American College of Physicians
Leading Internal Medicine, Improving Lives

December 31, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations [CMS-1720-P]

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule to modernize and clarify the Physician Self-Referral ("Stark") regulations. 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 commends the Administration for prioritizing its efforts to reduce the negative impacts of administrative burden and update the Stark Law. We appreciate that CMS took into account many of the comments and recommendations provided by the College in response to the 2018 Request for Information Regarding Physician Self-Referral Law and addressed them in this proposed rule. Specifically, we are pleased that the Agency recognized the ways in which outdated fraud and abuse regulations are at odds with CMS' goal of paying for value and attempted to address these concerns with the creation of new value-based exceptions. Under the traditional fee-for-service (FFS) system, which has been the backbone of federal health care programs and health care delivery for decades, financial incentives may exist to self-refer patients or over-utilize services. Payment in fee-for-service is tied to volume, incentivizes the quantity of medical services provided rather than high-quality, cost-effective care, which is more inefficient for the overall health care system. To mitigate against these motives, Stark Law

was implemented and updated over the years in order to draw a hard line and prohibit a physician from referring Medicare and Medicaid patients to an entity in which the referring physician has a "financial relationship" for certain "designated health services" (DHS). Since Stark Law is a strict liability statute, intent is irrelevant when its provisions are violated, and those in violation can face penalties in the tens of thousands of dollars per incident. Historically, in a volume-based system, Stark Law has played a crucial role in protecting the integrity of the Medicare program and protecting taxpayers' resources by reducing fraud and abuse and ensuring the provision of medically effective and necessary care.

However, the landscape of the federal health care system has been drastically altered since the last time Stark Law was meaningfully updated in 1993. Legislative efforts undertaken by Congress through the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) initiated the transformation of a federal health system that pays for value as opposed to volume. MACRA incentivizes physicians to transition to Alternative Payment Models (APMs) and other compensation arrangements that financially reward physicians for maintaining or improving quality of care and patient outcomes while achieving reductions in cost through initiatives like care coordination and risk sharing. In light of the decoupling of compensation from volume of care or services provided, the risk of overutilization greatly diminishes. When physicians are inherently penalized in value-based payment arrangements for rising costs, there is little incentive to provide inefficient and ineffective care. As a result, those hard lines established by Stark Law impose burdens and barriers that are no longer necessary under a value-based payment system. Rather, these regulations have the potential to actually impede innovations in care integration, care coordination, and patient engagement that could be beneficial both to the health of individual Medicare beneficiaries and the long-term solvency of the Medicare Trust Fund.

The new value-based exceptions, updated terminology, and other proposals as outlined in the proposed rule make meaningful progress in reducing administrative burden and better integrating the current value-based environment with the original intent of Stark Law regulations. However, we have concerns that some of the requirements for these new value-based exceptions are too prohibitive to be utilized by physicians and hence, continue to pose a barrier in the transition to APMs. ACP is pleased to offer the following comments which detail our recommendations on the provisions of the proposed rule.

New Value-Based Exceptions

ACP values and finds the overall goals of Stark Law to decrease overutilization and misutilization to be a worthy objective. It is important to protect the integrity of the Medicare program and counter the adverse influence of financial incentives on medical decision-making while also relieving physicians from excessive administrative burden and removing unnecessary obstacles for parties working together through APMs to improve patient outcomes, quality, and value of care. However, the "volume or value" prohibition has outlived its relevance in the context of a value-based system and actively prevents 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. In turn, the health system fails to capture the

positive care innovations in care delivery and services, cost savings, and improved patient experiences that can arise out of APMs. To address these concerns raised by ACP and others, CMS proposed the creation of several new exceptions that would protect remuneration for certain value-based arrangements.

The College commends CMS for taking action and beginning to lay the regulatory infrastructure to bring physicians and payers into the world of value. The full risk, meaningful downside risk, and value-based arrangement exceptions will create some of the stability needed for more physicians to be in a position to enter 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 exception is superior to a piecemeal approach with numerous different exceptions with varying requirements.** Such an exception 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 exceptions, as CMS 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 exceptions, particularly parts three and four of CMS' definition of a value-based enterprise. To be considered a value-based enterprise for purposes of meeting an exception, 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 recommend CMS consider and evaluate the impact this requirement would have on practices' ability to meet exceptions.** 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 CMS to improve upon the proposed rule by implementing our comments and recommendations for the specific new exceptions below.

