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Advancing Health in America

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
202 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS–1720–P Proposed Rule—Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to modernize and clarify the physician self-referral law, also known as the Stark Law.

We welcome CMS's acknowledgment of the chilling effect the Stark Law has had and continues to have on innovation and the transition to a value-based health care system. And we applaud the new direction CMS is taking in the proposed rule to provide space for the types of innovative arrangements among hospitals and physicians that can enhance care coordination, improve quality and reduce costs. Similarly, CMS's efforts to tackle the burdens created by the compensation regulations are a major step forward in putting "patients over paperwork" and making compliance more straightforward.

The AHA and America's hospitals and health systems stand ready to continue assisting CMS in modernizing the Stark Law for the 21st century and the world of value-based care and payment. We are pleased to see so many of the real-world issues and concerns hospitals experience every day managing within the current Stark regime addressed in the proposed rule. These include:

- Creating value-based exceptions designed to foster and support efforts to achieve a system of value-based care is a game-changer, opening the door to innovation.

Overall, the proposed exceptions would provide latitude for hospitals and physicians to work together to deliver high-quality, cost effective care with better outcomes. We provide specific modifications to better ensure those goals can be achieved.

- Tackling the problems created by the ambiguities and misinterpretation by courts and others of the three cornerstone conditions of the compensation regulations – commercial reasonableness, taking into account volume or value, and fair market value – is welcomed and should bring relief for hospitals. Clear, straightforward definitions are essential to compliance and to minimize the diversion of resources to unnecessary disputes over what is required. We provide recommended clarifications to enhance certainty.

- Minimizing documentation requirements that are little more than tripwires for noncompliance also is a significant improvement. We provide recommendations to better align the proposals with the goals of CMS's Regulatory Sprint.

Our detailed comments attached address the specifics of CMS's proposed changes, respond to questions on which input is requested, and provide recommendations for specific clarifications or modifications to the proposed regulations to achieve the goals.

Again, we thank you for your focus on this critical issue and for your consideration of our comments. Please contact me if you have any questions at mhatton@aha.org or (202) 626-2336.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel

AMERICAN HOSPITAL ASSOCIATION
DETAILED COMMENTS ON STARK PROPOSED RULE

NEW VALUE-BASED EXCEPTIONS

The creation of new exceptions designed specifically to foster and support efforts to achieve a system of value-based care is extremely significant. In finalizing the rule, CMS should adopt the proposed general framework and related definitions. We propose and urge CMS to adopt changes to specific conditions of the proposed exceptions to further reduce unnecessary limits on innovation and to adopt precise standards that leave no room for costly and avoidable litigation.

FRAMEWORK FOR THE NEW EXCEPTIONS

The AHA supports the basic, flexible foundation of the proposed value-based exceptions.

We endorse the view stated in the commentary and embodied in the text of the proposed rule that the Stark regulations should not require particular legal structures for a value-based enterprise or other foundational aspects of the proposed rule. Nor should any particular type of payment model (such as a shared savings or capitation model) be a precondition to receiving protection under the new exceptions. As CMS appears to recognize, constructive innovation takes place in many different forms, allowing for the varied circumstances and goals of patients, providers, and payors across the nation's health care system. Equally critical, an essential aspect of innovation is the ability to test different models and variables. Without protection under the Stark Law, many well-intended financial arrangements never would be launched and their benefits never would be realized.

In particular, we agree with these fundamentals in creating the exceptions:

- "Physician self-referral law policy is not the appropriate place to define or identify alternative payment models," and that the focus of the exercise instead should be "to remove the regulatory barriers that inhibit the transformation to value-based care."
- A value-based enterprise should be defined "in terms of the functions of the enterprise" and the "intention [of the rule should not be] to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise."
- Toward that end, CMS should <u>not</u> limit the definition of a value-based arrangement only to arrangements that involve care coordination or management, an alternative limitation and approach on which CMS seeks input. While care coordination and management are important elements in some value-based arrangement structures, they are not a common thread across all current

structures, and we believe that imposing so narrow a limitation would inhibit innovation now and in the future.

- Participants in value-based arrangements should have the flexibility to define their target patient populations in a variety of ways and the discretion to include government and/or commercial enrollees.

We agree that none of the exceptions should limit the types of remuneration protected. Each of the proposed exceptions would protect, for example, payment incentives, support tools and infrastructure assistance. To reverse course on that, and leave patchwork protections for different forms of remuneration in different circumstances, would jeopardize the workability of the proposed rule and defeat the central objective of reducing regulatory burdens and pitfalls for transformative value-based arrangements.

