American College of Physicians
Leading Internal Medicine, Improving Lives

December 31, 2019

Joanne Chiedi
Office of Inspector General
Department for Health and Human Services
Cohen Building, Room 5521
330 Independence Ave, SW
Washington, DC 20201

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements [OIG-0936-AA10-P]

Dear Ms. Chiedi,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the Inspector General's (OIG) proposed rule to update the Anti-Kickback Statute (AKS) and Beneficiary Inducements Civil Monetary Penalty (CMP) to better reflect the current environment. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP applauds efforts taken through the Regulatory Sprint to Coordinated Care initiative to identify areas of regulatory reform that promote the Administration's goals of facilitating high-value, high-quality, patient-centered care. We appreciate OIG's receptiveness to the College's recommendations and comments on necessary changes provided in response to the 2018 Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP. We are particularly pleased OIG is taking concrete steps to remedy the misalignment between the effects of existing fraud and abuse laws and the Department's goals to advance care coordination and value-based care. Historically, under the fee-for-service (FFS) system where compensation is tied to volume, a financial incentive existed to be on the receiving end of a referral or recommendation from another health professional. An unregulated, pay-for-

play environment can result in referrals and medical decisions being made that personally enrich the individual while posing inefficiencies and burdens on the overall health care system. In a volume-based system, AKS has been a key tool in the federal government's efforts to deter bad actors from centering profits over patient care. Since AKS is a criminal statute, knowing and willing violations of prohibited referrals can result in a felony and can be punishable by civil monetary penalties (CMP) in the tens of thousands of dollars per incident, unless the business arrangement falls within a safe harbor. As a result, AKS has been crucial in protecting the integrity of the Medicare program by reducing fraud and abuse, preventing corrupt medical decision making, and ensuring taxpayers' resources are utilized effectively in the provision of necessary care.

Since the last time AKS was meaningfully updated, Congress has undertaken efforts to lead a transformation of the American health care system from being volume-centric to one that is value-centric through the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA). Physicians are now incentivized to participate in new Alternative Payment Models (APMs) that aim to be more holistic and patient-centered in financially rewarding physicians for providing high-quality care with better outcomes at lower costs through innovative care coordination and risk sharing models. Inherent to a value-based system are features such as shared risk, global payments, and incentives that intertwine physician and patient goals and in turn reduce the risk of overutilization and inefficient and ineffective care. Unfortunately, outdated federal fraud and abuse rules have failed to keep up with these innovations and now serve as impediments to care integration, care coordination, and patient engagement, which are beneficial both to the health of individual Medicare beneficiaries and the long-term solvency of the Medicare Trust Fund.

Existing fraud and abuse laws and their enforcement are burdensome on practicing internists and have created an environment where physicians feel almost all of their behavior is suspect and inadvertent billing and coding errors made in the context of a complex system are being treated as fraud. The prevention and punishment of fraud in federal health care programs must be balanced with the reduction of unnecessary burdens for physicians who do not engage in illegal activities. In our RFI comments to the Department, we warned against rules and requirements that add unnecessary administrative burden that keep physicians away from their patients and asserted that the added compliance costs run counter to CMS' goal of providing efficient, high-quality care. The current paradigm requires practices expending additional resources employing attorneys, analysts, and compliance specialists to evaluate their financial relationships and compensation arrangements—resources that could be better spent on patients. For small practices, these costs cut deep into slim operating budgets while for large practices, compliance costs can easily add up to hundreds of thousands, if not millions, of dollars, which ultimately increases the cost of care for patients. In line with the College's Patients Before Paperwork initiative, ACP continues to call for rigorous research on the effect of AKS-related administrative tasks on our health care system in terms of quality outcomes, staff time, and cost of care for clinicians and practice staff, as well as patients and their families. **As part of this evaluation on the burden of fraud and abuse law, CMS must make every effort possible to streamline and align the terminology, language, and requirements across both Anti-Kickback Statute and Stark Law rules, where feasible, in order to simplify compliance**

and reduce physician confusion. While the proposed actions are positive steps in reducing unnecessary administrative burden and giving physicians more flexibility in providing patients with high-quality care, we are concerned that some of the new safe harbors are unfeasible for many physicians under the proposed terms. The College is pleased to offer the following comments which detail our recommendations on the provisions of the proposed rule.

