



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

December 30, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: CMS–1720–P, Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations; Federal Register Vol. 84, No. 201, October 17, 2019

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health care systems — including post-acute care providers — the California Hospital Association (CHA) welcomes the opportunity to respond to the recent Centers for Medicare & Medicaid Services (CMS) proposed rule to modernize and clarify implementing regulations of the physician self-referral law, also known as the Stark Law.

Our country's current health care delivery system is undergoing significant transformation. California's hospitals are leading this transformation in adopting innovative care delivery and payment models that improve the quality of care, make patients' needs central, and reduce health care costs per capita. Clinical integration with aligned incentives among hospitals, physicians, and other providers working as a team across sites of care, along with alternative payment models, are critical to achieving our shared goals of moving from a fee-for-service delivery system that rewards volume to a value-based delivery system that prioritizes patient outcomes. To be successful, it is critical that both the statutory and regulatory framework provide sufficient flexibility to accommodate the rapid pace at which providers are asked to innovate and transform through these models.

The Stark Law — which was enacted and primarily developed in a fee-for-service, hours-based environment — not only currently fails to accommodate these new models but serves as a difficult, if not insurmountable, barrier to utilizing them. CHA applauds the administration's recognition of these challenges and is encouraged by many of the changes proposed to modernize the physician self-referral laws.

Federal law does not create the only barrier to clinical integration for California hospitals and health systems. California also has state laws designed to prevent health care fraud and abuse that, while similar to their federal counterparts, differ both in scope and the specifics of prohibited conduct. This necessitates that any arrangement be separately analyzed for compliance with California law. Further, California law prohibits all but a handful of hospitals from employing physicians. This eliminates most hospitals' ability to align incentives with physicians through the terms and conditions of their employment.

When these additional burdens imposed by state law are combined with the current challenges imposed by the Stark Law and other federal fraud and abuse laws, California hospitals' cost of doing business is substantially increased. The need for complex business arrangements that appropriately navigate the current multifaceted regulatory framework presents an added cost that does not improve either patients' health outcomes or their health care experience. Importantly, by way of example, there is more flexibility under the employment exception to the Stark Law than under the applicable exceptions for independent contractor physicians, which must be relied on for many hospital-physician financial relationships in California. Thus, it is especially important to California hospitals that barriers and burdens at the federal level that impede improved care coordination be reduced to the greatest extent possible (see the "California Laws" section below for additional information about the unique challenges California hospitals face that impact compliance with the Stark Law).

CHA appreciates CMS' interest in improving the Stark Law and reducing the regulatory burden and costs it imposes on the nation's health care system. CHA also appreciates the thoughtful approach CMS has taken over the past two years, which has resulted in positive changes outlined in the proposed rule that we believe will reduce barriers to health care delivery and development of payment models that facilitate care coordination, while striking a balance to combat true fraud and abuse. CHA is generally supportive of many of the provisions outlined in the proposed rule. However, we believe additional changes are needed to advance our shared goals of care coordination and reduced administrative burden. Our detailed comments are noted below.

California Laws

California hospitals face unique obstacles to Stark Law compliance because of certain California laws, and have adopted a number of innovative clinical integration models to comply. Summarized below are three key California laws and their impacts.

Corporate Practice of Medicine

California's ban on the corporate practice of medicine is generally viewed as one of the strictest in the country, preventing hospitals from employing physicians (with very few exceptions). While most hospitals nationwide may be able to use the *bona fide* employment exception to save compensation arrangements in which compensation is not "set in advance" or is not set forth in writing, very few hospitals in California have that option. Accordingly, an alternative is necessary to allow legitimate arrangements to meet a Stark Law exception.

Nonprofit Medical Foundations

Many hospitals in California use an alternative to physician employment, based on California Health & Safety Code Section 1206(l). Under this model, a nonprofit entity that is tax-exempt under Section 501(c)(3) of the Internal Revenue Code, which could be the hospital itself or an affiliate (this entity is generally referred to as a "medical foundation"), operates a medical clinic staffed by a group of 40 or more physicians. These physicians cannot be employed by the medical foundation. However, they are generally employed instead by a medical group aligned with the medical foundation, and the group and its physicians typically agree to practice exclusively through the medical foundation, and reassign to the medical foundation their right to bill Medicare for their professional services. The prevalence of this model in California makes the analysis of indirect compensation arrangements extremely important to California hospitals.

