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*The mission of the American College
of Cardiology and the American
College of Cardiology Foundation
is to transform cardiovascular care
and improve heart health.*

March 22, 2018

The Honorable Bill Cassidy
United States Senate
Washington, DC 20510

The Honorable Todd Young
United States Senate
Washington, DC 20510

The Honorable Tom Carper
United States Senate
Washington, DC 20510

The Honorable Chuck Grassley
United States Senate
Washington, DC 20510

The Honorable Michael Bennet
United States Senate
Washington, DC 20510

The Honorable Claire McCaskill
United States Senate
Washington, DC 20510

Dear Senators Cassidy, Grassley, Young, Bennet, Carper, and McCaskill:

The American College of Cardiology (ACC) is pleased to respond to your letter from February 28, 2018. We thank you for seeking stakeholder comments and recommendations to enhance your bipartisan effort to increase health care price and information transparency to empower patients, improve the quality of health care and lower health care costs.

The ACC is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

The College commends you for your effort to create a more transparent and dynamic health care system that empowers patients and their providers. We look forward to maintaining dialogue with you as this important effort progresses.

To begin, we are grateful for the opportunity to provide feedback to the following four questions posed by your letter:

- How do we ensure that in making information available we do not place unnecessary or additional burdens on health care stakeholders?
- What current regulatory barriers exist within the health care system that should be eliminated in order to make it less burdensome and more cost-efficient for stakeholders to provide high-quality care to patients?

- How can our health care system better utilize big data, including information from the Medicare, Medicaid, and other public health programs, to drive better quality outcomes at lower costs?
- What other common-sense policies should be considered in order to empower patients and lower health care costs?

How do we ensure that in making information available we do not place unnecessary or additional burdens on health care stakeholders?

Administrative Burden and Clinician Burnout

For a majority of clinicians, the practice of medicine is rooted in a passion for improving and saving the lives of patients. Unfortunately, increasing administrative, regulatory and professional burdens are leading to widespread clinician burnout across the United States, affecting the ability of clinicians to provide high-quality, cardiovascular care. The College is making a concerted effort to address causes of burnout including challenges with electronic health records that take away from patient time, lack of interoperability of health information technology, onerous quality reporting requirements and the complex implementation of new payment models. In some cases, these burdens can detract from the core focus of the clinician: to provide the best cardiovascular care in a timely fashion.

One of the biggest barriers to patient access - and a significant cause of clinician burnout - is the payer-directed prior authorization of diagnostic imaging and medication. Tests, procedures, and prescription drugs are subjected to lengthy reviews by payer benefit managers, forcing delays in care, increased overhead costs for clinician practices, and a decrease in the time spent with patients. Nearly all clinician practices have been forced to hire additional staff to process and keep pace with prior authorization requests. Often, reviews are repeated and can last multiple business days. In addition to the significant clinician burden, these lengthy prior authorization reviews often lead to treatment abandonment by patients which further complicates the recovery process.

Recently, the College launched the Prior Authorization Reporting Tool (PARTool) to collect real world denial data from our members and their practices. Since its launch in November 2017, the PARTool has already collected over 450 reports of prior authorization experiences from 36 states and the District of Columbia. While the data are relatively new, early results show that nearly 60% of the prior authorization incidents resulted in a delay in patient care or a need to reschedule a patient's procedure. The College welcomes the opportunity to work with your staff as we continue to gather data to protect patient access to quality, cardiovascular care.

Medicare Site of Service Policy

The ACC is committed to continually improving the Medicare system through the collection and application of data and appropriately aligned, patient-centered payment incentives. Invariably, stakeholder discussion of these issues directs attention to differing Medicare payments for similar services based upon setting. Several years ago, the ACC developed the following principles for Medicare payments to shape any payment policy changes in this area:

ACC Principles for Site Neutral Payment

- Changes to Medicare payment should not harm access to care and quality of care, especially for vulnerable patient populations.
- Medicare payments should reflect the resources required to provide patient care in each setting—physician office, hospital outpatient, hospital inpatient. The “correct” payment may be different in different settings.
- Any payment differences across sites should be related to documented differences in the resources needed to ensure patient access and high-quality care. Some limits on payment differentials for the same service provided in different settings may be reasonable.
- Medicare payments for all sites of care should account for costs related to emergency capacity, compliance with regulatory requirements, geographic differences, quality improvement activities and higher need populations.
- Proposals to make significant changes to Medicare’s payment systems (e.g., site neutral payment proposals) should be carefully aligned with other rapid changes in health care, including the movement to value-based purchasing and alternative payment systems. Major changes should be implemented gradually to minimize any negative impacts on patient access and quality.