We also strongly endorse CMS's determination in commentary that the benefits of a value-based arrangement need not be *limited* to a target patient population. For example, if a hospital participating in a value-based arrangement with a collection of physicians provides data analytics support under one of the proposed exceptions, the regulations should encourage use of the analytics and the learning and experience gained from their application for the benefit of all patients, including those beyond the target patient population. Limiting the reach of the exceptions to the strict confines of a target patient population would be difficult (if not impossible) in practice for providers, inhibiting both innovation and its adoption beyond the laboratory of innovative arrangements. Given the importance of this principle, CMS should add express language to the exceptions or applicable definitions to prevent potentially contrary interpretations by enforcement agencies, courts or qui tam relators, making it clear that value-based arrangements may benefit patients beyond their targets without risk of losing protection from liability.

Similarly, we strongly agree that the exceptions should not include cumbersome and ambiguous fair market value, commercial reasonableness, or "volume or value of referrals" conditions. These are vestiges of the volume-based, fee-for-service environment and represent some of the strongest barriers to value-based innovation and the shift to value-based reimbursement. To insert any of these conditions in the proposed exceptions would significantly stifle the progress of the proposed exceptions and leave them as little more than new regulatory ink. The value-based movement would be left essentially where it is today.

It is critical that CMS not adopt the alternative proposal, described in the commentary, to prohibit value-based remuneration that is "conditioned on referrals." To do so would defeat the purpose of these exceptions. Hospital value-based arrangements almost by definition require the participation of physicians who order services from and admit patients to a hospital participating in that arrangement (such as shared savings models). In other words, many value-based arrangements will generate a benefit to physicians *only* when they order needed services or recommend

that a patient receive certain services. Indeed, a key aspect of value-based care is to *encourage change* in the way physicians *make orders or recommendations* – for instance, in a manner that is coordinated with care furnished by other providers, reduces overall utilization, improves clinical outcomes, or provides another form of value. If the finalized exceptions were to require a complete disconnection between what the physician receives and the medical judgments the physician makes, the value-based arrangement exceptions would be of minimal utility.

Target Patient Population. The breadth of the proposed definition of target patient population will allow hospitals the latitude to identify and focus on health issues specific to their community. However, language in the regulation and in the commentary require modification or clarification.

Requiring that the criteria for selecting the population be "legitimate" introduces ambiguity that in the current enforcement climate is likely to lead to endless litigation over its meaning. In the commentary, CMS indicates that the legitimacy standard is intended to control against two specific criteria: "a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping)." **The AHA supports clear and unambiguous language in the regulatory text to preclude those and any other types of targeting behaviors that CMS believes are abusive.** We also support the requirement that criteria be verifiable.

A CMS statement in the commentary also raises concern that many common and proven techniques for reducing costs could be called into question. "Generally speaking, choosing a target patient population in a manner driven primarily by a profit motive or purely financial concerns would not be legitimate." Given the expectation that many value-based arrangements (especially early arrangements) will pursue opportunities for appropriate reductions in cost or unnecessary care, both of which can impact financial performance. **CMS in the final rule must carefully clarify the distinction between reducing costs and problematic criteria.**

To illustrate further, CMS itself targets conditions like joint replacement through the Comprehensive Care for Joint Replacement (CJR) program because of the hope and belief that shared accountability and collaboration will yield cost savings. As it does under many other value-based programs and demonstrations, CMS allows providers participating in CJR to share in the benefits of cost reduction. Broad, ambiguous statements undermine the simplification objectives of the Regulatory Sprint and, by extension, inhibit the transition to value-based care. **CMS should acknowledge that it is acceptable to choose populations for which activities like standardization alone could generate appropriate cost reductions (i.e., financial benefits).**

Value-based Purpose. The proposed definition of value-based purpose identifies four distinct purposes on which a value-based arrangement may be based. Overall, they appear sufficiently flexible to accommodate innovative beneficial arrangements. **We**

urge that the purposes be finalized as proposed with one modification, and that CMS clarify statements in the commentary that could limit the achievement of value-based goals.

