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July 27, 2018

The Honorable Mike Kelly
1707 Longworth House Office Building
Washington, DC 20515

The Honorable Ron Kind
1502 Longworth House Office Building
Washington, DC 20515

The Honorable Marwayne Mullin
1113 Longworth House Office Building
Washington, DC 20515

The Honorable Ami Bera, MD
1431 Longworth House Office Building
Washington, DC 20515

Dear Representatives Kelly, Kind, Mullin, and Bera:

The American College of Radiology (ACR), a national medical specialty society representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists, appreciates the opportunity to respond to the request for information (RFI) from the recently formed Health Care Innovation Caucus in the House of Representatives. We applaud this bipartisan group of Representatives joining together to develop new ways to enhance health care quality and lower costs for consumers. The ACR anticipates that the caucus will explore policies that modernize payment models and accelerate access to new technologies so patient health care outcomes may improve.

The specialty of Radiology has traditionally taken a leading position in adapting technologies and innovative reimbursement methodologies. The ACR hopes that its agenda will complement the goals of the Health Care Innovation Caucus. As a result, the ACR is pleased to provide more detailed responses to the various questions posed in the RFI below:

Value-Based Provider Payment Reform

***What barriers in each of the following areas limit the full potential of innovation in Medicare and Medicaid?
Focal Areas: Payment and Reimbursement; Policy and Regulation; Data and Reporting***

The Department of Health and Human Services (HHS), especially the Centers for Medicare and Medicaid Services (CMS), is committed to reducing bureaucratic red tape, lessening the regulatory burden on providers, and helping the United States achieve better health care outcomes. To help the Department achieve this goal, Eric Hargan, Deputy Secretary at HHS, initiated a “Regulatory Sprint to Coordinated Care.” In general, the ACR applauds the effort to reexamine the burden of existing regulations. We believe that the Health Care Innovation Caucus will look for ways to complement this endeavor, as well.

One key component of the “Regulatory Sprint to Coordinated Care” is the reexamination of laws prohibiting physician self-referral. HHS released a separate RFI pertaining to this topic on June 20th with comments due on August 24th. In response to HHS’s RFI, the House Ways and Means Health Subcommittee held a hearing on July 17th exploring potential ways to modernize the physician self-referral law. In light of these efforts, the ACR anticipates that the Health Care Innovation Caucus will receive multiple comments pertaining to the physician self-referral law from various health care stakeholders regarding existing policy and regulatory barriers to innovation in Medicare and Medicaid.

Enacted in 1989, the *Ethics in Patient Referrals Act*, colloquially referred to as the “Stark Law,” after its primary champion, former Congressman Fortney “Pete” Stark (D-CA), seeks to separate a physician’s decision making

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process pertaining to patient care from any potential form of personal financial benefit. In order to accomplish this laudable goal, the law bans doctors from referring patients for certain designated health services (DHS), such as diagnostic imaging services (e.g. X-rays, CTs, MRIs, and Nuclear (PET) scans), payable by Medicare to entities in which they or any immediate family member have a financial interest. The law also prohibits the entity from filing claims with Medicare, or billing another individual, entity, or third-party payer for those referred services. Consequently, the *Ethics in Patient Referrals Act* is intended to ban self-referral, or the practice of physicians referring patients to entities where they stand to benefit financially.

These restrictions apply in all circumstances unless Congress or the Centers for Medicare and Medicaid Services (CMS) outlined specific exemptions to the law and these exceptions do not pose a risk of program or patient abuse. In addition, the Stark law is a strict liability statute, meaning that all instances of noncompliance, no matter how large or small and irrespective of underlying intent, are deemed violations. Actions deemed in violation of the Stark law typically result in substantial financial penalties.