Health Plans and the Delegated Model

California has an advanced and well-developed model of delivering health care services in a managed care environment, often referred to as the “delegated model” because California health plans *delegate* financial risk to physicians and hospitals. Health plans generally delegate risk by paying providers a fixed per-member, per-month “capitated” amount, in exchange for which providers agree to accept responsibility for providing or arranging for the covered services required by those members. Another variant is the accountable care organization-type (ACO) model, in which providers are paid fee-for-service, but actual expenditures are compared to a per-member, per-month budgeted amount, and the providers receive a share of savings (or owe a share of costs overruns) based on periodic comparisons of the actual expenditures to the budgeted amounts. Importantly, however, under both of these models providers are permitted to accept risk only for the services for which the providers are licensed. In other words, physicians may accept financial risk only for professional services, and hospitals may accept risk only for institutional services. This is because under California’s Knox-Keene Health Care Services Plan Act of 1975 and its implementing regulations, any party that accepts risk for both institutional and professional services (referred to as “global risk”) must be licensed as a health care services plan. Securing a health care services plan license, however, is complex, time consuming, and expensive, and is well beyond the reach of most hospitals, physician groups, or even advanced ACOs or provider networks. For this reason, we request some refinements be made to the proposed value-based exceptions that will permit advanced, at-risk California provider networks to qualify for these exceptions.

Proposed Value-Based Exceptions

CHA appreciates CMS proposals to facilitate the development of desirable and innovative value-based arrangements. CHA encourages CMS to consider the following important refinements to eliminate unintended obstacles that many providers, *especially in California*, will likely experience in attempting to satisfy the proposed exceptions, as currently drafted.

Full Financial Risk

CMS proposes an exception that permits certain arrangements if the value-based enterprise is at “full financial risk,” defined to mean the value-based enterprise is financially responsible on a prospective basis for the cost of “all patient care items and services” covered by the applicable payer for each patient in the target patient population for a specified period of time.

However, it **might not be possible to satisfy this standard in California**. As addressed in the “Health Plans and Delegated Model” above, in California only licensed health plans are permitted to take prospective risk for the cost of all patient care (other states also might allow only health plans to take full risk). A value-based enterprise, even consisting of providers that had banded together, would be unable to satisfy this exception without becoming a licensed health plan. Becoming a licensed health plan is an enormously expensive and time-consuming process, well beyond the reach of most hospitals, and would entail a fundamental restructuring of the parties’ arrangements.

A secondary issue in this definition is the phrase “**all** patient care,” which potentially forecloses the possibility of excluding certain high-cost or specialty services. It is very common, however, even in the most advanced value-based arrangements, for provider-organized, value-based arrangements to forgo financial responsibility for selected services (e.g., organ transplant or pharmacy benefits). **In other**

words, the “full financial risk” exception unreasonably limits the range of “at risk” arrangements that it protects.

Therefore, as an alternative to the current wording, CHA urges CMS to modify the definition to clarify that the value-based enterprise and its participant, may be “collectively” responsible for the cost of “substantially” all patient care items and services (not all), and clarify that each provider participant (or provider type) can be responsible for services it is licensed to provide, as long as they are collectively at risk for “substantially all” patient items and services. CHA suggests defining “substantially all” to mean at least 75% of the cost of all patient care items and services.

If a value-based enterprise is collectively at risk for substantially all services furnished to the target patient population, there should be little risk of program or patient abuse, compared to being at risk for all services. If a hospital is at risk for hospital services, it has an enormous stake in a value-based enterprise, as all of its potential revenue is at risk. There is no need to have it also financially at risk for services furnished by professionals. Also, being at risk for 75% or more of services should be viewed as “substantially all” by CMS, consistent with prior interpretations — such as used by CMS in the definition of “group practice” at 42 CFR § 411.352(d) and (h).

In addition, an arrangement should qualify for full risk if the value-based enterprise or its participants are at full financial risk for the items and services to which the protected remuneration relates.

CHA also recommends that CMS consider adding a value-based, risk-sharing exception comparable in scope to the current risk-sharing exception. More specifically, CHA urges CMS consider the following:

“Compensation pursuant to a risk-sharing exception (including but not limited to withholds, bonuses, and risk pools), between a value-based enterprise at full financial risk (either directly or indirectly, through its participants, acting collectively) and a physician (either directly or indirectly through a subcontractor) in connection with items or services provided to patients who are part of a target patient population.”