New Value-Based Safe Harbors

ACP finds value in AKS' objective to curb fraudulent and abusive financial arrangements and decrease the misutilization of health care services. While protecting the integrity of the Medicare program and countering adverse influence on medical decision-making is of utmost importance, federal fraud and abuse law must also find an appropriate balance in minimizing excessive administrative burden and removing unnecessary obstacles for parties working together through APMs to improve patient outcomes, quality, and value of care. However, the focus on "volume or value" under current law is quickly losing its relevance in an era of value-based care. Rather than preventing fraud and abuse, in many cases these rules are actively preventing APMs from financially rewarding participating physicians for providing high-quality care and holding them accountable for failing to adhere to best practices and patient outcome standards. As a result, Medicare and other federal health programs lose out on the positive innovations in care delivery and services, cost savings, and improved patient experiences that can arise out of APMs. OIG addresses these concerns, as raised by ACP and others, by proposing the creation of several new safe harbors that would protect remuneration for certain value-based arrangements.

The College applauds OIG for taking the first steps to lay the regulatory infrastructure necessary to bring physicians and payers into the world of value. The full financial risk, substantial downside financial risk, care coordination arrangement, and patient engagement safe harbors will create some of the stability needed for physicians to consider entering into value-based arrangements that prioritize care coordination and other high-value activities that promote quality patient care. However, we believe that a singular broad value-based arrangement safe harbor is superior to a piecemeal approach with numerous different safe harbors with varying requirements. Such a safe harbor should be inclusive of all types of value-based arrangements and activities and offer a uniform set of qualification requirements. Choosing a piecemeal approach with multiple new safe harbors, as OIG did in this proposed rule, adds to the burden and confusion of an already complex law.

We are also worried about the impact some of the new definitions will have on physicians' ability to qualify for the safe harbors, particularly parts three and four of OIG's definition of a value-based enterprise. To be considered a value-based enterprise for purposes of meeting a safe harbor, the two or more parties must "have an accountable body or person responsible for financial and operational oversight of the value-based enterprise" and "have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose." We are concerned that small or rural practices may not have the staff, resources, or bandwidth to have in place the accountable body infrastructure and OIG should consider and evaluate the impact this requirement would have on practices' ability to

meet safe harbors. In addition to protecting the integrity of federal health programs, ACP believes that the central goal of these regulatory reforms to accommodate value-based arrangements should be to help shift physicians from fee-for-service to APMs by reducing administrative burden and making it as easy as possible to participate. We urge OIG to improve upon the proposed rule by implementing our comments and recommendations for the specific new exceptions below.

Full Financial Risk Safe Harbor

Under this safe harbor, both in-kind and monetary remuneration would be protected for arrangements in which value-based enterprises (VBEs) have assumed "full financial risk" for providing items and services for a target patient population. To be considered "full financial risk," the VBE would have to be paid prospectively and be financially responsible for all of the costs of care for all patients in a target population. Further, a VBE participant would be prohibited from claiming additional, separate payment in any form for care covered under the value-based arrangement. Arrangements would have to be for a minimum period of at least one year. Both VBEs and a VBE participant would be protected for the duration of the agreement, beginning no earlier than the six months prior to the date by which the VBE must assume full financial risk. Prior to safe harbor protection, the arrangement must be set out in writing and signed. The VBE must adequately implement an operational utilization review program as well as a quality assurance program to monitor for underutilization, patient goals, and measureable outcomes.