Protecting only efforts to reduce costs for payors under the "appropriately reducing cost" value-based purpose is too limiting. Cost reductions for provider participants in a value-based enterprise also should be protected. The benefit of hospitals reducing costs would extend to CMS in the form of lower costs reported to Medicare, and, therefore, lower Medicare reimbursement to hospitals. In addition, internal cost savings programs are some of the longest-standing types of value-based arrangements (e.g., gainsharing). Achieving efficiencies that appropriately reduce costs should be rewarded and protected.

CMS should clarify that success is not a condition to qualify for protection when the value-based purpose of an arrangement is improving the quality of care. CMS's solicitation of comment on "permissible ways to determine whether quality of care has improved" could be read (or misread) to create such a condition. Imposing an "ultimate success" requirement could effectively end quality improvement efforts out of concern that success is never guaranteed. We assume this is not what CMS intended. **CMS should make clear in regulation that quality improvement is a process and protection applies throughout the quality improvement process.**

CMS should not replace the proposed value-based purpose of appropriately reducing cost with the alternative discussed in the commentary. None of the other proposed purposes include cost reduction. Cost reduction is a critical aspect of value-based arrangements and needs to be protected so long as quality is maintained. CMS's alternative proposal could significantly hinder the move to value-oriented care.

Monitoring. CMS's suggestion that its regulations give rise to "implicit" compliance obligations will create confusion and likely litigation over whether requirements not stated explicitly in the regulation are conditions to be met in order to avoid liability. The commentary injects the notion of an implicit duty several times. For example, CMS commentary states, "We expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes, regardless of whether the arrangements are value-based, and have in place mechanisms to address identified deficiencies, as appropriate. *In fact, there is an implicit ongoing obligation for an entity to monitor its financial relationship with a physician for compliance with an applicable exception*." In this era of relator-driven litigation and enforcement activity, the ambiguity of "implicit" duties is unacceptable. The Stark Law is a strict liability statute proven to result in draconian penalties. **Any enforceable duty must be expressly stated in the regulation itself**.

CMS's expectations for monitoring performance must recognize that the goals of a value-based activity are *prospective*. The purpose of the exceptions is to

encourage innovation – to encourage participants to come together and engage in activities that are *reasonably designed* to achieve a value-based purpose. Those activities should, of course, be evaluated at the outset and when it is up for renewal. That approach is consistent with how providers approach other arrangements for purposes of Stark Law analysis (e.g., fair market value of a lease). Compliance with the structural elements of exceptions is not measured every moment in time over the life of the relationship. Indeed, given the nature of the collaborative process fostered by these arrangements, value-based deliverables would most likely grow as changes in practice are adopted, evaluated, adjusted and re-evaluated over their lifespan. **CMS should reject any construct that requires termination of an arrangement simply because a goal or metric proves difficult to achieve.** To do otherwise would defeat the purpose of the new exceptions from the start. "Reasonably designed" cannot mean that cause for doubt or unexpected result at any point, makes the entire arrangement noncompliant and means that all of a physician's designated health services (DHS) referrals to the hospital are suddenly not payable under Medicare.

If any monitoring requirement is adopted, CMS must be clear on *what* exactly hospitals are being called upon to monitor. The proposed rule commentary does not come close to providing sufficient clarity or the certainty required. Depending on the scope and required frequency of any monitoring obligations, the burdens on participants could be tremendous. In arrangements where physicians are measured against hundreds of care protocols or quality metrics, continuous monitoring of the clinical evidence with respect to each metric simply is unrealistic. It also would call into question whether the attention to paperwork has overtaken attention to patient care.

Similarly, CMS should reconsider its commentary asserting an implicit condition that technology and other infrastructure "must be necessary and not simply duplicate technology or other infrastructure that the recipient already has." As stated, this requirement would be much more of a burden to providers than a benefit to the Medicare program. If a physician already has the same technology or infrastructure (e.g., data analytics services), it is unlikely the physician would benefit personally from receiving another version of the same thing, but it could be essential to interoperability, data collection or performance within a value-based enterprise. The real effect of this provision would be needless diversion of resources away from value-based initiatives. The speed and frequency of changes in technology would require continuous assessments of what is or is not duplicative by hospitals and CMS.