Meaningful Downside Risk

There is a proposed exception permitting certain arrangements if the value-based enterprise is at “meaningful downside risk” per two proposed definitions, one of which requires that the physician is potentially financially responsible for paying the entity no less than 25% of the value of remuneration the physician receives.

CHA applauds the inclusion of this exception, but urges CMS to consider lowering the threshold from 25% to 10%. CHA believes that setting a 10% threshold still reflects a “meaningful” risk level and will encourage more parties to enter into value-based arrangements. In particular, for physicians who have not yet participated in a risk-based payment model, having 25% of compensation at risk may not be palatable until they gain some experience and comfort with this type of arrangement.

In addition, CHA urges CMS to modify the wording in light of operational realities to provide that at least the threshold percentage of the physician’s aggregate potential compensation must be at risk, based on actual performance compared with the value-based enterprise’s objective performance metrics. As a practical matter, it is extraordinarily rare to encounter arrangements in which physicians are paid first, and then expected to return part of the compensation after the fact, if the physician has

not satisfied certain subsequent conditions. In fact, for those rare situations where California hospitals employ physicians, California employment law makes it virtually impossible for an employer to recoup compensation previously paid.

Value-Based Arrangements Exception

The proposed “Value-Based Arrangements” (no financial risk required) exception should be finalized as proposed. This is the only one of the three exceptions that does not require the acceptance of significant risk. Maintaining that option is essential to spur the shift to value-based payment models across the spectrum of hospitals and communities.

Further, CHA does not support any of the alternatives discussed in the proposed rule, each of which would dramatically reduce the utility of the exception. More specifically:

- The exception should **not** be limited to nonmonetary remuneration, as doing so would preclude commonplace structures, such as financial incentives, that encourage adherence to care protocols and shared savings models.
- It should **not** require 15% (or other) cost sharing by value-based arrangement participants. The requirement would preclude a host of innovative value-based arrangements and take a disproportionate toll on small and rural physician practices, which are a key component in successfully improving care across patient populations.
- It 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.

Price Transparency

CMS asked for comment about whether the value-based exceptions should require price transparency. The answer is emphatically no. Price transparency is a completely unrelated topic, best addressed separately. Mixing price transparency into the value-based exceptions only complicates, rather than promotes, provider adoption of value-based arrangements.

In short, adding a price transparency requirement introduces an additional regulatory barrier to coordinated care, resulting in a significant disincentive in accelerating the move to value-based arrangements. This is directly counter to one of the overall goals of the proposed rule: removing regulatory barriers to encourage providers, suppliers, and physicians to enter into innovative arrangements that improve quality outcomes and efficiencies, and lower costs.

In addition, as a general matter, price transparency raises a number of legal issues including, without limitation, anti-competitive concerns with respect to disclosure of confidential negotiated rates with payors. As outlined in CHA’s [comments](#) to CMS on the FFY 2020 outpatient prospective payment system proposed rule, the agency is acting outside its legal authority in requiring hospitals to disclose confidentially negotiated rates with payers. CHA supports efforts to ensure that patients have timely access to estimates of out-of-pocket costs for health care services, but that - information is best provided by their health plan. It is important to note that California’s hospitals already provide consumers with significant information on their estimated costs for health care services, but publicly

posting privately negotiated rates could, in fact, undermine the competitive forces of private market dynamics, and result in increased prices.

Other Comments – Value-Based Exceptions

In addition, CHA supports the four types of value-based purposes on which an arrangement may be based and the latitude to choose any one of the purposes to focus on coordinating/managing care, improving quality, appropriately reducing costs, and transitioning to service delivery and payment based on quality and control of costs. CHA supports CMS finalizing as proposed with one modification: “Appropriately reducing costs” also should include cost reductions for providers participating in the arrangement, the benefit of which will extend to the Medicare program and improve value overall. It should not be limited to reducing the costs of payers. CHA does not support CMS’ proposed alternative to require that care coordination or management be a condition for protection.

Isolated Financial Transactions; Proposed Isolated Payment Exception

The regulations currently provide an exception for remuneration paid to physicians as part of an “isolated financial transaction” so long as certain requirements are satisfied. One requirement is that the transaction involves only a single payment, consistent with fair market value, for the items or services provided. Because the exception does not require the arrangement to be in writing, it has long been used by health care providers to protect unwritten arrangements of various types, including the provision by physicians of services over a period of time, so long as the compensation paid in connection with the arrangement entails only a single payment.