ACP Comments: The College appreciates OIG decision to simplify and dispense with documentation requirements to meet the terms of the safe harbor. Minimal documentation is appropriate and preferred because with the assumption of full responsibility for the financial risk of the arrangement, the concern for fraud and abuse is mitigated while burdensome tasks and compliance costs are also reduced for physicians. However, as there are no compensation arrangements to our knowledge out there requiring full risk ACP is concerned that the requirements for parties to take on full risk are too prohibitive to be practically useful for many physicians. Even though many practices are interested in starting or joining a risk bearing value-based arrangement, there are substantial up-front investments required which can be straining on a practice's limited resources, particularly posing a challenge for those small, rural, or underserved practices with smaller patient pools to spread risk. APMs take years to design, test, implement, and refine and tens or hundreds of thousands, if not millions of dollars, to develop. Expecting full-financial risk is not feasible for many practices, and prominently featuring it as central to the Department's strategy to pursue value-based care favors larger corporate practices and institutions. Safe harbors should aim to bring physicians of all types and settings into value-based arrangements, not lock them out. Aside from the unattainable risk requirements, ACP also believes that this proposal does not provide practices with a long enough period of protection in the run-up to implementing a full financial risk value-based arrangement. More than six months are required for physicians to adequately become established and engaged in a value-based arrangement of this type. Additionally, the timeline of implementation protections differs from the implementation periods of other arrangements' fraud and abuse waivers, creating additional confusion and complexity in an otherwise already complex law. For example, the Accountable Care Organization (ACO) Pre-Participation Waiver

provides protection for ACO-related start-up arrangements in preparation for participating in the Medicare Shared Savings Program (MSSP) for the year prior to the application due date. Hence, we urge CMS to extend protections for the implementation period to 12 months for the full financial risk safe harbor. This will better align and make consistent the exception requirements and timeframe established throughout AKS.

Substantial Downside Financial Risk Safe Harbor
As proposed, this safe harbor would protect both in-kind and monetary remuneration for VBEs and participants that "meaningfully share" in "substantial downside financial risk" for providing items and services for a target patient population. For the purpose of this safe harbor, OIG considers a VBE to be at "substantial downside financial risk" if they are subject to (i) shared savings with repayment obligation of at least 40 percent of shared losses; (ii) episodic or bundled payment arrangement with repayment obligation of at least 20 percent of losses; (iii) prospective population-based payment for defined subset of care for target population; or (iv) partial capitation where payment reflects at least 60 percent discount of expected FFS payments. Value-based arrangements are considered to "meaningfully share" in the downside risk if (i) a risk-sharing payment where VBE participant is at risk for 8 percent of amount at risk under agreement; (ii) a partial/full capitated payment; or (iii) for physicians, a payment meeting the downside financial risk exception in CMS' physician self-referral proposed rule. The arrangement must be established in writing and contain a description of the VBE's substantial downside financial risk as well as a description as to how the recipient meaningfully shares in the risk.

ACP Comments: The College is generally supportive of a safe harbor to protect those engaged in some sort of risk sharing arrangement in order to promote participation in value-based arrangements. That said, we believe that the proposed threshold to qualify as meaningfully sharing in substantial downside is too prohibitive to be feasible for many physicians and that the forms of substantial risk identified by OIG are set at arbitrary levels. It's possible that beneficial arrangements may fall outside these defined percentages and not be protected under the safe harbor, while undesirable arrangements could be designed to comply. Additionally, as previously mentioned, APMs can take years to design, test, implement, and refine and tens or hundreds of thousands, if not millions of dollars, to develop. These realties create great challenges for small and rural practices to participate in APMs. Smaller financial reserves limits practices' ability to make up-front investments in enhanced care coordination protocols and new technologies as well as weather financial risk without putting their practice in possible financial jeopardy, and their smaller patient populations makes it difficult to adequately spread risk. Hence, stringent risk thresholds are biased towards larger health systems as they tend to have more reserve capital, more sophisticated infrastructures to support practice transformations, and larger patient populations over which to spread risk. Currently, only one-third of ACOs take on any sort of downside risk, and most of those that do are larger, integrated systems. The proposed risk threshold effectively locks out those in independent and physician-owned practices that may not have the resources, or smaller and rural practices who may not have a patient population size sufficient to diversify risk, from being protected in entering into value-based arrangements.