The ACR has been a strong proponent of the Stark law since its inception, especially in traditional Medicare fee-for-service systems. The majority of the ACR's legislative advocacy has focused on advocating for a reasonable balance between authorizing legitimate in-office care that benefits patients and pursuing abusive referral arrangements that exploit the loopholes, specifically the in-office ancillary services exception (IOASE). Under this exception, health care providers are permitted to self-refer for DHS prescribed during a patient's office visit so long as specific criteria are met, principally that the service can be provided on the same day as the individual visits their referring physician. For Radiology, the exception was designed to facilitate patient convenience by permitting individuals to receive simple x-rays or other forms of standard imaging during an initial visit to a referring physician. Congress deemed this form of self-referral to promote coordinated care and facilitating faster diagnoses and patient treatments.

Regrettably, academic research¹² and reports produced by the federal government³ both have substantially documented that the IOASE is often misused by physicians to now self-refer critical, complex medical services which rarely can be performed at the time of any initial patient visit to a referring physician. These impartial experts and scholarly reports conclude that self-referral increases inappropriate utilization of services, subjects patients to medical procedures with questionable clinical utility, and results in tremendous unnecessary Medicare spending.

In light of these realities, the ACR has routinely advocated for Congress to enact legislation that removes advanced imaging (CTs, MRIs, and Nuclear scans) from the Stark IOASE as it relates to the traditional Medicare fee-for-service system. As an interim step, the ACR was instrumental in ensuring lawmakers included select provisions in the Patient Protection and Affordable Care Act (PPACA) requiring ordering physicians whenever self-referring individuals for CTs, MRIs, and other forms of advanced imaging services to provide patients with a written copy of other imaging facilities that could provide these important procedures. Despite its support for modifications to this particular exemption, the ACR advocates for its application to physicians using the IOASE to self-refer services which fall under the category of standard imaging, such as x-rays. The ACR remains steadfast in its view that many self-referral arrangements in the traditional Medicare fee-for-service system jeopardize quality care and undermine program integrity.

¹ Ezekiel, Emanuel, MD, et. al. "A Systematic Approach to Containing Health Care Spending. *New England Journal of Medicine*. August 2, 2012. Available at: <https://www.nejm.org/doi/full/10.1056/nejmsb1205901>.

² Rivlin, Alice M. et. al. "A Bipartisan Rx for Patient-Centered Care and System-Wide Cost Containment." Bipartisan Policy Center. April 18, 2013. Available at: <https://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Cost%20Containment%20Report.pdf>

³ US Government Accountability Office. Medicare: higher use of advanced imaging services by providers who self-refer costing Medicare millions. Available at: <http://www.gao.gov/assets/650/648988.pdf>.

Yet, federal policymakers, both in Congress and at CMS continue moving Medicare to a value-based payment system, rather than the current fee-for-service model. Various Alternative Payment Models (APMs), especially those requiring physicians to assume two-sided financial risk, or responsibility for excess costs or savings in relation to certain pre-established benchmarks, are the principal pathways federal policymakers seek to advance value-based care.

The ACR strongly supports the movement towards value-based care, including gainsharing policies. In fact, the ACR acknowledges that APMs or other types of care coordination strategies will potentially mitigate underlying concerns about financially-motivated referrals for advanced diagnostic imaging services in the future. Yet, many existing APMs continue to compensate advanced diagnostic imaging services via unmanaged fee-for-service arrangements. Considering this reality, the ACR believes it is unwise to provide blanket exceptions to the Stark law within value-based care systems. More specifically, the ACR supports retention of the Stark law in APMs that retain reimbursement for diagnostic imaging services via fee-for-service arrangements. Requirements that APMs assume financial risk, in general, or notify the patient about self-referral arrangements are not sufficient reasons alone to relax the Stark law. Instead, the ACR supports modernizing the Stark law, including IOASE prohibitions, only within APMs that actively manage for appropriate utilization of diagnostic imaging services and are not paid on a volume based, fee-for-service model.

As a result, the ACR urges the Health Care Innovation Caucus to exercise caution and strongly consider unintended consequences when weighing any potential changes to the Stark law, in general. While we recognize the need to facilitate innovation and greater adoption of APMs, this desire needs to be appropriately balanced with the need to remove financial self-interest from the health care process.

