifying APM Participant (QP) under the Quality Payment Program, a clinician must receive at least 50 percent of Medicare Part B payments or see at least 35 percent of Medicare patients through an Advanced APM entity. These thresholds are set in statute under MACRA. For many clinicians, especially specialists and those in areas with smaller patient populations, this threshold is difficult to meet. Congress should consider whether flexibility in these thresholds is needed to support the participation of more clinicians in Advanced APMs.

The ability to access and utilize technology that supports care coordination is crucial to successful participation in a value-based payment model. Technology can be patient-facing, such as systems used to deliver valuable telehealth services described above, or it can be used to support internal workflow and care coordination, such as platforms to help clinicians view their patient populations and determine those who are high-risk or require additional care coordination or follow up. Implementing even one of these systems can require extensive financial, infrastructure and staffing investment. The ACC

urges Congress to explore ways to not only ensure that clinicians in rural and underserved areas have the opportunity to participate in value-based care models, but that they also have access to the resources needed to successfully maintain practice stability and enhance patient care under these models.

Expanding Access and Hospital Competition

The United States depends on competition to maintain a robust health care system. Competition allows hospitals to offer services at lower costs and deliver better outcomes. Health care prices are typically much higher in regions with only one or two hospitals and little meaningful competition. Yet in many states, a certificate of need must be obtained before a hospital can be built. We believe these requirements should be eliminated. Congress should consider policies that promote competition because when hospitals compete, patients win.

The ACC supports the repeal of the moratorium on expansion of and new construction of physician-owned hospitals (POH). The ACC supports clinician ownership in facilities, equipment or services that benefit patients through the delivery of appropriate, high quality, medical care. Facilities owned in whole or in part by clinicians should strive to enhance quality of care, efficiency, and patient access, while ensuring that ownership interests are directed to improving the delivery of care through implementation of quality systems and measures. This dedication to clinical excellence should be demonstrated by adherence to evidence-based guidelines, quality standards and appropriate use criteria, and participation in quality reporting initiatives such as the ACC's National Cardiovascular Data Registry. Additionally, the care provided by clinician owned entities should be made equally accessible to all patients and ownership must be clearly disclosed and transparent to all. The ACC is a longtime supporter of clinician owned entities as a way to deliver appropriate, high quality, medical care.

The restrictions on POHs have effectively eliminated the formation of new hospitals and additional choices for patients to receive quality care. As hospitals continue to merge and consolidate, removing these restrictions will lead to much needed competition and significant Medicare savings.

We urge Congress to advance the *Patient Access to Higher Quality Health Care Act of 2019*. This legislation has been introduced in both chambers of Congress as H.R. 3062 and a yet to be numbered Senate version. This would repeal the moratorium on expansion and new construction of POHs.

Enhancing the Graduate Medical Education System

The Resident Physician Shortage Reduction Act of 2019

The College is committed to addressing the shortage of physicians that threatens patient care, especially in rural and underserved areas. By 2032, demand for physicians will exceed supply by a range of 46,900 to 121,900 full-time equivalent physicians[6]. While this is a serious issue for all Americans, it is especially problematic because of our aging population and physician retirement trends. A person's need for a physician increases with age, and the U.S. population aged 65 and older is predicted to grow 50% by 2030.

Though shortfalls will affect all Americans, the most vulnerable populations, like those in rural and underserved areas, will be the first to feel the impact of the deficit of physicians. **Congress should pass S. 348/H.R. 1763, *The Resident Physician Shortage Reduction Act of 2019***, which would increase the number of resident slots nationally by 3,000 new resident trainee slots per year over five years, for a total of 15,000 new residency slots.

The College is also encouraged to see new and innovative approaches to encourage physicians to practice in rural and underserved areas, including state-based efforts that offer loan repayment for service to certain geographic areas.

Diversity and Inclusion

The College is committed to addressing issues surrounding diversity and inclusion in the medical profession. Simply put, in medicine as well as business, the most successful organizations harness the power of diversity and inclusion to strengthen their effectiveness and ability to have an impact. In cardiology, the case for diversity includes the mission-driven need to ensure health equity for increasingly diverse patients and populations

In 2017, the College established The Task Force on Diversity and Inclusion, which is charged with providing strategic recommendations to the College regarding diversity and inclusion in cardiovascular medicine, recognizing that diversity in medicine is essential to quality patient care. The College's Diversity and Inclusion initiative is central to the ACC's 2019-2023 Strategic Plan, which includes the long-term goal of diversifying the cardiac care workforce. While this issue is not unique to cardiovascular medicine, we remain committed to increasing diversity in our profession.

We encourage Congress to view the College as a willing partner in evaluating policy proposals to diversify the medical workforce, which is essential to addressing social determinants of health and improving patient outcomes.

[6] https://www.aamc.org/system/files/c/2/31-2019_update_-_the_complexities_of_physician_supply_and_demand_-_projections_from_2017-2032.pdf

Conclusion

The College commends you for your efforts to improve care in rural and underserved areas. We are committed to working with you to provide solutions that benefit patients and the healthcare system as a whole.

The ACC thanks you for the opportunity to provide comments on this Request for Information and looks forward to our ongoing dialogue. For additional questions or comments, please contact John Kristan, Associate Director for Legislative Affairs, at JKristan@ACC.org or 202-375-6801.

Sincerely,

Richard J. Kovacs, MD, FACC
President