Full Financial Risk Exception

As proposed, the full financial risk exception protects remuneration paid under value-based arrangements between value based entity (VBE) participants in a VBE that have taken on "full financial risk" for the cost of all items and services covered under Parts A and B for patients in a target population. The VBE must be financially responsible on a prospective basis, or contractually obligated to be fully responsible within six months of commencement of the agreement, and for the entire duration of the value-based arrangement under which protection is sought. Protected remuneration must relate to value-based activities for the target population and includes gainsharing payments, shared savings distributions, and other similar compensation arrangements. The remuneration cannot serve as an inducement to reduce or limit medical necessary services or items, nor can it be conditioned on referrals of patients not part of the target population or businesses not covered by the value-based agreement. While

there are no documentation requirements, records of the methodology for determining the actual amount of remuneration must be maintained for at least six years and be made available upon request.

ACP Comments: The College appreciates CMS' decision not to impose any documentation requirements to utilize this exception. With the parties involved being responsible for the full financial risk, there is less concern for fraud and abuse. Hence, the minimal documentation requirement is appropriate as it adequately protects the integrity of federal health programs while minimizing burdensome tasks for physicians and reducing compliance costs. While the exception would cover value-based arrangements such as capitation and global budget payments, ACP is concerned that the requirements to take on full risk are too prohibitive to be practically useful for most physicians. Often, practices have the desire to start or join risk bearing value-based arrangements, but doing so requires a significant amount of up-front investments that many practices simply do not have, particularly posing a challenge for small and rural practices with limited resources and smaller patient pools. Expecting full-financial risk is not feasible for many practices. Exceptions should be designed with the goal of bringing physicians into value-based arrangements, not locking them out. Additionally, the College strongly believes that this exception, as proposed, does not provide practices enough time to implement full financial risk value based arrangements. Physicians need more than six months to adequately get set up and engaged in a value-based arrangement of this type. Further, the terms of this exception may create confusion as they differ from the timelines of other similar fraud and abuse rules. 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 exception.** This will better align and make consistent the exception requirements and timeframe established across the various exceptions.

Meaningful Downside Financial Risk Exception

CMS proposes an exception that protects remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for not achieving the value-based purpose of the VBE for the entire duration of the agreement. CMS proposes to set the threshold at 25 percent of the value of remuneration to qualify as meaningful downside risk. Protected remuneration must relate to value-based activities for the target population and includes gainsharing payments, shared savings distributions, and other similar compensation arrangements. The remuneration cannot serve as an inducement to reduce or limit medical necessary services or items, nor can it be conditioned on referrals of patients not part of the target population or businesses not covered by the value-based agreement. The nature and extent of the risk must be established in writing and records of the methodology for determining the actual amount of remuneration must be maintained for at least six years and be made available upon request.

ACP Comments: The College is generally supportive of an exception that will protect those engaged in some sort of risk sharing arrangement as a means to promote participation in value-

based models. However, we believe that the proposed threshold of 25 percent to qualify as meaningful downside risk is too prohibitive to be feasible and useful for most physicians. Small and rural practices face unique and often greater challenges to participation in APMs, which includes but is not limited to lower levels of financial reserves to make up-front investments in enhanced care coordination protocols and new technologies and to weather financial risk without putting their practice in possible financial jeopardy, and smaller patient populations over which to spread risk. Larger health systems tend to have more reserve capital, more sophisticated infrastructures to support practice transformations, and larger patient populations over which to spread risk. As it stands in the current environment, roughly 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 utilizing this exception. **ACP recommends decreasing the required risk threshold to qualify as meaningful downside risk to 5 percent in order to align the threshold with the Medical Home Model nominal amount standard.** In so doing, CMS 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. Further, the College contends that Advanced APMs should be explicitly included in this exception and automatically qualify as meeting the definition of meaningful downside risk.