Improved Access to Innovative Imaging Screening Technology Saves Lives

As the American population ages and an increasingly high number of citizens battle both chronic conditions and cancer simultaneously, the need to enhance access to imaging based screening technology will become even more important. Radiologists perform and interpret numerous life-saving early detection screening services for a variety of deadly cancers, including low-dose CT (LDCT) scans for lung cancer and CT Colonographies (CTC) for colon cancer. As a result, we urge the Health Care Innovation Caucus to preserve adequate reimbursement for LDCTs administered in the hospital outpatient department, as well as explore revamping the current system of reimbursement for Medicare covered early detection screens. We also urge the Caucus to work with your House colleagues to pass H.R. 1298, the CT Colonography Screening for Colorectal Cancer Act, bipartisan legislation to mandate Medicare coverage of CTCs without patient cost sharing. This particular colon cancer screening procedure is underutilized by patients largely due to refusal by CMS and HHS to cover this innovative study.

Lung cancer is the deadliest cancer killer in the United States. With more than 150,000 Americans dying of lung cancer annually, this disease kills more patients than breast, colon, and prostate cancer combined. A primary reason lung cancer is extremely lethal is because the disease symptoms do not manifest themselves until the cancer has advanced to an almost incurable state. As a result, the need for early detection is instrumental in the battle to lower patient mortality from lung cancer.

Thankfully, in August 2011, the National Lung Screen Trial (NLST),⁴ a randomized control trial of approximately 54,000 patients between the ages of 55 and 74 who are heavy smokers and at high risk of developing lung cancer, found a 20 percent reduction in mortality from lung cancer for patients screened with low-dose CT technology in

⁴ The NLST was run by the National Cancer Institute (NCI) and the American College of Radiology Imaging Network (ACRIN).

comparison to individuals who were screened with standard annual x-rays.⁵ This study was so successful that it was ended early because it was unethical to withhold the low-dose CT screening from the control group. In addition to the mortality reduction, the diagnosis of lung cancer at an early stage is critical when it can be treated much less expensively and with less toxicity to the patient than more advanced disease.

The NLST results became the catalyst for a cascade of policy changes affecting private insurance and Medicare coverage of LDCTs. In fact, in 2013, the United States Preventive Services Task Force (USPSTF) assigned a new, higher grade of “B” to annual LDCTs for asymptomatic patients between the ages of 55 and 80 who have a 30-year pack history of smoking (i.e. individuals who smoke at least one pack of cigarettes per day for 30 years). Patients with a similar smoking history who have ceased tobacco use within the last 15 years also qualify for the scan. Per the preventive care provisions of the Patient Protection and Affordable Care Act, private insurance is mandated to cover any screening procedure that receives a grade of “B” or above without any form of patient cost sharing, including co-payments, coinsurance, and deductibles. While USPSTF grades do not automatically lead to Medicare coverage of screening services, CMS did initiate a National Coverage Determination (NCD) process and ultimately determined in February 2015 that the evidence was sufficient to mandate coverage of LDCTs without cost sharing in Medicare, as well. To qualify for LDCT scans, asymptomatic Medicare patients must be between the ages of 55 and 77, have a 30-year pack history (or be a heavy smoker who ceased tobacco use within the last 15 years), and complete a shared-decision making visit with a qualifying physician to discuss the risks and benefits of yearly screening.

Despite the success and clinical value of the LDCTs for lung cancer screening, this technology has not been widely adopted. As a result, patients are not receiving the full benefit of early detection. In 2016, fewer than 2 percent of the more than 7.6 million eligible patients were screened for lung cancer.⁶ Further, the Centers for Disease Control and Prevention found that “nonmetropolitan rural counties had higher incidence of and deaths from several cancers related to tobacco use and cancers that can be prevented by screening,”⁷ indicating that this screening is needed most in rural areas.