REQUIREMENTS SPECIFIC TO EACH OF THE EXCEPTIONS

"Value-Based Arrangement" Exception. We urge CMS to finalize the "Value-Based Arrangement" exception without adding financial risk or other limitations. Finalizing an exception that is not tied to financial risk is essential to spurring the shift to value-based payment models. Financial risk is far from the norm in existing arrangements. This is evident, for example, in the analogous context of the Medicare Shared Savings Program (MSSP), which has had few accountable care organizations transition from the

"upside only" MSSP model (under "Track 1") to other MSSP models that involve risk sharing. As that experience has shown, most providers are not yet prepared to accept outcomes-based financial risk and such models are not something that can be rapidly adopted. In addition, well before many providers can realistically bear risk for the cost of care, they need the tools that enable them to transform clinical judgments and care protocols. To illustrate, a 2018 New England Journal of Medicine (NEJM) survey found that "infrastructure requirements, including information technology" was the most commonly cited barrier (42% of respondents) to implementing value-based reimbursement models. Participants cannot provide these tools without protection under the Stark Law, and if that is only available once financial risk has already been adopted, many participants are unlikely to ever receive them.

CMS should decline to adopt the three alternative proposals discussed in the commentary that would each dramatically reduce the utility of the exception.

- CMS should not limit the scope of the proposed exception to nonmonetary remuneration. This alternative would greatly restrict the flexibility of this exception and would unduly limit many commonplace value-based arrangement structures, such as financial incentives to adhere to care protocols and shared savings models.

- CMS should not require 15% (or other) cost sharing by value-based arrangement participants. The requirement would preclude a host of innovative arrangements and take a disproportionate toll on small and rural physician practices, which are a key component in successfully improving care across patient populations. Particularly for arrangements involving only infrastructure assistance, participants sometimes do not have the financial incentive to front any part of the costs.

- CMS should not require that "performance or quality standards must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery." This alternative presents too ambiguous a standard, not consistent with the bright line test for which the agency strives under the Regulatory Sprint.

Full Financial Risk Exception. The "full financial risk" exception should be revised to focus on whether the value-based enterprise (network of participants in a value-based initiative) has full financial risk for the items and services *to which the protected remuneration relates*. Under the proposed rule, "full financial risk" is defined such that the value-based enterprise is accountable for the cost of *all* patient care items and services covered by the applicable payor(s) in the target population. For Medicare, the commentary interprets that to mean responsibility for all items and services covered under Parts A and B. As a result, a hospital providing care management analytics or pay-for-performance bonuses tied solely to reducing the costs of inpatient care would not be protected. **The "full financial risk" exception should allow hospitals to furnish incentives related to inpatient care, outpatient care, or both, regardless of**

whether the enterprise also is accountable for other items and services. Such arrangements pose little risk of encouraging inappropriate utilization because hospitals already bear accountability for the cost of inpatient and outpatient services through inpatient and outpatient prospective payment rates and readmission and other downside penalties.

Meaningful Financial Risk Exception. For the physician "meaningful financial risk" exception, the proposed 25% threshold is far too high. The 25% threshold seems to be taken from the federal "physician incentive plan" rules, applicable to Medicare and Medicaid managed care plans and federal health maintenance organizations. But that is not logical because the physician incentive plan rules approach the matter from the other direction – namely, the point of those rules is that if physicians take on any more than 25% risk, there is such a concern about ***stinting*** on care that additional steps need to be taken to make sure beneficiaries are getting *enough* care. To choose a risk-sharing threshold that sufficiently ensures physicians are encouraged not to overutilize, CMS should choose a much lower figure.

We recommend the "meaningful financial risk" threshold be established at a more pragmatic 10% in the final rule. For hospitals to put these risk-based arrangements into place and to be successful in value-based activities, physicians must be willing to participate. It is highly unlikely for individual physicians to put 25% of their compensation at risk, especially "downside" risk, as the proposed rule would require. In competitive physician services markets, that threshold would make these arrangements impossible. In a 2018 Deloitte survey of U.S. physicians, most physicians said they were willing to link around 10% of total compensation to quality and cost measures. That threshold would be higher than the average amount of physician compensation linked to performance goals today: based on the Deloitte survey, 43% of physicians either receive small performance bonuses of up to 5% and 28% of physicians are not eligible for bonuses, whatsoever. Among all bonuses, most (55%) are tied to productivity, with only 47% tied to quality. Only 36% of surveyed physicians have any bonus tied to utilization of resources, in any respect. This evidence suggests that incentives would not need to be nearly as high as 25% to influence decision-making.