Value-Based Arrangements Exception

CMS proposes a broader, catch-all value-based arrangement exception that protects remuneration for those participating in compensation arrangements that qualify as a value-based arrangement, regardless of the level of risk involved. Protected remuneration must relate to value-based activities for the target population and includes gainsharing payments, shared savings distributions, and other similar compensation arrangements. The remuneration cannot serve as an inducement to reduce or limit medical necessary services or items, nor can it be conditioned on referrals of patients not part of the target population or businesses not covered by the value-based agreement. In exchange for the additional flexibility in covered arrangements, this proposed exception has additional requirements to qualify. The arrangement must be established in writing and signed by parties in advance, and include the value-based activities undertaken; how the activities further the value-based purpose; the target population; the type of remuneration; methodology of determining remuneration; and the performance or quality standards used, if any. Further, the records of the methodology for determining the actual amount of remuneration must be maintained for at least six years and be made available upon request. If measures are used, they must be objective and measurable and determined prospectively.

ACP Comments: The College appreciates the broad scope CMS created in qualifying for this exception and believes this will be the most useful and utilized of the three new exceptions proposed for physicians. The lowered entry requirements and flexibility in protecting both monetary and in-kind remuneration creates an avenue for physicians and other entities to begin engaging in value-based activities that lay the groundwork and pave the way for

physicians to eventually take on more risk and accountability for outcomes in a value-based arrangement. Given the flexibility in arrangements and activities that qualify for the exception compared to the other proposed exceptions, we understand the need for there to be more documentation and qualification measures required to counter any sort of risk of fraud and abuse. However, we are concerned that the level of proposed documentation required for this exception is excessively burdensome and the administrative requirements will make it difficult and expensive for the average physician to utilize. Consistent with our *Patients Before Paperwork* initiative, we urge CMS to provide financial, time, and quality-of-care impact statements of these documentation requirements for public review and comment and should continually review and consider streamlining or eliminating duplicative administrative requirements.

We are also concerned about the burden a potential 15 percent contribution requirement would have on physicians, particularly those in small or rural practices, and urge CMS to refrain from implementing any sort of cost sharing requirement for physicians. Additionally, we have some hesitation around the implications of the requirement to include "objective and verifiable" criteria, if available, and urge CMS to be flexible on this. Part of the purpose behind the new exception is to spur new models and participation in value-based arrangements. Participants to a new value-based arrangement need time to learn the new system and may not be prepared to meet stringent measures from the get-go. Additionally, the benefit of primary care and preventive services that internists provide are not always realized immediately—it can sometimes take numerous years to reap the benefits of positive outcomes. **While we agree that the goal behind utilizing outcome measures are important, we are concerned about the validity of what may be considered "objective and verifiable 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 the Merit-based Incentive Payment System (MIPS)—or 37 percent—were valid.[1] CMS needs to clarify what is an objective and verifiable measures entail 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).

Health-IT Related Exceptions

Electronic Health Records Items and Services Exception

CMS is proposing to update its EHR software exception to require that any donated software must be deemed interoperable by being certified under the Office of the National Coordinator's for Health Information Technology (ONC) certification program as of the date of the donation. To qualify, donors would be prohibited from engaging in information blocking as defined by the 21st Century Cures Act/ONC proposed rule. If ONC finalizes its proposed rule, CMS would add those regulations as they relate to Stark Law as well as align definitions of interoperability. Per commenters' request, CMS is also clarifying that certain cybersecurity software and services to

[1] MacLean, Catherine H., Eve A. Kerr, and Amir Qaseem. "Time out—charting a path for improving performance measurement." *New England Journal of Medicine* 378, no. 19 (2018): 1757-1761.

protect the EHR are included in the exception. Further, CMS is considering eliminating or reducing the 15 percent contribution requirement either for all recipients or specifically small or rural physician organizations. The Agency also proposes eliminating the prohibition on donations of replacement EHR technology. While the exception was set to sunset on December 31, 2021, CMS is proposing to eliminate the sunset provision and make the exception permanent.

Cybersecurity Technology and Related Services Exception
CMS is also proposing a new exception to protect in kind remuneration of cybersecurity technology and services, except for hardware. Donors could not require referrals or business as a condition of receiving the donation, nor could recipients require receipt of a donation as a condition of doing business. The arrangement, including name of donor, description of technology and services, the timeframe of donations, a reasonable estimate of the value, and any applicable financial responsibility shared by the recipient, must be documented in writing. The Agency is considering numerous alternative proposals that could allow for some form of hardware to be donated, ranging from specific and stand-alone to a broader range of hardware, and potentially requiring a cybersecurity risk assessment to determine reasonable need for the hardware.