Two key explanations behind the slow adoption of LDCTs is an unexplained reluctance among primary care physicians to refer qualifying patients for this procedure, as well as insufficient reimbursement for the lung cancer screening CT in the hospital outpatient setting. Current reimbursement for LDCTs in the hospital outpatient setting is barely above \$60, while a standard chest CT (CPT Code 71250) is reimbursed at approximately \$200. **Therefore, we urge the Health Care Innovation Caucus to work with the ACR to pressure CMS to provide more adequate reimbursement for LDCTs in the hospital outpatient setting, specifically increasing the rate to equal that of the standard chest CT.** In addition, we urge the Caucus to engage the ACR and other medical specialties that offer similar types of early detection screens to revamp the overarching reimbursement structure for these types of procedures administered in hospital outpatient departments. Finally, our organization echoes sentiments expressed in separate comments submitted by the ACR co-founded Access to Medical Imaging Coalition (AMIC). AMIC cautioned against the imposition of any site-neutral payment policies due to their extreme impact on access to early detection cancer services, including LDCT lung cancer screens.

Patients are fortunate that both private insurance and Medicare provide LDCT lung cancer screens without cost sharing. However, CMS has been reluctant to cover other innovative early detection imaging screens for different types of deadly cancers. For example, colon cancer is another leading cause of death in the United States and while

⁵ Study details available here: <https://www.cancer.gov/types/lung/research/nlst>.

⁶ J Clin Oncol 36, 2018 (suppl; abstr 6504).

⁷ Henley SJ, Anderson RN, Thomas CC, Massetti GM, Peaker B, Richardson LC. Invasive Cancer Incidence, 2004–2013, and Deaths, 2006–2015, in Nonmetropolitan and Metropolitan Counties — United States. MMWR Surveill Summ 2017;66(No. SS-14):1–13. DOI: <http://dx.doi.org/10.15585/mmwr.ss6614a1>.

Medicare pays for several colorectal cancer screening procedures, including optical colonoscopy, it does not currently cover CTC. The Department's reluctance to cover this important screening procedure is surprising since in June 2016 the USPSTF assigned a grade of "A" for colon cancer screens, in general, for adults between the age of 50 and 75. Acknowledging that there is no "one size fits all" approach to screening for this particular cancer, the Task Force, surprisingly, did not assign a specific grade to any particular screening tool. Instead, the USPSTF listed a multitude of acceptable screening options, including CTC, which must be provided to patients by private insurers without any form of patient cost sharing.

Ample clinical evidence proves that CTC is equivalent to optical colonoscopy in preventing colon cancer by detecting pre-cancerous polyps (i.e. 5mm or greater) and identifying early stage colon cancer in patients 65 and above⁸. Additional studies also illustrate that CTC is equally, if not more, cost effective than optical colonoscopy. CTC is also an American Cancer Society approved screening test and was already covered by the top five national private payers prior to the USPSTF grade change⁹. Despite these analyses and endorsements, CMS continues to deny requests to initiate a Medicare NCD. **As a result, we urge the Health Care Innovation Caucus to work with House leadership to enact H.R. 1298, the CT Colonography Screening for Colorectal Cancer Act, bipartisan legislation mandating Medicare cover CTC.** Passage of this legislation will ensure that patients who follow the current guidelines and begin screening at age 50 will retain access to CTC without any form of cost sharing even after they become Medicare eligible. More than 80 bipartisan members of Congress are already cosponsors of this important bill, including Rep. Mike Kelly, and we encourage the Caucus to utilize its collective influence to push the House to expeditiously pass this important bill.

Technology and Health IT

What impact does health IT and data interoperability have on successfully running value-based payment models and contracting? What are some ways to improve interoperability and the sharing of data?

The ACR supports legislative and regulatory policies that seek to promote the electronic exchange of medical images and corresponding data.

Radiology has historically been ahead of the physician community in terms of embracing technological innovation and data standardization. Collaboration between radiologists and the medical imaging device industry that began in the 1980s resulted in the development and universal adoption of what became the Digital Imaging Communications in Medicine (DICOM) standard for the management of medical images and related data. Radiologists worked with the general health IT community in the late 1990s and beyond to establish the Integrating the Healthcare Enterprise (IHE) standards organization to facilitate transactions between and across disparate health IT systems. U.S. imaging providers had access to and widely adopted radiology information technology, such as Picture Archiving and Communication Systems (PACS), Vendor Neutral Archives (VNAs)/cloud-based storage, Radiology Information Systems (RIS), and more, long before the federal government incentives from HITECH for the "meaningful use of certified Electronic Health Record (EHR) technology" resulted in the emergence of EHR software.