The proposed rule asserts that the isolated transactions exception is not intended to protect arrangements where a party makes a single payment for services provided over a period of time. The proposed rule would modify the definition of “isolated financial transaction” to include a statement that an “isolated financial transaction” cannot include “a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).”

Although this new interpretation is discussed in the proposed rule as a “clarification” of existing policy, it has never been advanced by CMS in the rulemaking process or other formal guidance to the health care industry. This “clarification” represents a significant departure from the plain meaning interpretation of the exception that has been widely held within the field, and we urge CMS to reconsider.

The Stark regulations currently define a transaction as “an instance or process of two or more persons or entities doing business,” meaning that the term “transaction” includes not only “instances” of business, but also a “process.” The term “process” suggests an ongoing arrangement in which two or more parties are “doing business.” Under the current regulations, the definition of a “transaction” is subsumed within the definition of an “isolated financial transaction,” which means “one involving a single payment between two or more persons or entities...” Both the statute and regulation provide examples of “isolated transactions” that include the one-time sale of property or a practice, but these are offered only as examples, without any indication or suggestion that they are intended to be exhaustive. Accordingly, the plain wording of the regulations, as currently written, in no way prohibits a single, fair market value payment for services performed over a period of time (assuming the other requirements of the exception are satisfied).

It is absolutely critical to recognize that there is no harm that this new interpretation remedies, nor any existing problem that it solves. To the contrary, it exposes well-meaning providers to draconian penalties simply because physicians have begun (or have chosen to continue) to care for patients during the period of days, weeks, or months it may take to finalize the terms of their contractual arrangement. The parties are proceeding notwithstanding that negotiations on final contractual terms are in progress, rather than refraining from providing patient care until the terms are finalized. We do not believe CMS intends to punish this type of conduct but, without change, it will have such an effect.

An example of such a circumstance could be where a hospital's exclusive professional services and coverage agreement with an anesthesiology medical group is on the verge of expiring. The medical group is owned by the anesthesiologists that provide services at the hospital. The parties intend on continuing the relationship but, despite good faith efforts to reach a resolution, disagree as to the amount of compensation increase for the renewal term. Such agreements often have complex compensation methodologies, including a potential compensation guarantee, consideration of the number of professionals needed to staff the operating rooms, productivity compensation, and quality incentive bonuses; thus, they can take significant time to negotiate. The medical group continues to provide services to ensure uninterrupted care, without payment, with the understanding that the parties will continue to negotiate and get an opinion from a valuator to confirm the final compensation methodology is within fair market value. Under such circumstances, there is no harm to the Medicare program or Medicare beneficiaries. However, because the compensation is not "set in advance" and will likely total over \$3,500 for the time period during which negotiation is completed, there would be no exception upon which the parties could rely if the proposed regulations are finalized as written.

Another example could be where a hospital executive engages a specialist physician to consult on implementation of a new clinical specialty application to be integrated into the hospital's electronic medical records platform. The executive tells the physician that the hospital will pay a fair market value hourly rate, but no written agreement is executed for any number of reasons (e.g., the executive leaves the organization abruptly or the proposed letter agreement is misdirected due to an error in the physician's email address). The physician nonetheless in good faith provides several hours of consulting services to the hospital's information technology department, resulting in a more refined application that makes it easier for physicians in the specialty to capture significant data in patient medical records. In this case, under California law, the physician would have a bona fide claim against the hospital for payment based on a verbal contract, quantum meruit, and detrimental reliance – legal theories that allow a party who has in good faith provided services to another to recover the fair market value of those services. The hospital is faced with either paying the physician to avoid a compelling lawsuit by the physician, or arranging for a refund of all amounts paid by the Medicare program for designated health services billed by the hospital which were referred by the consulting physician. So long as any payment to the physician for the services provided does not exceed the fair market value of those services, a negotiated settlement of the physician's claims should be permitted under the one-time transaction exception and would not result in an additional charges to the Medicare program or harm to Medicare beneficiaries.