ACP Comments: EHR systems are instrumental in facilitating care coordination 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. Despite their central role in the transition to a value-based system, many physician practices—particularly small, independent, and rural practices—are unable to fully unleash the potential benefits of EHRs primarily because they can be cost prohibitive, with upfront implementation fees exceeding tens of thousands of dollars and annual maintenance costs in the thousands. As a result, many physicians rely on the EHR Stark exception for external assistance in furnishing an EHR system. **The College applauds CMS for eliminating the sunset period and making the EHR exception permanent.**

However, existing law places limits on the financing of costly EHR and data analysis infrastructure for physicians, even when such coordination can improve decision making and is in the best interests of the patient, treatment facility, and physician. EHRs are vital in accomplishing value-based goals and it is important CMS advance proposals that give physicians the necessary means to acquire health information technology (IT) that meets their needs. Hence, ACP supports eliminating the 15 percent contribution requirement for all parties. This will make the technologies necessary for providing 21st century care more accessible to not only 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. In light of an environment where technology is constantly improving and practices are continually required to update their EHRs to keep up with the latest functionalities, ACP appreciates the Agency's proposal to eliminate prohibitions of replacement EHR technology. The current prohibition on the donation of equivalent technologies locks physicians into vendors that they may be dissatisfied with or may not meet their needs, requiring them to pay

full cost for a new system as well as the 15 percent contribution for the original donated system.

We also appreciate CMS' intention in reducing administrative and compliance burden and making it easier to understand acceptable types of donations by aligning the exception's definitions of "interoperability" and "information blocking" with ONC's definitions as laid out in their proposed rule. However, as we pointed out in our comments to ONC, we are concerned about the federal government's definition of interoperability which focuses solely on high volumes of data transferred or access to every piece of health information ever collected and is based on 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.

Additionally, ACP is supportive of CMS' proposal to expand protection to additional services through the creation of the cybersecurity technology exception. The importance of an adequate cybersecurity infrastructure has grown exponentially in recent years, with increasing frequencies of cyberattacks and a health system increasingly based around the frequent transfer of patient data, quality reporting, and electronic referrals and consultations. 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 donor's EHR and electronic communications systems, creating vulnerabilities for cyberattacks if one party is inadequately protected. Furthermore, personal health information is some of the most sensitive and private information for an individual. Without the necessary privacy and security controls, it is critical to acknowledge the very real risk present that may ultimately impact the patient's inclination to share information with their physician.

Updated Terminology

Commercially Reasonable
CMS proposes to update "commercially reasonable" and is considering two possible definitions, defining it as either "an arrangement that furthers a legitimate business purpose and is on similar terms and conditions as like arrangements" or "an arrangement that makes commercial sense and entered into by a reasonable entity and physician of similar size/type/scope/specialty."

ACP Comment: The College thanks CMS for acknowledging the concerns outlined in our RFI comments that the current definition of "commercially reasonable" is too subjective and vague, making it challenging for physicians to interpret and comply. Under current law, meeting "commercial reasonableness" is a criterion to meet many of the existing exceptions. As currently defined, one could reasonably interpret "commercially reasonable" as discouraging integration of different types of providers to promote care coordination and other services that benefit the community, such as charity care. While the employment of a physician or operation

of a specific department or practice may command a net loss, it still may result in achieving value-based goals. ACP believes CMS' clarification that the determination of commercial reasonableness is not one of valuation, nor determined by whether the arrangement is profitable for one or more parties, is appropriate and will facilitate Agency goals of transitioning physicians to a value-based system.

Volume or Value Standard
CMS proposes updating the volume or value standard to clarify that compensation takes into account volume or value only when the compensation methodology includes referrals/other business generated as a variable and the compensation correlates with the value of that variable.

ACP Comment: The College is supportive of CMS decision to update the definition of the volume and value standard to more clearly identify the methodology to determine whether this standard is met. Making standards and requirements bright-line, objective tests is fundamental as part of any regulatory scheme to reduce administrative and compliance burden for physicians and ensure that the average party is able to easily comprehend what is required of them. ACP believes that the updated volume or value standard, as proposed, appropriately represents what policymakers intended in establishing this requirement and adequately establishes an objective determination of when remuneration takes into account volume or value.