Yet, despite the technological capabilities of many imaging providers, and extensive efforts by radiologists in the field to support the connectivity and data needs of their patients and referring providers, there has always been a disconnect between federal payment programs and the general need for medical image exchange. Due primarily to non-technological factors and artificial barriers, a large amount of imaging data continues to be shared between

⁸ Johnson, Daniel M. MD, MMM, et. al. "The National CT Colonography Trial: Assessment of Accuracy in Participants 65 Years of Age and Older." *Radiology*. May 2012. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/22361006>

⁹ Pyenson, Bruce, et. al. "Medicare Cost of Colorectal Cancer Screening: CT Colonography vs. Optical Colonoscopy." *Abdominal Imaging*. September 9, 2015. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26350285>

disparate providers on antiquated CD and DVD optical disc storage media instead of via available electronic exchange methods.

CMS and the Office of the National Coordinator for Health IT (ONC) have launched several activities related to interoperability and data exchange. CMS is currently rebranding and revising the former “Advancing Care Information” performance category of the Merit-based Incentive Payment System (MIPS) into “Promoting Interoperability,” and is working with multiple agencies to facilitate a patient-enabled-exchange initiative, called MyHealthEData.” ONC has administered a federal Health IT Certification Program since 2010 and has annually updated an “Interoperability Standards Advisory”—a compilation of voluntary interoperability standards and implementation specifications for specific use cases. ONC is currently working to implement provisions from the 21st Century Cures Act to establish a Trusted Exchange Framework and Common Agreement, and to define “information-blocking” to penalize developers and providers who engage in such activity. While electronic exchange of medical images and related data is sometimes mentioned in federal initiatives, most of those efforts have focused on technologies and basic data elements administered within primary care and other care management settings. More needs to be done to address non-technological barriers to connectivity and to proliferate electronic exchange of medical images and corresponding data. These policies should include:

- Prioritizing electronic exchange of radiology orders, medical images, and radiology reports between providers using disparate health IT systems within the context of the hospital-focused Promoting Interoperability Program (formerly EHR Incentive Program) as well as the Quality Payment Program for eligible clinicians. This should include radiology IT-driven, specialty-appropriate regulatory requirements and incentives for hospitals, radiologists, and other imaging specialists participating in federal payment programs.
- Leveraging the ACR-endorsed “information-blocking” prohibitions mandated by the 21st Century Cures Act to penalize providers (e.g., dominant regional hospitals and health systems) and developers that discourage or prevent referring clinicians from engaging in electronic exchange with unaffiliated imaging providers.
- Ensuring prompt implementation by CMS of the Protecting Access to Medicare Act (PAMA) mandate that referring providers consult Appropriate Use Criteria (AUC) prior to ordering advanced diagnostic imaging services for Medicare patients. The ACR is pleased that the Calendar Year (CY) 2019 Medicare Physician Fee Schedule (MPFS) proposed rule, once again, reaffirmed a January 1, 2020 start date by which ordering physicians must begin consulting AUC prior to referring Medicare beneficiaries for advanced diagnostic imaging services (CT, MRI, Nuclear Scans). The ACR is hopeful that CMS will not make any changes to this important start date via the CY 2019 MPFS final rule which is expected to be released sometime in November 2018.
- Requiring qualified health information networks (QHINs) and health information networks (HINs) that participate in the ONC’s Trusted Exchange Framework and Common Agreement to enable access to medical imaging data.

What technology is needed to integrate physician networks to be able to effectively manage a population’s health?

Integrated physician networks should ideally be equipped with EHR technology incorporating AUC-based clinical decision support (CDS) to inform advanced diagnostic imaging orders. Such technology should also enable secure connectivity with disparate imaging providers, including those unaffiliated with the EHR software developer or the provider/employer/facility that supplied the EHR technology. This connectivity should facilitate electronic ordering of imaging studies from disparate providers and seamless integration of the resulting data back into the EHR. Regulators should ensure that integrated physician networks cannot engage in aggressive or passive anticompetitive or fraudulent behaviors intended to discourage patients from receiving high quality imaging care outside the integrated network.