ACP urges OIG to decrease the required risk threshold to qualify as meaningfully sharing in substantial downside risk to 5 percent in order to align the threshold with the Medical Home Model nominal amount standard. In so doing, OIG would reduce confusion and compliance burden while facilitating and encouraging more widespread participation in APMs by small and rural practices that often care for some of our nation's most vulnerable patient populations and stand to benefit the most from these innovative payment models. Similar to the full financial risk safe harbor, and to align with the ACO Pre-Participation Waiver, we believe protections should extend to include a 12-month implementation period. Further, the College contends that Advanced APMs and other payer Advanced APMs should be explicitly included in this safe harbor and automatically qualify as meaningfully sharing in substantial downside financial risk.

Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor

This proposed safe harbor would protect in-kind remuneration exchanged between VBEs participating in an arrangement directly connected to the coordination and management of care to be used in appropriate value-based activities. Evidence-based outcome measures that reflect advanced care coordination must be established to measure the recipient of the remuneration against. Recipients of the in-kind remuneration would be responsible to pay at least 15 percent of the offeror's costs. The arrangement must be commercially reasonable and must be set forth in writing and signed prior to the arrangement. If this monitoring and reporting process finds that the value-based arrangement is unlikely to further care coordination, resulted in deficiencies in care quality, or unlikely to achieve quality measures, the agreement must be terminated within 60 days.

ACP Comments: The College generally supports OIG's intent behind their care coordination arrangements safe harbor. As we transition to a value-based system where physicians become responsible for a patient's health throughout the health care continuum, additional flexibility is needed in working across different physicians and sites of care to coordinate a patient's care and manage their health. Under existing fraud and abuse law, various compensation arrangements or sharing of tools and resources with the goal of improving care coordination and outcomes may have violated AKS. While the care coordination arrangement safe harbor may be broader than the full and substantial downside financial risk safe harbors, we believe a more general safe harbor protecting value-based activities with value-based purposes would be more useful to physicians and their patients. Expanding the safe harbor to generally protect value-based activities, rather than only those connected to the coordination and management of care, would reduce regulatory burden and make compliance easier to understand as it would be better aligned with the value-based arrangements exception in CMS' proposed rule updating Stark Law. Additionally, allowing the safe harbor to more generally protect value-based arrangements would better serve rural practices whose geographic seclusion may preclude them from care coordination and management activity between VBEs. ACP strongly believes that, in addition to care coordination, the entire spectrum value-based activities deserve to be rewarded and should be protected in this safe harbor.

ACP is also concerned about the burden induced by the requirements that must be met under the safe harbor as well as its limitation to in-kind remuneration. Given the flexibility in

arrangements and activities that qualify for the safe harbor compared to the other proposed safe harbors, we understand OIG's desire for more documentation and qualification measures to counter any sort of risk of fraud and abuse. However, we believe that the proposed requirements are overly burdensome for physicians to comply with and that small and rural practices may not have the resources necessary to meet the requirements, which would lock them out from participating in value-based arrangements. In order to reduce some of the associated compliance burden, OIG should allow parties to meet the documentation requirement with a collection of documents rather than one single document. We also believe that, in order to reduce compliance burden and align this safe harbor with CMS' proposed Stark value-based arrangements exception, OIG should also permit monetary remuneration in addition to in-kind remuneration. Financial incentives for physicians are an effective mechanism in promoting care coordination, improved outcomes, cost efficiencies, and proper utilization and should be protected in the context of APMs and other value-based arrangements. **We are strongly opposed to any level of contribution requirement for remuneration to receive protection under the safe harbor.** Such a contribution requirement would impose compliance burden in establishing the agreement and tracking the cost sharing, as well as be cost prohibitive to the extent a practice may not be able to participate in a value-based arrangement, particularly those in small or rural practices.