Fair Market Value
The definition of "fair market value" was revised to eliminate the connection to the volume or value standard. That is, fair market value means the value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction. For office space, the value cannot take into account the additional value a prospective tenant would add to the proximity or convenience for making or receiving referrals.

ACP Comment: The College applauds CMS for adopting our recommendation to remove the "volume and value" aspect from the definition of "fair market value." Similar to our concerns with commercial reasonableness, many of the exceptions rely on fair market value to determine eligibility and, as currently written, creates confusion and compliance burden as physicians have to rely on costly consultants to make evaluations. ACP agrees with CMS' reading of the statute that the volume and value standard is a standalone requirement and independent of the definition of "fair market value." We believe this change offers more certainty and clarity and will better accommodate APMs and other innovative care delivery models that enable and reward physicians for providing efficient and effective quality care.

Group Practices and Profit Distribution
CMS updated the rule to address the distribution of profit earned as a result of engaging in value-based activities for physicians in a group practice. In order to facilitate value-based arrangements for group practices, the proposed rule would deem profits distributed to a physician that directly attributable to a physician's participation in a VBE not to take into

account the volume or value of a physician's referrals. However, to qualify as a group practice, CMS is now requiring that the profits derived from all the designated health services must be aggregated and distributed and can no longer be separated by service type.

ACP Comment: The College is generally supportive of updates to profit sharing within group practices. Under current law, payments to a physician in a group practice are prohibited from taking into account the volume or value of a physician's referrals to the group practice, in practice prohibiting any sort of shared savings, gainsharing, or productivity bonuses. This proposed change will encourage physicians in group practices to participate in value-based models that further the Agency's value-based goals and improve patient care. However, given the time and effort involved in making changes to physician compensation arrangements, we are concerned about the impact and burden that requiring aggregated DHS profits will have on physicians in practices that have separated profits by service type until now. We are further concerned this will have downstream effects as this updated definition of a group practice may impact those who can qualify for the widely utilized In-Office Ancillary Services Exception.

Additionally, we reiterate our call from the RFI comments that CMS investigate the unintended liability and consider expanding the definition of a group practice to include MIPS "voluntary virtual groups" in order to reduce the burden of participating in APMs and other value-based models. Under MIPS, practices may establish a set of agreed-upon clinical protocols that will be used by all virtual group participants to try to achieve a high performance score within the quality performance category in MIPS. These "virtual groups" may begin to resemble the characteristics of a group practice, yet not meet the defined requirements of being classified as a group practice for purposes of the Stark Law, potentially creating barriers to participating in value-based models if they do not qualify for another exception.

Other Proposals

As part of CMS' Patients Over Paperwork initiative, the Agency has prioritized evaluating and streamlining regulations in order to reduce unnecessary burden, increase efficiencies, and improve the patient experience, and these efforts are reflected in many of the updates in the proposed rule. ACP has long contended that existing fraud and abuse laws and their enforcement are overly burdensome on practicing internists. In our RFI comments to the Agency, 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 Stark Law-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 Stark Law and Anti-Kickback Statute rules, where feasible, in order to simplify compliance and reduce physician confusion. We applaud CMS for responding to our feedback and proposing numerous changes and additions that will provide leeway in meeting the requirements of an exception and complying with Stark Law while still protecting the integrity of federal health programs.

Writing and Signature Requirement Grace Period
The writing or signature requirement for compensation arrangements would be considered satisfied if the arrangement meets all of the other requirements for the exception (aside from the writing or signature requirement) and the parties obtain the required writing or signatures within 90 calendar days from the date the arrangement failed the writing or signature requirement.

ACP Comments: The College is supportive of CMS allowing for a grace period in fulfilling the writing and signature requirements of compensation arrangements for the purpose of qualifying for an exception. Oftentimes at the beginning of a particular compensation arrangement there can be temporary periods of noncompliance as physicians and other parties nail down and finalize the exact terms of the arrangement and translate that to a written agreement. This proposal grants additional flexibility while the short-term nature of it ensures adequate protection from being abused and will be particularly useful for physicians engaging in last minute arrangements.