What new technology exists to lower costs, improve efficiency, or improve the quality of care that isn't already widely-deployed?

Electronic Exchange of Radiology Orders, Images, and Corresponding Data

Electronic access to patients' imaging history and radiology data by appropriate clinicians would reduce unnecessary and duplicative imaging studies, thereby lowering health care costs for patients and payers and reducing patients' exposure to radiation. Access to prior and complementary images and data by radiologists can also improve their services, thereby improving accuracy and generally enhancing early detection, diagnosis, and treatment.

Appropriate Use Criteria-based Clinical Decision Support

Congress mandated (via PAMA) that CMS require referring providers to consult AUC guidelines prior to ordering advanced diagnostic imaging services for Medicare patients. While CMS has yet to fully implement this mandate, AUC consultation has been successfully integrated into the electronic radiology ordering entry process via real-time CDS tools. In fact, AUC-CDS has now been successfully adopted through EHR integration in over 250 health systems and 2,000 acute care facilities in all 50 states. As mentioned above, the ACR is pleased that CMS reaffirmed the January 1, 2020 start date for ordering physicians to begin consulting national medical specialty society developed AUC prior to referring Medicare beneficiaries for advanced diagnostic imaging services. The College is closely monitoring the CY 2019 MPFS rulemaking process for any potential changes. Nevertheless, these tools have also been incorporated as advanced functionality within some of the most prevalent inpatient and ambulatory EHR solutions in the United States.

Consultation of AUC by referring providers using CDS functionality has been shown by early adopters to reduce inappropriate orders for imaging services. Appropriate ordering results in lower costs and reduced radiation exposure without intrusive and costly interference into the practice of medicine by payer-contracted radiology benefit managers. AUC-CDS can also improve care outcomes by informing the referring clinician of potentially more appropriate tests for the patient's given indication(s).

Healthcare Augmented Intelligence (AI)/Machine Learning (ML)

There have been many exciting and innovative applications of AI/ML methods in the medical imaging domain, particularly in the areas of case prioritization/triage, advanced visualization, administrative/measurement functions, and more. It is critical to ensure these promising solutions are safe and effective, provide reasonably explicable outputs, are integrated into the clinical workflow of radiologists and imaging specialists, and are subject to validation and real world performance monitoring by qualified third parties.

To that end, the ACR established its Data Science Institute (DSI) program in 2017 to collaborate with physicians, patients, industry leaders, and federal agencies to develop a framework for implementing machine learning/augmented intelligence in medical imaging, interventional radiology, and radiation oncology. The ACR DSI is working to define use cases and associated data elements to analyze AI algorithm performance across multiple sites and to provide clinical validation/certification prior to, and as a component of, Food and Drug Administration (FDA) review. ACR DSI is also engaging with developers on workflow integration/deployment considerations and to enable registry-based post-market data collection to assist developers with compiling and reporting real world performance data to FDA.

We encourage the caucus to support legislative and regulatory policy approaches to imaging and other healthcare AI/ML applications that promote innovation while ensuring the safety, effectiveness, and clinical utility of the tools. Beyond the obvious quality and safety benefits, third-party clinical validation and performance monitoring of imaging AI/ML algorithms would also establish provider trust and spur market growth and adoption.

House Health Care Innovation Caucus
American College of Radiology

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We appreciate the opportunity to comment on this RFI and we look forward to working with the Health Care Innovation Caucus. Should you have any questions, please do not hesitate to contact Cynthia Moran, Executive Vice President, Economics, Government Relations and Health Policy, American College of Radiology, either via phone (202-223-1670) or email (CMoran@ACR.org).

Sincerely,

A handwritten signature in black ink, appearing to read "William T. Thorwarth, Jr. MD, FACR". The signature is fluid and cursive, with a large initial "W" and "T".

William T. Thorwarth, Jr., MD, FACR
Chief Executive Officer
American College of Radiology