We also have some hesitation around the implications of requiring "progress toward…evidence-based outcome measures that reflect advanced care coordination" and urge OIG to be flexible with this. Participants to a new value-based arrangement need time to learn the new system and may not be able to make large gains in progress towards the outcome measures. Sometimes there are environmental or socioeconomic factors beyond the physician's control that can impact outcomes. Additionally, the benefit of primary care, preventive services, and chronic care management that internists provide are not always realized immediately—it can sometimes take numerous years to reap the benefits and positive outcomes. In an internal medicine context, financial costs may be frontloaded for a patient newly receiving care under a value-based arrangement as they receive preventive services, while the prevention of a serious health event as a result of the preventive care is not realized until later. **While we agree that the goal behind utilizing outcome measures are important, we are concerned about the validity of what may be considered an outcome measure and the lack of existing measures.** A 2018 analysis by ACP's Performance Measurement Committee found that only 32 of the 86 performance measures relevant to ambulatory general internal medicine included in Merit-based Incentive Payment System (MIPS)—or 37 percent—were valid. CMS needs to clarify and further define acceptable outcome measures to reduce confusion and as consistent with previous ACP recommendations, CMS should ensure all quality and cost measures are independently assessed and approved by a third party multi-stakeholder organization, including but not limited to ACP's own Performance Measurement Committee, the National Quality Forum (NQF), and the Measure Applications Partnership (MAP).

Arrangements for Patient Engagement and Support to Improve Quality, Health, Outcomes, and Efficiency Safe Harbor

This proposed safe harbor would protect in-kind remuneration for patient engagement tools and supports to improve care quality and outcomes, so long as they are furnished directly by a

VBE participant to a patient in the target population and are directly connected to care coordination and management. Eligible remuneration could include preventive items, goods, and services including health-related technology, patient health monitoring devices, or other supports and services to identify and address social determinants of health, but cannot be gift cards or any other cash equivalent. The aggregate retail value of the patient tool or support would be limited to $500 on an annual basis and cannot be offered if it is likely to be diverted, sold, or used by the patient for other purposes. The tool or support would be required to be furnished directly to the patient by a VBE participant and must be directly connected to the furthering of care coordination and management of the patient. They must specifically advance a combination of goals, including adherence to a treatment regime, follow-up care plan, management of a disease or condition, improvement in a measureable health outcome, and ensuring patient safety. Further, the tool or support must be recommended by the patient's licensed clinician and not result in medically unnecessary or inappropriate care.

ACP Comments: The College is generally supportive of the creation of a safe harbor that protects the provision of patient engagement tools. These tools and supports can increase patient engagement in monitoring and tracking their own health, establishing closer relationships with their primary care physician, and in turn result in early identification of illness and cost-effective treatment in the appropriate setting. ACP appreciates that OIG has already established a safe harbor allowing for the provision of free or discounted transportation for patients to and from the site of care, but believes it does not go far enough to address the numerous factors that impact a patient's health and outcomes. This proposed exception, which goes beyond OIG's existing safe harbors and better encompasses other aspects of social determinants of health, is necessary to promote care coordination and value-based care. We request that, in order to improve clarity and minimize compliance burden and confusion, OIG to offer an extensive list of permissible patient supports.

To achieve optimal patient outcomes and further the goals of a value-based system, we must begin to consider the factors impacting a patient's health existing outside the door of the physician's office. Social determinants of health, such as socioeconomic status, access to food and transportation, geographic location, and education, can have just as much of an impact on health status as obtaining care. With this in mind, we argue that protected assistance should include both financial and material support, including transportation, counselling and coaching, meal preparation, existing and emerging self-monitoring health technologies, and other supports which aid in providing patients with independence and positive health outcomes.