Moreover, **this issue is most acutely felt in states such as California with strong corporate practice of medicine restrictions.** In many other states, if physicians begin providing services for a hospital before the details of the contract have been worked out because there are pressing patient care needs, there is a ready solution: these hospitals can treat the physicians as employees for the interim period, because

the *bona fide* employment exception does not require either that compensation be set in advance or a written agreement. Accordingly, it is acutely important that the isolated transaction exception be interpreted by CMS in the same way it has been interpreted heretofore by those adhering to its plain wording, to permit a single payment at fair market value to cover services performed over a period of time.

CHA does not support CMS' proposed revisions to this exception and believes the agency should continue to allow the exception to be interpreted in accordance with its plain wording, as outlined above.

If CMS does not reconsider and allow for the isolated transaction exception to apply in circumstances such as those described above, ***CHA strongly urges CMS to exercise its rulemaking authority under 42 U.S.C. § 1395nn(b)(4) to adopt a new exception in 42 C.F.R. § 411.357 as follows:***

(cc) Isolated Payments. An isolated payment, such as a one-time payment in exchange for services provided or settlement of a *bona fide* legal dispute, if all of the following conditions are met:

- (1) The amount of the remuneration included in the one-time payment is –
 - (i) Consistent with the fair market value for the items or services provided; and
 - (ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.
- (2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.
- (3) There are no additional exchanges of remuneration between the parties for 6 months after the isolated payment is made, except for remuneration in the context of services or financial relationships that are specifically excepted under the other provisions in §§ 411.355 through 411.357.

Adopting such an exception would avoid the significant detrimental effect on hospitals in California (and other states that prohibit employment of physicians), as well as protect other legitimate arrangements that might not fit within the employment exception.

Notably, this proposed exception contains the three fundamental safeguards that apply in many of the applicable exceptions: the compensation must be fair market value, commercially reasonable, and not take into account the volume or value of referrals or other business generated, thereby providing sufficient safeguards against potential abusive arrangements. While this proposed exception does not require that the arrangement be in a signed writing, several exceptions do not include such a requirement.

CHA believes CMS has the authority to make such a change if necessary. Under 42 U.S.C. § 1395hh(a)(4), if a final regulation includes a provision that is “not a logical outgrowth of a previously published notice

of proposed rulemaking or interim final rule,” the provision is treated as a proposed regulation and does not take effect until there is further opportunity for public comment. The provision is then published as a final regulation. CHA believes that the adoption of this new exception should be considered a “logical outgrowth” of the proposed rule, as it stems from discussion in the preamble regarding the widespread industry interpretation of the isolated transactions exception. Further, it could be anticipated that CMS would either retract its initial proposal based on stakeholder feedback or otherwise amend regulations to incorporate such feedback.

Limited Remuneration to a Physician

CHA appreciates the inclusion of a proposed new exception for limited remuneration to a physician to provide flexibility for non-abusive business practices. As noted by CMS, a variety of facts and circumstances could lead to an arrangement that does not satisfy all requirements of an applicable exception. This could occur despite a hospital’s legitimate need for the services and despite compensation being fair market value and not taking into account the volume or value of referrals or other business generated by a physician.

However, CHA believes that the aggregate annual limit of \$3,500 (adjusted for inflation) under this proposed exception is far too low to accommodate non-abusive compensation arrangements.

For example, \$3,500 could be too low if a hospital has a sudden and immediate need to secure restricted emergency department or psychiatric unit on-call coverage (e.g., when another physician is unexpectedly unavailable and there is an acute shortage of such specialists locally). Under such a scenario, it is possible that, due to the urgency of the need, the physician would agree to start providing services while the parties negotiate or seek to determine the appropriate compensation, and then reduce the arrangement to writing. Restricted call coverage of this type could reasonably exceed \$3,500 for a weekend, or even a single day (depending on specialty, patient mix, type of hospital, demands on physicians, etc.), and the parties would not have the time to reach an agreement on the details of the arrangement before the \$3,500 limit is reached in order to meet another applicable exception.

This issue is particularly acute in California, where few hospitals can employ physicians, particularly if CMS also finalizes its proposed modifications to the isolated transactions exception. In other states, if a physician begins providing services while details of a contract are worked out, the hospital can simply employ the physician.

In addition to increasing the fixed dollar amount of the cap, CHA also believes it is sensible to add a flexible standard (e.g., tied to a percentage of the physician’s annual income) as, presumably, the importance to a physician of a particular payment is influenced by the dollar amount and by the relative portion of the physician’s total compensation.