Relaxation of Office Space and Equipment Rental Requirements
The proposed rule updated the definition of fair market value to add two separate, broad definitions of the fair market value for the rental of office space and the rental of equipment. The exception for payments by a physician was updated to protect arrangements for the rental or lease of office space. Further, it clarified that the fair market value exception for office space and equipment rental would allow for the space or equipment to be shared with others in certain conditions, so long as the lessee have use of the equipment or space exclusive of the lessor or related entity.

ACP Comments: The College appreciates the proposed update around who can use rented equipment and space without violating fraud and abuse law. This proposal provides certainty to physicians in clarifying that the sharing of rented office space or equipment is permissible, including in situations where a physician would like to invite a guest physician into the premises in order to coordinate and jointly treat a mutual patient. Allowing those who are not the lessor to utilize the space provides additional flexibility to physicians while also making sure remuneration for rental of space and equipment does not corrupt any medical decision-making.

Remuneration Unrelated to Designated Health Services
The exception for remuneration provided from a hospital to a physician is restructured to clarify that remuneration will not be considered a designated health service if it is for services or items not related to patient care services. Further, it protects payment for services that can legally be and typically is provided by a person who is not a licensed medical professional.

ACP Comments: The College supports the broadening of the remuneration unrelated to DHS exception in providing leniency and clarity. Administrative burden would be reduced for physicians receiving remuneration in the context of business or operational affairs, such as providing administrative services or business input on a board or the selling or transference of office furniture.

Limited Remuneration to a Physician
This proposal would protect limited remuneration of up to $3,500 per calendar year offered by an entity in exchange for items or services actually provided by a physician, so long as it meets the volume or value standard, does not exceed fair market value, and is commercially reasonable.

ACP Comments: ACP commends CMS for its proposal to accommodate low-cost, short term, and sporadic arrangements entered into by physicians and practices under the limited remuneration exception. Sometimes last minute situations arise where physicians are unable to establish a written and signed agreement prior to the provision of services and hence are unable to satisfy the requirements for some exceptions. We believe the flexibility offered in this proposal will offer immense benefit in the form of reduced compliance burden and that the small dollar amount over a calendar year timeframe provides adequate protection against the threat of this exception being used in a fraudulent or abusive manner.

Reforming Period of Disallowance Rules
CMS proposes eliminating the current guidelines for determining the period in which a physician may not make a referral nor an entity able to bill Medicare for a referral as a result of failing to meet an applicable exception. The Agency clarifies that the disallowance period begins on the date the arrangement does not satisfy requirements and ends on the date the arrangement ends or is brought back into compliance. The proposed rule further establishes guidelines for remedying compensation noncompliance. If a discrepancy in compensation is a result of an unintended administrative or operational error, parties may correct the error by collecting the overpayment or providing the underpayment, so long as the arrangement is live and the arrangement is ongoing.

ACP Comments: The College believes that existing law has 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. While it is important to prevent and punish fraud in federal health care programs, this goal must be balanced with reducing unnecessary burdens for physicians who do not engage in illegal activities. ACP respects that CMS recognizes unintentional and non-malicious mistakes can arise that do not warrant punitive measures. This is a common sense and practical change that decreases compliance burden and will provide a reasonable avenue to remedy legitimate administrative or operational errors that temporarily result in noncompliance.

Conclusion

Thank you for considering our comments. As the American health care system continues to shift from one based on volume to one based on value, we appreciate CMS' ongoing commitment to streamlining or eliminating duplicative requirements and modernizing federal fraud and abuse laws to reflect this new environment. Many of the new exceptions and other changes contained within the proposed rule are a step in the right direction in reducing administrative burden and providing additional guidance and flexibility for physicians to comply with Stark Law, while still providing adequate safeguards are in place to protect the integrity of federal health programs and ensuring taxpayer resources are being used on quality care and improving patient outcomes. However, we are concerned that the thresholds for the risk sharing value-based arrangements are unattainable for many physicians, particularly those in smaller or rural practices, and urge the Secretary to work with stakeholders to identify more accessible thresholds that will be more useful for physicians while still accomplishing the fraud and abuse deterrent goals of the Agency. 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