Particularly, **ACP believes that reducing or waiving patient cost sharing for high-value, preventive services should be permitted as a patient engagement tool.** Patients may decide to forego high-value preventive services, such as cancer screenings or immunizations, because the cost sharing requirements may pose barrier to accessing care. Both patients and federal health programs benefit from waiving these cost sharing requirements—reducing barriers to accessing preventive care can improve health outcomes for patients while also ensuring efficient use of taxpayer resources. Alleviating the financial burden of obtaining medical services for patients would reduce the barriers to care and make it more likely one could identify and address a medical condition before it worsens and requires more complex specialty or emergency care.

Reducing medication copays could also improve treatment plan adherence rates. Doing so would increase access to health care for those that need it most and could result in cost savings down the road by reducing more expensive advanced care and hospital readmissions, aligning with Medicare's goal of providing high-value care. OIG should also permit the waiver of cost sharing in cases where the collection costs outweigh the amount of the cost share, which would be common sense measure to reduce administrative burden while improving access to care. While the Department proposes limiting patient supports to $500 per year, ACP also urges OIG to permit patients with good faith financial need to exceed the monetary cap.

The College believes that the patient engagement safe harbor should not be limited to only tools and supports provided by a VBE participant. We have already expressed our concern over the potentially burdensome requirements of meeting the definition of a VBE, specifically that the requirement to have in place an operational oversight body or individual may be infeasible given financial and bandwidth limitations and would prevent small and rural practices from participating in value-based arrangements. Given the potential outcomes and savings benefits for both patients and federal health care programs, we urge OIG to allow the safe harbor to apply to any arrangement involving patient engagement supports and tools, not only those qualifying as VBEs. Additionally, we are concerned about the safe harbor's requirement for physicians to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient. Oftentimes, it can take a substantive period of time to realize the effects of an intervention and the measurement of these effects often utilize outcome measures which may be unreliable. ACP believes that such a requirement would be overly burdensome on already resource-strained small, rural, independent, and underserved practices and would limit them from offering any sort of tool or support.

Health-IT Related Safe Harbors

Cybersecurity Technology and Related Services Safe Harbor

As proposed, this safe harbor would protect the donation of certain cybersecurity technologies and related services. Protected technologies would include software or other information technology, other than hardware, used for the purpose of protecting information by preventing, detecting, and responding to cyberattacks. Donated technology must be used predominantly to implement and maintain effective cybersecurity. Donors cannot take into account, nor condition, volume or value of referrals or other business in determining recipient eligibility or amount of donation, nor can recipients demand a donation as a requirement of doing business. A signed, written agreement including description of technology and services, reasonable value of donation, and any sort of financial responsibility shared by the recipient is required. OIG is considering and seeking comments on whether it should take an alternative approach to allow hardware donations, so long as a risk assessment is conducted to determine if it is reasonably necessary. Should the Department pursue this avenue, they are considering whether to limit the types of hardware allowed and whether to require a 15 percent recipient contribution requirement, with the potential for small and rural practices to be exempt.

Electronic Health Records Safe Harbor

Under the existing EHR safe harbor, donated technology is required to be interoperable and donors are prohibited from data blocking. OIG proposes aligning these requirements and

prohibitions to align with the definitions of interoperability and data blocking as outlined in the recent 21st Century Cures Act and the ONC proposed rule. The safe harbor was also updated to clarify that it protects certain cybersecurity software used to protect EHRs and to eliminate the prohibition of donations of equivalent items and services, which will allow for updates and replacement technologies. The safe harbor, which was originally set to sunset in 2021, is being made permanent.

ACP Comment: The College is supportive of OIG's proposal to expand protection to additional services through the creation of the cybersecurity technology safe harbor. With the implementation of federal health IT legislation resulting in a health system increasingly based around the frequent transfer of patient data, quality reporting, and electronic referrals and consultations, the frequency of cyberattacks, and with it the importance of an adequate cybersecurity infrastructure, has grown exponentially in recent years. Personal health information is some of the most sensitive and private information for an individual and cybersecurity breaches could harm patient safety in exposing confidential patient information and breaking that patient-physician trust. Further, the health care system's reliance on EHRs, without adequate security, creates a scenario where cyberattacks can disable these networks and systems and cause an interruption in the provision of patient care. Even though there is often a mutual interest between both the donor and the recipient in protecting each other's data and network, particularly in scenarios where recipients directly and regularly interact with the donors EHR and electronic communications systems, many physicians are underprepared given the costly nature of cybersecurity and the current AKS restrictions on health IT financing under existing law.