Accordingly, CHA proposes replacing proposed 42 C.F.R. 411.357(z)(1) with the following:

Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed the greater of an aggregate of \$10,000 per calendar year (as adjusted for inflation in accordance with paragraph (z)(2) of this section) or an amount not to exceed ten percent (10%) of the physician’s total cash

compensation from the entity or the entity's affiliates in the most recent fiscal year, if all of the following conditions are satisfied

In addition, CHA urges CMS to strike proposed 42 CFR 411.357(z)(1)(v). This provision appears to render a financial relationship ineligible for this exception if compensation “for the use of premises, equipment, personnel, items, supplies, or services” is determined using a formula based on a percentage of revenue or, under some circumstances, determined using a formula based on per-unit of service fees that are not time-based. The regulation text may be intended to address timeshare arrangements or other arrangements similar to a traditional office space or equipment lease, but the proposed language is so broadly drafted that its scope is entirely unclear and should be removed. Further, **it is unclear why this restriction on compensation methodology is included in this exception. It does not appear in any other Stark Law exception. Additionally, the restriction is completely unnecessary, since the exception already includes the restriction on compensation for lease of office space or equipment that appears in other exceptions.**

Fundamental Terminology and Requirements

CHA generally supports the proposed revisions to provide further clarity regarding application of certain fundamental terminology, but suggests additional refinements. In addition to addressing proposed revisions regarding fair market value, commercial reasonableness, and taking into account the volume or value of referrals or other business generated, this section also includes comments on the concept of set in advance.

Fair Market Value

CHA appreciates the flexibility of the proposed new definition but is concerned about whether it has inadvertently created confusion and uncertainty.

As we understand it, the traditional analysis of whether an arrangement was considered fair market value was based on the perspective of a hypothetical buyer and seller, while the new definition is based on the perspective of the actual buyer and seller in the arrangement being evaluated. CHA is concerned that allowing the parties' special circumstances to determine fair market value could expose the parties to second-guessing about whether those circumstances included consideration of illegitimate factors. Likewise, we are concerned about parties potentially losing the touchstone of being able to rely on an objective determination of fair market value, based on a hypothetical buyer and seller.

The challenge of establishing fair market value is particularly acute for small, independent hospitals or health systems with limited resources. In some instances, small rural hospitals may need to compensate a physician above what would be considered fair market value based on use of published surveys, in order to recruit a physician to relocate to the region and fill a dire patient need. CHA appreciates the flexibility that the proposed definition provides to account for these particular circumstances. However, CHA is concerned about the impact of the example in the preamble, which states that a small hospital could be overcompensating a physician when using published surveys if the hospital is located in an area where the cost of living is low with close proximity to good schools and desirable recreational opportunities, and the hospital has a poor payer mix, declining reimbursement rates, and a tenuous economic position. Making this assessment requires a knowledge of valuation principles, along with other time and resources, that may not be available to a small, rural hospital when evaluating each of its physician relationships. Many rural hospitals do not have the option of engaging a valuation firm (which

can be expensive) and may not have internal resources to appropriately quantify the value of the local school district, recreational opportunities, or other factors in assessing physician compensation in this nuanced fashion.

To assist small and rural hospitals, CHA encourages CMS to clarify that, if an arrangement is fair market value based on a hypothetical buyer and seller, then it is deemed fair market value under the Stark Law's new definition of fair market value. In addition, if an arrangement is consistent with fair market value based on the actual parties and the particular transaction being considered, it satisfies the Stark Law definition of fair market value, even if it would not be fair market value to a hypothetical buyer and seller. This will provide safety, certainty, and greater flexibility.

In addition, CHA also urges CMS to adopt a rebuttable presumption that compensation is fair market value if (1) a party has secured a fair market value opinion from a qualified, independent valuation expert before the agreement with a physician commences, and (2) the compensation is between the 25th and 75th percentiles, for the applicable specialty, based on an average of three or more physician compensation surveys selected from the most recently published annual compensation data from MGMA, Sullivan Cotter, ECG Management Consultants, Medscape, Merritt Hawkins, and AMGA.

Taking Into Account the Volume or Value of Referrals or Other Business Generated

CHA greatly appreciates CMS's efforts to propose a bright line test for determining whether remuneration takes into account the volume or value of referrals or other business generated. To provide further clarity, CHA requests that CMS further modify the proposed special rule at 42 C.F.R. § 411.354(d)(5)(i)(A) as follows:

The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a written or otherwise expressly articulated variable....