Price Transparency. We urge CMS not to move forward with a requirement for physicians to provide a notice or have a policy regarding the provision of a notice that advises patients that their out-of-pocket costs may differ depending on their insurance coverage and where the services are delivered. Such a requirement would be counter to the agency's efforts to reduce unnecessary paperwork that benefits neither patients nor providers, but worse, it is likely to both concern and confuse patients. We have repeatedly requested that CMS use its position of influence to bring stakeholders together on a voluntary basis to determine a workable solution to providing patients with information on their estimated out-of-pocket costs, wherever and whenever they seek it. This proposal would be a step backwards, and so we urge CMS to abandon it.

REFORMS AND CLARIFICATIONS TO REDUCE STARK LAW BURDENS

CMS's proposed clarifications to clearly distinguish the three cornerstones of existing statutory exceptions – commercially reasonable, taking into account the volume or value of referrals, fair market value – are major breakthroughs. These components have long been the source of controversy and litigation. We believe CMS's clarifications will make an important difference practically and legally.

CMS's articulation of distinctions between the "big three" Stark Law conditions should be preserved in the final rule. The proposed rule and commentary examines each cornerstone in the larger context of distinguishing proper from improper financial arrangements, legitimate compensation for services, space and equipment from disguised fee splitting and other payments for referrals. CMS should keep this context in mind in adopting final regulations. As CMS recognizes in commentary:

- "Commercial reasonableness" is a question of whether the items or services have utility to the purchaser/payor;
- "Takes into account the volume or value of referrals" is a question of how payment is calculated under the arrangement; and
- "Fair market value" is a question of whether the compensation paid is or would be too much or too little to secure the items or services.

Commercially Reasonable. CMS's discussion of the meaning of "commercially reasonable" in the commentary is extremely helpful. We do not think the last sentence of the proposed definition, however, which states that an arrangement "may be commercially reasonable even if it does not result in profit for one or more of the parties," fully reflects that discussion. **CMS should finalize the proposed definition of "commercially reasonable" with one modification. The last sentence should state that "Commercial reasonableness is unrelated to the profitability of the arrangement to one or more of the parties."** Given the degree of confusion related to this term and the severe consequences if a court concludes there has been a violation, CMS should leave no room for anyone to attempt to make a connection to profit.

In addition, it would helpful to include in the final rule a clarification that the use of the term "referrals" in the definition is limited to Medicare DHS referrals. The language would read: "commercially reasonable *even if no Medicare DHS referrals were made between the parties.*" While the term "referrals" is defined in the regulations to mean Medicare DHS services only, this will make clear that the definition applies consistently throughout the rule.

Takes into Account the Volume or Value of Referrals. The proposed definition of "takes into account the volume or value of referrals" provides much-needed clarification of terms that have proven to be a source of confusion among providers, physicians, enforcement agencies, qui tam relators and courts. However, further clarification is necessary with respect to productivity compensation and indirect compensation

arrangements. **CMS should finalize the proposed definition of compensation that "takes into account the volume or value of referrals," and take several steps to clarify that personal productivity compensation is protected in all settings.**

We commend the proposed definition's focus on whether DHS referrals appear in the plain terms of the formula used for compensation (in the words of the proposed rule, "include the physician's referrals as a variable"). Similarly, we commend CMS for reiterating prior commentary addressing productivity incentives for proceduralists and other hospital-based physicians – that productivity bonuses for physicians working in a hospital will not take into account the volume or value of the physician's DHS referrals to the hospital, even if a hospital facility fee is "inevitably" linked to the physician's work.

As CMS recognizes in commentary, however, only the bona fide employment exception has an express provision deeming personal productivity pay to not create a "volume or value" problem. To help provide security for productivity compensation regardless of employment or contractor context, we recommend three steps:

CMS should make clear in regulatory text that compensation for personal productivity is permissible under the personal services, fair market value compensation, and indirect compensation arrangements exceptions to remove any lingering confusion arising from this disparity.

CMS should confirm that the "volume or value" proposed definition applies to the question of whether an indirect compensation arrangement *exists* (and not just for the purpose of the "volume or value" conditions necessary to satisfy an exception). One element of the indirect compensation arrangement definition looks to whether "aggregate compensation" takes into account (i.e., as a variable) the volume or value of referrals to the DHS entity. Hospitals should have complete clarity on how the proposed definition applies to the existence of indirect compensation (which hospitals need to know in order to determine whether a Stark exception must be satisfied to avoid liability). Hospitals also should have complete clarity on the difference between the "volume and value" element of the indirect *definition* and the "volume and value" element of the indirect compensation *exception*. We are concerned that these uncertainties will lead to unpredictable, potentially severe results in litigation.

CMS should recalibrate its discussion that seems to indicate compensation tied to personally performed services is subject to the longstanding deeming rules for unit-based compensation. That commentary is at odds with the new definition and creates confusion. Since personally performed services are not referrals, it seems plain that productivity incentives do not "include the physician's referrals as a variable" and as a result the "volume or value" standard would not come into play. **CMS should simply state that productivity compensation does not take into account referrals, even for physicians working in the hospital setting.**

These exact concerns are on display in recent litigation. Productivity pay for personally performed services is a ubiquitous form of compensation paid by hospitals or their affiliates to surgeons and other proceduralists who attend to patients almost exclusively in a hospital setting. Hospitals have long understood these forms of compensation as Stark-compliant, because they are consistent with repeated CMS commentary approving personal productivity bonuses, regardless of setting (including the "Phase II" commentary cited by the proposed rule).

In *United States ex rel. Bookwalter vs. University of Pittsburgh Medical Center*, however, a panel of the U.S. Court of Appeals for the Third Circuit found fault in allegations that surgeons each received productivity bonuses tied to work relative value units (wRVUs) awarded for surgeries they each performed personally. Relying on commentary on the definition of "referral" indicating that the technical component of a service performed in a hospital falls within the broad definition of referral under Stark, the panel found that wRVU-based compensation established a "correlation" between pay and referrals, which the Court identified as a "volume or value" issue. Along with a general allegation that the hospital knew of the compensation methodology, the Court stated this was a plausible basis to find the existence of an indirect compensation relationship between the physicians and the hospital and to cast doubt on whether an exception was satisfied. The Court found that alleged "correlation" sufficient to survive dismissal and potentially to force the hospital into costly, disruptive discovery. CMS must immediately rectify the confusion resulting from the decision in *Bookwalter*. In the final rule, **CMS should provide guidance that the *Bookwalter* reasoning on wRVU-based compensation is inconsistent with the definition proposed, which articulates the agency's longstanding view of productivity compensation**.

Fair Market Value. CMS should finalize the proposed clarification of the "fair market value" definition, and also address key concerns created by the commentary***.*** **CMS should adopt the proposed clarification that fair market value does not turn in any way on whether compensation takes into account or anticipates referrals.** It also should finalize a proposed change in the definition of "general market value," – the language "bargaining between well-informed buyers and sellers *who are not otherwise in a position to generate business for the other party*" should be deleted. As CMS has recognized, "fair market value" and "taking into account referrals" are distinct concepts that serve different functions in Stark Law analysis. Blending these concepts, as courts have done in *United States ex rel. Drakeford v. Tuomey Regional Medical Center, Bookwalter,* and *United States ex rel. Singh v. Bradford Regional Medical Center,* has led to confusion, litigation and a torrent of unnecessary effort to reexamine arrangements long believed to comply with law. The changes CMS has proposed are essential to restoring clarity to the definitions.

CMS's commentary discussing application of the definition to a hypothetical negotiation with a medical director has created confusion that should be addressed in the final rule. CMS's statement that "parties to a potential personal service arrangement must not consider that the physician could also refer patients to

the entity when not acting as its medical director" muddles the proposed regulatory changes. Most transactions between a hospital and a physician will involve a physician in a position to refer. CMS should not require hospitals to search for market data that isolates transactions with physicians who are not in a position to refer. CMS should retract this statement and clarify that parties can rely on similar transactions in the marketplace to determine fair market value.

In addition, we agree with CMS's clarification that "fair market value" should be read as relating to a hypothetical transaction between parties and "general market value" (with which fair market value must be consistent, under the statutory definition) should look to the particular circumstances of each party (such as the particular physician's level of specialty and skill). To further clarify the scope of "general market value," **we recommend that CMS address the ability of hospitals to use existing written offers to a physician from other similarly situated providers to support a valuation**. This would be necessary, for example, with respect to highly-skilled physicians whose salaries might be outside surveys and they receive bona fide written offers from other similarly situated entities.