Given the sensitive nature of the information contained within EHRs and the vulnerability of the current state of health IT, **ACP is strongly opposed to OIG instituting a 15 percent cost sharing requirement for any recipients of donated health IT and related services.** Health IT is vital in accomplishing value-based goals, but implementing, maintaining, and securing those technologies is costly, often ranging in the thousands to tens of thousands of dollars annually for a practice. OIG must advance proposals that give physicians the necessary means to acquire health IT that meets their needs and removing an arbitrarily imposed cost barriers is in the best interests of patients, treatment facilities, and physicians. Doing so will make accessible the technologies essential to providing cutting edge care not only for small and rural practices, but also physicians in independent practices, underserved areas, or other populations that have otherwise been priced out from fully implementing innovative health IT.

The College is also supportive of the proposed EHR safe harbor changes and **applauds OIG for eliminating the sunset period and making the EHR permanent.** EHRs are vital in a value-based system, facilitating the coordination of care by enabling the transmission of patient information throughout the continuum of care to allow for appropriate diagnoses and treatments and the tracking of patient outcomes. With an innovative industry and the constant improvement of technology, physicians are pressured to continually update their EHRs to keep up with the latest functionalities and regulatory requirements. ACP appreciates OIG's proposal to eliminate the prohibition of replacement EHR technology as the current prohibition locks physicians into dissatisfactory arrangements with vendors who may not meet their needs, requiring them to

pay full cost for a new system as well as any cost sharing requirement for the original donated system.

We also appreciate OIG's intent of reducing burden and making it easier to understand the acceptable types of donations by aligning the safe harbor's definitions of "interoperability" and "information blocking" with ONC's definitions as laid out in their proposed rule. However, as identified in our comments provided to ONC in response to their proposed rule, we maintain our concern about the federal government's definition of interoperability, which we believe inappropriately focuses solely on high volumes of data transferred or access to every piece of health information ever collected. This notion is built upon the underlying misconception that indiscriminately sending all data is promoting or enhancing interoperability and improving patient care. To truly empower patients to take control and access their personal health information in a manner that better facilitates care coordination, federal interoperability efforts must prioritize the transfer of and access to secure, meaningful data in order to avoid confusing patients, who are lacking context, and overburdening physicians with irrelevant information.

Other Proposals

Local Transportation Safe Harbor

Several updates were made to the local transportation safe harbor to better accommodate those patients living in rural areas with limited access to clinicians. The distance limit for transporting patients from rural communities is proposed to increase to 75 miles, from the existing limit of 50 miles. Additionally, the distance limit for transporting patients being discharged from a medical facility to their residence is entirely eliminated. OIG is also considering expanding transportation protections for additional populations and purposes, and seeks comment on whether transportation for non-medical services that may impact health outcomes should be covered, such as transportation to food banks, social services, etc.

ACP Comment: The College supports the local transportation safe harbor and agrees with OIG that the distance limit for transporting patients in rural communities needs to be increased. **However, we urge OIG to go beyond their proposed increase of 75 miles and increase the limit to at least 100 miles to better meet the needs of rural patients.** Within the framework of a value-based care system, the health of patients must begin to be viewed in totality, rather than disjointed in separate encounters. Patients of all geographic and socioeconomic background must be met where they are at and empowered with the resources and support they need within their communities to adhere to care plans and engage in healthy activities. For example, patients without reliable transportation may not have a prescription filled or avoid attending an appointment and as a result have their underlying condition worsen to a more advanced point that is more timely and costly to treat.