The ACC acknowledges the ongoing interest in this topic among policymakers, and we pledge to maintain an open and productive dialogue with Congress and other stakeholders as we all work toward the goal of strengthening and improving care for Medicare patients.

Data Release Must Promote Quality Care

The College continues to provide the Centers for Medicare and Medicaid Services (CMS) with annual input on information transparency initiatives such as Medicare’s Physician Compare and Hospital Compare resources. These websites provide data on quality program participation and quality measure performance of clinicians and hospitals participating in Medicare to encourage quality improvement by those providing care and to aid patients in making informed decisions about their care. As part of these transparency efforts, the College continues to advocate that the release of such data must be accurate and provided in a manner that clearly supports patient decision-making and promotes the delivery of quality care.

The ACC appreciates that prior to each update of the Physician Compare and Hospital Compare websites, clinicians and facilities are provided with the opportunity to preview their data prior to public release. This provides the opportunity for these stakeholders to review and understand their data and work with CMS to address any potential errors to ensure that the public has access to accurate data. Similar processes for reviewing and ensuring data accuracy should be central to further information transparency initiatives.

Any data on the cost of care provided by clinicians and hospitals must be accompanied by data on the quality of care provided. It cannot be assumed that low cost automatically correlates to high-quality care. Congress and the Administration should work with the ACC and other medical societies to continue to improve what quality data are publicly reported to ensure that it truly

reflects clinical performance and patient outcomes and is presented in a manner that supports patient decision-making.

What current regulatory barriers exist within the health care system that should be eliminated in order to make it less burdensome and more cost-efficient for stakeholders to provide high-quality care to patients?

Moratorium on Physician-Owned Hospitals

The ACC is a longtime supporter of clinician-owned entities as a potential source of appropriate, high-quality, medical care. The College strongly supports S. 1133, the *Patient Access to Higher Quality Health Care Act of 2017*, which would repeal the moratorium on expansion and new construction of physician-owned hospitals (POH).

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](#) (NCDR), a clinical data registry suite of eight inpatient registries and two outpatient registries. 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.

Additionally, physician-owned facilities should pursue appropriate accreditation for the services provided and ensure appropriate physician and support personnel credentialing. Hospital facilities must comply with all Medicare regulations. In particular, hospital facilities must have written policies for managing medical emergencies that occur on site and must not rely on 911 as a substitute for providing patients emergency services, such as appraisal and initial treatment of emergencies in compliance with Medicare program requirements.

Physician-owned entities should also adhere to all state and federal regulations and abide by the American Medical Association Code of Medical Ethics, the American College of Cardiology's Code of Ethics, and the American Board of Internal Medicine's Physician Charter on Medical Professionalism.

Physician Self-Referral Prohibition

As we continue the long-awaited transition to a value-based payment system, care coordination and efficiency are essential concepts. Modernization of physician self-referral restrictions ("Stark Law") would facilitate clinician participation in the Quality Payment Program.

To that end, the ACC and several other clinician groups have joined together to convey our strong support for S. 2051, "The Medicare Care Coordination Improvement Act of 2017," sponsored by Senator Portman and Senator Bennet and cosponsored by Senator Cassidy. As the coalition letter of support states, "this bill would substantially improve care coordination for patients, improve health outcomes and restrain costs by allowing physicians to participate and succeed in alternative payment models (APMs).

The bill would modernize the self-referral law that was enacted nearly 30 years ago, which created barriers 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 of 2017' will provide 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. Specifically, the bill would

1. Provide the Department of Health and Human Services (HHS) the same authority to waive the prohibitions in the Stark Law and associated fraud and abuse laws for physicians seeking to develop and operate APMs as was provided to Accountable Care Organizations in the Affordable Care Act;
2. Remove the "volume or value" prohibition in the Stark Law so that physician practices can incentivize physicians to abide by best practices and succeed in the new value-based alternative payment models. This protection would apply to physician practices that are developing or operating an alternative payment model (including, Advanced APMs, APMs approved by the Physician-Focused Payment Model Technical Advisory Committee, Merit-based Incentive Payment System (MIPS) APMs and other APMs specified by the Secretary).
3. Ensure that CMS's use of its current administrative authority promotes care coordination, quality improvement and resource conservation."

How can our health care system better utilize big data, including information from the Medicare, Medicaid, and other public health programs, to drive better quality outcomes at lower costs?

Data Access

Quality measurement is an essential element of improved patient care. However, the development of quality measures is costly. Combining existing datasets such as data from Medicare claims and data from clinical registries can reduce the costs of quality measure development. However, current regulations restrict access to the Medicare claims dataset to select groups that meet the requirements of the qualified entity (QE) program. Under the QE program, groups seeking access to the Medicare claims dataset must combine the dataset with another claims dataset. Unfortunately, there are no additional reliable and valid national claims datasets that can be used for this purpose in the field of cardiovascular care. Thus, medical societies interested in quality measure development and reporting, such as the College, are unable to access Medicare claims data for the purposes of developing quality measures.

Providing the ACC and other medical specialty societies with access to the Medicare dataset would allow such groups to match the dataset with high-quality, validated clinical data collected in clinical data registries, such as the College's NCDR. Matching the clinical data from NCDR with data from CMS would permit the ACC to model/calculate risk-adjusted outcomes measures

such as 30-day complication rates, 30-day readmission rates and potentially others for Medicare patients.

Clinical data registries such as NCDR often have difficulty obtaining access to mortality information on patients who have undergone procedures. Obtaining information on patient death, along with other outcomes, is critical to understanding patient outcomes, assessing the quality of care patients receive, identifying appropriate patient selection criteria, improving clinician education and more.

Under 42 USC § 405(r)(9), the College believes that HHS has the authority to match Medicare claims data with death data contained in the Social Security Death Master File (SSDMF) and to provide the linked dataset to clinical data registries for use in improving care quality. The ACC urges Congress to work with the Secretary to exercise this authority and to provide clinical data registries with access to Medicare claims data linked with the death data to allow for enhanced accuracy of patient outcomes information. Such accuracy will augment the ability of clinical data registries to provide clinicians with accurate information on improving the quality of care patients receive.

What other common-sense policies should be considered in order to empower patients and lower health care costs?

Empowering Patients

Policymakers should encourage CMS to partner with the Centers for Disease Control and trustworthy medical specialty societies – such as the ACC – who have already established credible, patient-facing resources and tools. CardioSmart, the ACC's bilingual patient education and empowerment initiative, helps individuals prevent, treat, and manage cardiovascular disease. After establishing a personalized dashboard, patients can take steps to help manage their cardiovascular care. Users can download a medication reminder app, sign up for monthly eNewsletters, and/or search for CardioSmart events within their local community. Additionally, patients can further research their cardiovascular condition or access easy-to-understand descriptions of diagnostic tests and medications. Tools such as CardioSmart ensure that patients have the ability to obtain, process, and understand information related to their cardiovascular well-being and in turn, utilize that information to make appropriate health care decisions in consultation with their clinicians.

Partnering with medical specialty societies such as the ACC and utilizing established, credible resources such as CardioSmart can help CMS save time and money while promoting dependable health education and information.

The ACC recognizes the crucial role an informed and motivated cardiovascular patient can play in implementing his or her own treatment, preventing complications, and slowing or preventing the progression of disease. CardioSmart contains patient education and self-management tools for a number of cardiovascular conditions.

There is a critical role for individual patient preferences in the decision-making process, from diagnostic testing to therapeutic intervention. While this factor is clearly important in all patients,

it becomes increasingly crucial as complexities escalate due to age, multiple chronic conditions (MCC), polypharmacy, social context, and other factors. Therefore, in developing strategies to optimize health and quality of life for individuals with MCC, it is essential to recognize the fundamental role of the patient's perspective. The notion of patient preferences as a driver of decision-making becomes complicated by the fact that many patients' choices reflect only limited awareness of treatment effects. Not only is medical science constantly changing, but questions of cognitive ability may arise for elderly patients. The complexity of MCC, the variability of patient health literacy, and the limitations of educational resources to disseminate accurate, current scientific information may work to confound successful implementation of self-care management strategies. Some elderly patients with chronic conditions do not own or have access to computers and prefer face-to-face interactions. Education and information must be provided to these patients in a format that is easily understandable and translatable, particularly in situations where there is shared decision-making with medications. Empowering patients to measure and transmit their condition by creating ongoing feedback with the clinician is also very important. This could include remote sensors, home laboratory testing, even something as simple as managing anticoagulants with atrial fibrillation.

On behalf of the ACC, its members, and the patients we serve, thank you for your efforts to advance the cause of efficient, high-quality health care. ACC stands ready to partner with you and other stakeholders to achieve that goal.

Sincerely,



C. Michael Valentine, MD, FACC
President, American College of Cardiology