Eliminating Unnecessary Complexity. The AHA commends CMS for its efforts to reduce the number and significance of other features in regulatory language that have proven over decades to be trip wires to unreasonable Stark Law liability. **Specifically, CMS should finalize the following proposals, with the additional changes noted, each of which will not cause any increased risk of abuse to the Medicare program**:

- The "limited remuneration to a physician" exception for annual payments under $3,500. This will be extremely helpful to avoid liability for non-abusive conduct and will save CMS resources in resolving self-disclosures related to arrangements that do not pose risks to federal health care programs.
- The deletion of Anti-Kickback Statute compliance as condition of regulatory exceptions, since that carries its own consequences. Based on the same principles, CMS also should delete requirements of compliance with state/billing/claims submission law.
- The special rule on parties being permitted to execute writings within 90 days. However, in addition, a compensation arrangement <u>also</u> should be deemed to satisfy the writing requirement if the arrangement constitutes an enforceable contract under applicable state law.

We also ask CMS to reconsider its views on its "isolated transactions" proposal. We understand the conceptual distinction of an "isolated transaction" as not involving ongoing payment for ongoing items or services furnished. Nonetheless, <u>*where no payment has yet been made for those items and services*</u>, it is perfectly reasonable to see a single payment for items or services already furnished as a single transaction. This is commonly the case where a hospital arranges with a physician to provide services, but fails to keep proper records of that arrangement and the physician

provides services for a period of time, before the documentation issue is discovered and before payment is made (more than 90 days later). In order to be protected, the arrangement must be at fair market value and cannot take into account referrals. In short there is no harm in that situation. In this respect, the isolated transactions proposal would simply create more self-disclosures of technical violations and unnecessary Stark exposure. **We urge CMS to reconsider the isolated transactions exception in the final rule and permit isolated payments for services that may have been already commenced.** This would be consistent with the agency's stated objective "to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly[.]"

ELECTRONIC HEALTH RECORDS (EHR) AND CYBERSECURITY

We appreciate CMS's inclusion of updates to the current EHR provisions and urge the removal of remaining barriers and uncertainty from the exception in connection with the adoption of EHR technology.

Removal of the "sunset" provision will provide needed certainty to the field. It will support EHR adoption by new physicians entering the market, as well as assist late adopters in implementing technology critical to supporting patient care.

We urge removal of the 15% recipient contribution requirement for <u>all</u> physician recipients. Removing it for small and rural practices, as proposed, is helpful; however, removing it for all recipients would make an important difference in achieving the shift to value-based care arrangements. It would remove a barrier to the kind of data integration and real-time information sharing that is essential.

For similar reasons, the AHA supports CMS's proposal to allow for donation of replacement EHR technology. There are many situations where a physician practice may wish to migrate to a different EHR product, including to achieve advanced functionalities or to improve health information exchange capabilities. Switching to a new EHR vendor system often presents financial and technical challenges because, as CMS observed, under the current exception, physicians are forced to choose between keeping the substandard system and paying the full amount for a new system. This change aligns well with efforts underway at the Office of the National Coordinator for Health Information Technology (ONC) to require increased technical functionality in order to make exporting patient records more feasible and to thus mitigate vendor "lock-in."

CMS should <u>not</u> finalize its proposal to incorporate ONC's definition of electronic health information (EHI) for purposes of defining the type of information that is part of an EHR. The AHA opposed ONC's proposed definition as overly broad, specifically regarding price information. At the time of this submission, the final information blocking rule has not been released. As a result, we do not know if our concern has been addressed, nor can we be certain how that will play into the EHR exception. **CMS**

should provide another opportunity for comment prior to finalizing a definition that relies on an ONC definition.

The cybersecurity exception should be adopted with a modification providing protection for hardware. The creation of this exception, long advocated for by hospitals and health systems, will support more robust capabilities for health care providers to protect against and respond to growing cybersecurity threats. It appropriately recognizes the imperative for all physicians to have appropriate access to tools and services to secure and protect patients' health information. **However, the AHA recommends adding protections for hardware necessary for cybersecurity within the proposed exception's definition of technology.** Protecting hardware necessary for fully functioning cybersecurity systems is important, and the protection should be broad enough to encompass advances in cybersecurity technology, including advances in hardware. An example of an important cybersecurity hardware component is a two-factor identification token for identity verification and system access control. Cybersecurity is necessary to enable safe, effective health information exchange, and thus is crucial to improved care coordination and improved health outcomes at the individual and population levels.

The AHA supports a deeming provision that would allow donors and recipients to demonstrate that donations are "necessary and used predominantly to implement and maintain effective cybersecurity." **Specifically, we support CMS's suggestion to deem that donors and recipients satisfy this condition if the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework, such as those developed by the National Institute of Standards and Technology.**