ACP strongly supports OIG expanding the coverage of a safe harbor to protect the provision of transportation for non-medical services. Given all of the factors in one's life that we know to affect their overall health, the delivery and management of care can no longer end at the door of the physician's office. Proactively addressing social determinants of health at their roots can reduce future downstream medical costs and improve outcomes. For example, patients living in a "food desert" may have difficulties obtaining fresh foods that are not high in sugars and fats,

potentially leading to increased health care costs down the road if they develop nutritional issues that require medical attention. Positively reinforcing healthy decisions at the primary care level can preserve health and avoid increased health care costs from being accrued at the specialty and emergency level.

ACO Beneficiary Incentive Program
OIG proposes codifying an exception to protect an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program under the Medicare Shared Savings Program to encourage Medicare beneficiaries to obtain medically necessary primary care services so long as it meets the requirements of the program.

ACP Comment: Similar to the College's support for the new patient incentive safe harbor, ACP is also supportive of granting the same safe harbor to ACOs and providing them the flexibility to use funds to encourage positive patient behavior. We believe that incentivizing patients to access care at the primary care level can have a meaningful impact on improving patient outcomes and reducing downstream medical expenses by keeping patients out of more costly settings such as hospitals.

Beneficiary Inducements CMP Exception: Telehealth Technologies for In-Home Dialysis
OIG proposes to create an exception to the beneficiary inducements CMP rule that would allow for the provision of certain telehealth technologies to in-home dialysis patients. In order to be protected, the technology must not be of excessive value, substantially facilitates telehealth services related to the patient's ESRD, and not be duplicative of adequate technology already owned by the patient. Telehealth technologies include audio and video communications equipment that allow for real-time, two way communication between the patient and clinician, but do not include telephones, fax machines, or electronic mail systems. The technology must be furnished directly by the clinician currently caring for the patient and cannot be part of any advertisement or solicitation. Additionally, the cost of the technology cannot be shifted to the government, other payors, or patients.

ACP Comment: The College is strongly supportive of the creation of an exception to the beneficiary inducements CMP rule to protect physicians and other health care professionals in providing patients with technology devices to assist in the deliverance of ESRD-related care remotely. We are generally supportive of expanding the availability of telehealth technologies and services and believe that utilizing technology for telehealth visits can improve patient outcomes and quality of care by allowing physicians to remotely monitor symptoms and provide help and advice in administering home dialysis care. That said, we believe that telehealth can only reach its true potential of enhancing patient-physician collaboration, increasing access to care, and reducing costs when used as part of a longitudinal care approach centered on an established, ongoing relationship between patient and physician. Since the *Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017* authorized and the *Bipartisan Budget Act of 2018* funded the provision of monthly clinical visits for home dialysis patients via telehealth, physicians were left with confusion and put in an uncertain position as to whether providing the technology to conduct these services would be considered remuneration and be prohibited under AKS. Implementing an exception

that allows physicians to provide telehealth technologies to their patients, like tablets, creates the clarity and certainty needed for physicians to provide high-quality, high-value in-home dialysis care. ACP further contends that the beneficiary inducement CMP exception should also include the hardware, support, maintenance and educational services, as well as the software or applications that may be required to perform the telehealth service.

Conclusion

Thank you for considering our comments. With the continued transition of the American health care system to one focused on value, stakeholders should review and consider streamlining or eliminating duplicative requirements. The College urges the Secretary to identify barriers and unnecessary burdens that the AKS place on the delivery of value-oriented care that the administration will intend to address and begin identifying solutions to minimize or remove these barriers and burdens that could include but is not limited to expanding existing and creating new safe harbors to address the entire continuum of care and revise or terminate provisions inhibiting value-based compensation models for physicians. ACP reiterates the importance of HHS and OIG engaging stakeholders throughout the entirety of the process of reevaluating the fraud and abuse laws in the era of value-based payment and delivery reforms. Please contact Brian Outland by phone at 202-261-4544 or email at boutland@acponline.org if you have any questions or need additional information.

Sincerely,

Ryan D. Mire, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians