January 15, 2021

The Honorable Ami Bera, MD
U.S. House of Representatives
172 Cannon House Office Building
Washington, D.C. 20515

The Honorable Mike Kelly
U.S. House of Representatives
1707 Longworth House Office Building
Washington, D.C. 20515

The Honorable Ron Kind
U.S. House of Representatives
1502 Longworth House Office Building
Washington, D.C. 20515

The Honorable Markwayne Mullin
U.S. House of Representatives
2421 Rayburn House Office Building
Washington, D.C. 20515

Dear Representatives Bera, Kelly, Kind, and Mullin:

On behalf of the more than 82,000 members of the American College of Surgeons (ACS), we thank you for your important work aimed at improving the quality of healthcare and reducing the growth in health spending. We share your goal of moving our nation’s healthcare system to one that better incentivizes value and we welcome the opportunity to share our thoughts on the recently finalized Stark law and Anti-Kickback Statute (AKS) rules and other reforms that will help incentivize value-based payment arrangements.

Finalized Rulemaking on Stark Law

Whether real or perceived, barriers to care coordination or other team-based care models have caused unintended delays to improving the quality and efficiency of care to patients. The ACS is generally supportive of the recently finalized rules and believes that they will remove barriers to cooperation and better coordinated care. The threat of running afoul of these laws certainly had a chilling effect on innovative practice arrangements and payment models that may otherwise have benefited patients. The vast sums of money spent complying with the statutes can now be redirected to quality improvement efforts or devoted to reducing costs to patients.

The ACS welcomes the additional exceptions to accommodate innovation in alternative payment models (APMs) and other value-based payment arrangements, as well as the acknowledgment that many of these arrangements already meet requirements of existing exemptions. ACS supports the modernization of physician self-referral regulations to reflect the changing nature of payment models in healthcare. The focus on team-based, coordinated, high-value care over siloed, fee-for-service based payments will result in innovative models, both in federal health programs and in the wider commercial market. These new innovative models will have different financial incentives and goals than were in place when Stark law and the AKS were implemented.
Moving toward innovative payment and delivery system models will encourage participants to refocus efforts on providing better outcomes through team-based care, care coordination, and other methods. The finalized changes to Stark Law and AKS will ultimately encourage an environment where this type of activity can prosper, obviating the need of prohibitions and penalties, such as those created by the Stark Law.

While much of what ACS commented on in the proposed rule was adjusted or addressed in the final rule, some areas could still be improved or were left out entirely. Price transparency for example was one area considered in the proposed rule which was not ultimately included in the final regulation. The ACS commented that as an issue of great importance and broad implication, price transparency should be addressed outside the context of these regulations. However, the ACS continues to contend that true price transparency could both help provide patients with meaningful information they need to support their health decisions and serve as an additional safeguard against unwarranted self-referrals. Unfortunately, the information currently available to patients, and the proposals finalized last year, fall short of what would be needed to meet the above goals. Meaningful price transparency would have widespread benefit in helping to reduce or hold down costs, which is a critical component of increasing value.

The ACS advocates for the adoption of another potential way to fill the current gaps in price transparency through the work of the not-for-profit PACES Center for Value in Health Care. The PACES Center hopes to achieve greater price transparency through the creation of standard definitions for episodes of care that could allow for meaningful cost comparisons and information on what patients are likely to pay, in total, for treatment of a given condition or procedure. The work is based on the Episode Grouper for Medicare (EGM), which was originally developed for CMS to organize claims information into logical episodes of care. The PACES Center is capable of providing narrow, but representative, ranges of expected costs based on the specific patient’s characteristics, health history, insurance, and diagnosis. This allows for remarkable insights not only to patients but also to the care team and payers. There is currently no single source of accurate information on patient out-of-pocket cost or total cost of care. Recent efforts have not been patient centered and instead focus on hospitals and insurers.

ACS appreciates the insights provided by the PACES methodology and have utilized it as part of a new program developed with the Harvard Business School’s Institute for Strategy and Competitiveness to improve the value measurement process. This program, known as the ACS THRIVE (Transforming Healthcare Resources to Increase Value and Efficiency), is currently being piloted in several locations and is expected to help hospitals and surgical practices improve surgical patient outcomes while lowering the cost of delivering care.
The Healthcare Innovation Caucus specifically requested information on additional modernizations to the Stark Law and AKS. However, if the underlying goal is to facilitate value-based partnerships, we believe there are other significant barriers within the federal government that have prevented efforts for incentivizing value-based care from moving forward. ACS encourages members of the Healthcare Innovation Caucus to consider other barriers such as the examples below as well as ways to remove them and move us forward on the path to meaningful value.

**Modernize MIPS to Align Physicians and Facilities Around the Patient**

The Merit-based Incentive Payment System (MIPS) included in the Medicare Access and CHIP Reauthorization Act (MACRA) was intended to modernize Medicare physician payments and put them on the path to value-based payment models. Unfortunately, efforts to incentivize value in MIPS have been hampered by the program’s reliance on legacy measurement programs. These programs were developed for different purposes and were not designed for a value-based, coordinated care environment. The current statute continues to separate measures into lists for the various MIPS components of quality, improvement and EHR data exchange. Strict requirements that MIPS measures adhere to the same narrow structure prevent novel approaches to improving quality and value.

In 2019, the Centers for Medicare and Medicaid Services (CMS) announced its intent to offer MIPS Value Pathways (or MVPs) as a reporting method in MIPS. The goal was to make MIPS more meaningful by reducing reporting burden while improving quality and lowering cost to patients. The ACS was supportive of these goals and has worked since late 2019 with CMS to explore the viability of MVPs for geriatric surgical patients. Despite CMS’ openness to discuss new concepts, ACS and other physician specialty societies have encountered barriers when proposing innovative solutions to meet the goals of MVPs and increase value for patients. It has become apparent that these barriers are significantly statutory in nature and would require legislative relief.

The ACS concept would ideally take a novel approach to quality by shifting the focus from measuring adverse events such as readmissions, surgical site infections and mortality after they have occurred, to measuring efforts and progress toward implementing quality programs proven to reduce and prevent adverse outcomes. Patient reported outcome measures, specific to the condition would be used to help assess value from the patient’s perspective, and adverse events would still be tracked as an additional way to assure patient safety.

Credit in the quality category would therefore be dependent upon successfully implementing a quality program. This involves adhering to clinical protocols, having the correct personnel and equipment, and undertaking quality improvement efforts, all of which can be verified through programs such as the Geriatric Surgery Verification
Program (GSV). The GSV was developed with support from the John A. Hartford Foundation and features standards developed by an ACS-led coalition of more than 50 stakeholder organizations. To further focus incentives around the patient, alignment would be broadened to include facilities by coordinating measures in the Hospital Inpatient Quality Reporting Program or the Hospital Value-Based Purchasing Program.

Alignment with facilities is necessary due to their role in supporting a verification program. Facilities are also crucial in the collection of patient-reported outcomes (PROs) and the creation of quality improvement activities and cycles based on collected patient-specific feedback. This type of relationship might previously have been hampered by Stark and AKS concerns, but the benefits of such coordination within a quality framework could now spread beyond Medicare, across all patients regardless of who is paying for their care.

MVPs are intended to be an improvement over the current MIPS framework, but under current statutory requirements they are likely be limited to minor structural changes. To accomplish the type of incentives the ACS has laid out in its quality framework will require fundamental changes to CMS’ authority in carrying out MACRA. Until this occurs, MVPs will suffer from the same shortcomings as the existing MIPS program that have previously been expressed to Congress in multiple hearings and countless meetings. Without reform MVPs will not create the pathway to value envisioned in MACRA. To move forward, it is important that MVPs and MIPS in general be focused not simply on determining individual updates, but on creating incentives for the delivery system to come together around the patient to deliver higher value care.

CMS must be empowered to create incentives that align all providers (including both clinicians and facilities) around the patient and achieve buy-in for a culture of improvement within a quality program. Additionally, explicit authority for measures that evaluate the entire team involved in caring for the patient, including the facility, would also be beneficial. ACS would welcome the opportunity to further discuss our quality as a program concept and other opportunities for innovating in Medicare.

Innovation in Value-based APMs

Another barrier we have encountered in promoting value-based payment is in the area of alternative payment models (APMs) in Medicare. In addition to improving value in fee-for-service Medicare through MIPS, the MACRA law is also intended to gradually move the majority of physicians into APMs. These value-based payment arrangements hold great promise for reducing the price paid for health services for both patients and the government while creating incentives to improve quality and value. To facilitate this move MACRA created incentives for physicians to move into APMs such as
bonus payments for early APM adopters and differential payment updates starting in 2026 with annual increases three times greater for those participating in advanced payment models than for those in MIPS. In December, Congress granted further flexibility by lowering the threshold for APM participation for two additional years.

MACRA also included a process for development and approval of new payment models to ensure that sufficient options were available to allow all interested eligible clinicians to participate. This process involved the submission of stakeholder developed models to an advisory body known as the Physician-focused Payment Model Technical Advisory Committee (PTAC) for review, refinement, comment and recommendation to the Secretary of Health and Human Services (HHS) about whether or not they believe the model should be implemented. Regulations clarified that recommended models would be developed and tested by the Centers for Medicare and Medicaid Innovation (CMMI) under its existing authority.

Unfortunately, despite dozens of submissions from physician societies including many which were recommended for implementation or limited scale testing, none of these models have been made available for physician participation. The ACS was the first to propose an APM to the PTAC and among the first to have our model reviewed and recommended for testing. Since then, numerous others have gone through the same rigorous process which includes submission of a detailed and exhaustive application, public comment, interaction with a preliminary review committee which in our case involved dozens of responses to questions for clarification and refinement, and an appearance at a public meeting of the full PTAC during which the model is voted on. In ACS’ circumstance, the committee then submitted its recommendation to the Secretary of HHS who directed CMS to work with us in evaluating the model for testing. However, after very limited interaction, CMS decided that they would not move forward with the model and since then numerous other submitters have experienced a similar process.

This is unfortunate since several of these models have held great promise for increasing value for Medicare patients. It has also had a chilling effect on the willingness of the clinical community to put in the effort to develop and propose new models. This is obviously counter to Congressional intent in creating a pathway for physician developed models. While CMS and CMMI have done an enormous amount of work in developing models, many of these models fail to adequately incorporate and value the work of surgeons and other specialty physicians. More could be done to partner with stakeholders and experts in clinical medicine who undertake the effort to develop physician-focused models that better recognize the value of care they provide and incentivize improvement.

Congress should consider ways to help guide the work of CMMI to ensure that the Medicare patients can benefit from the work and expertise of the physician community. Legislation clarifying that it is the intent of Congress that models...
recommended by the PTAC be tested through demonstrations or pilots at CMMI and setting aside resources expressly for this purpose could have a huge downstream impact.

Congressional Action for Moving to Value-Based Care

The recently finalized Stark Law and AKS rules take important steps to help incentivize innovation in alternative payment models (APMs) and other value-based payment arrangements. We applaud the Healthcare Innovation Caucus for their leadership in prioritizing value-based care delivery and we encourage you to consider solutions to other existing barriers to developing innovative payment models. Empowering CMS and stakeholders to develop innovative quality programs that will increase value in MVPs as well as facilitating testing of physician-focused APMs would help to create value incentives in Medicare. ACS would welcome the opportunity to further discuss our concepts and legislative options for innovating in Medicare. For more information on those concepts, or if you have any questions please contact Amelia Suermann at asuermann@facs.org in our Washington DC office.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director