CHA also requests similar modifications to section (d)(5)(ii)(A), regarding other business generated. In addition, CHA proposes similar modifications to sections (d)(5)(i)(B) and (d)(5)(ii)(B), to provide that there "is a written or otherwise expressly articulated predetermined, direct correlation" between a physician's prior referrals or other business generated and the prospective rate of compensation. **While the preamble provides helpful insight about application of the proposed provisions, based on the proposed regulatory language itself it is currently unclear how the formula or predetermined correlation would be assessed. It is possible that the language could be interpreted to introduce an element of subjective intent. CHA's requested modification would help provide further clarity. In addition, CHA requests that an express statement be added that, for purposes of applying paragraph (d)(5), the test is not one of subjective intent.**

Set in Advance

In the spirit of providing additional flexibility and bright-line tests for providers with respect to non-abusive arrangements, CHA urges CMS to include an additional deeming provision in 42 C.F.R. § 411.354(d).

The provision would state that compensation is considered "set in advance" if: (1) the parties have agreed in advance that compensation will be fair market value without taking into account the volume

or value of referrals prior to commencement of an arrangement, (2) the parties work with reasonable diligence to establish the specific compensation amount or methodology, (3) the parties in fact establish the specific compensation amount or methodology within 90 days of commencement of the arrangement, and (4) the resulting compensation, once established, is fair market value and commercially reasonable without taking into account the volume or value of referrals or other business generated.

So long as the compensation is ultimately fair market value and commercially reasonable, and both parties have agreed in advance to these conditions of the arrangement, there would be no harm to the Medicare program or Medicare beneficiaries.

At the same time, this proposal addresses an issue that is particularly acute in California because few hospitals can use the *bona fide* employment exception (which has no “set in advance” requirement). This issue is further problematic if CMS also finalizes its proposed modifications to the isolated transactions exception. As addressed in prior sections, negotiation of the compensation methodology can be complicated and take time to finalize, and it may not be possible to determine a mutually agreeable, fair market value methodology in the time needed to meet patient care needs.

Indirect Compensation Arrangements and Applicable Exceptions

Indirect Compensation Arrangements

Although not addressed in the preamble, the proposed regulations include revisions to the definition of an indirect compensation arrangement which omit the phrase “varies with.” The applicable test would, therefore, be whether the “aggregate compensation takes into account the volume or value of referrals or other business generated.” CHA appreciates this proposed revision and strongly supports the change.

CHA also greatly appreciates the reaffirmation of CMS’ longstanding position that physician compensation arrangements (whether employment or independent contractor relationships) which compensate a physician for his or her personally performed services using a unit-based compensation formula do not take into account the volume or value of the physician’s referrals or other business generated. As noted in the preamble, aggressive relators and recent case law in the False Claims Act context have exacerbated the challenge of complying with the Stark Law. This has created compliance uncertainty regarding legitimate arrangements with standard compensation methodologies that pose no risk to the government or to patients.

CHA respectfully requests that CMS discuss in the final rule the following example to facilitate shared understanding between CMS and providers that compensation arrangements based on personal productivity would not meet the definition of an indirect compensation arrangement. By way of example, we provide the following scenario:

The sole corporate member (the “Parent”) of a nonprofit medical foundation which owns and operates a multi-specialty clinic (the “Foundation”) is also the sole corporate member of a general acute care hospital (the “Hospital”). The Hospital and the Foundation have entered into a master professional services agreement whereby the Foundation agrees to provide emergency department and inpatient coverage and

consultation, including in the specialty of cardiology, to the Hospital in exchange for a fee. The Foundation then contracts with a cardiologist to provide full-time, exclusive services at the clinic as well as coverage at the Hospital, and pays the cardiologist a base compensation and a productivity bonus – e.g., a fair market value, fixed dollar amount per wRVU beyond a threshold level. The Hospital bills Medicare Part A as appropriate. The Foundation bills Medicare Part B as appropriate (the cardiologist has reassigned her right to bill Medicare Part B to the Foundation). The cardiologist is a referral source for the Hospital. There is a chain of relationships between the Hospital and the cardiologist, and each time the cardiologist performs a service on behalf of the Foundation in a hospital setting, the hospital bills for the corresponding designated health services.

CHA believes it is correct to assume that, under the proposed regulations, a “correlation” between compensation for the cardiologist’s personally performed services and the Hospital’s designated health services revenue for the referred services is not sufficient, on its own, to create an indirect compensation arrangement. Although the cardiologist’s aggregate compensation varies with the volume of referrals, it does not take into account the volume or value of referrals.

Applicable Exceptions for Indirect Compensation Arrangements

The proposed regulations state that, except for the special rule for indirect compensation arrangements involving value-based arrangements, only the exceptions at §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements. The preamble to the proposed regulation states that “[n]o other exception in § 411.357 is applicable to indirect compensation arrangements.”

CHA requests that CMS consider expanding the indirect compensation arrangements exception under 42 C.F.R. § 411.357(p). CHA understands and appreciates clarification with respect to applicable exceptions. However, there are unintended, negative consequences if this proposed provision is finalized as drafted. **In short, the result would be that indirect compensation arrangements are subject to a more restrictive exception than direct compensation arrangements under certain circumstances. There is no reason to provide a more stringent standard for indirect compensation arrangements, but there should be more flexibility.**

For example, if a physician and hospital have a direct compensation arrangement they could, where appropriate, rely on 42 C.F.R. § 411.357(z) (the new proposed exception for limited remuneration), 42 C.F.R. § 411.357(g), or any other exception in 42 C.F.R. § 411.357 that does not include a requirement that the arrangement be in a signed writing.

In contrast, if a physician and a hospital have an indirect compensation arrangement, under the current indirect compensation arrangements exception, the only type of arrangement that does not need to be in writing is an employment arrangement. For example, if a hospital has an indirect compensation arrangement with a physician via a medical foundation, and the medical foundation compensates the physician \$500 for providing short-term services outside of the parties’ written agreement, the parties could not rely on the proposed exception for limited remuneration and would not meet the indirect compensation arrangements exception.

Accordingly, CHA proposes that CMS consider the following modification to the indirect compensation arrangements exception at 42 C.F.R. § 411.357(p)(2):

The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except: (i) in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; or (ii) in the event that the compensation arrangement meets the requirements of §§ 411.357(g), (i), (k), (o), or (z).

Special Rule on Writing and Signature Requirements

CHA supports the proposal to incorporate a special rule for noncompliance with the writing requirements to provide additional flexibility for non-abusive financial relationships. CHA also appreciates CMS's guidance that "records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance," as well as CMS' statement that parties could look to the following items to establish that compensation was set in advance: emails, texts, internal notes to the file, or similar payments between the parties or documents recording similar payments to similarly situated physicians.

However, there remains some uncertainty about how parties can establish that compensation is set in advance if there is not a writing and there has not been a steady, consistent stream of payments. For example, it is not clear how much detail must be included in emails or texts to support that compensation is set in advance. And in many cases negotiation of the compensation terms between hospital leadership and physicians may have occurred only during in-person conversations, meaning there is no paper trail to refer to.

In addition, out of an abundance of caution, some hospitals will not issue payments to referral sources until the arrangement is set forth in a signed writing, so that legal or compliance departments can review the arrangement. In such cases there is not a prior stream of steady payments to rely on. Further, while use of a fee schedule or comparison to other similar arrangements may be useful for a simple medical director or on-call coverage agreement, in many instances compensation methodologies are more complicated and are customized to the specific relationship.

While CHA applauds the inclusion of this special rule overall, CHA also urges CMS to adopt the following two modifications:

First, CHA requests that CMS adopt the proposal regarding "set in advance," as discussed above.

Second, CHA urges CMS to include a provision in proposed 42 C.F.R. § 411.354(e)(3)(i) that a compensation arrangement is deemed to comply with an applicable exception, except with respect to the writing or signature requirement, if the parties memorialize in the signed writing that the parties met all other elements of the exception as of the commencement date of the arrangement. If the parties are willing to attest in a signed writing that the compensation was set in advance (to the extent

required), and the arrangement otherwise meets an applicable Stark Law exception, CHA believes it is reasonable to rely on such attestation and infer that all applicable requirements were met. Notably, an additional safeguard against abuse exists because, if a person were to attest that all elements were met in a signed writing knowing the attestation is false, the person could have potential exposure under the False Claims Act. Such information would be useful as evidence to establish the requisite scienter under that law.

Third, CHA recommends that the personal services exception at 42 C.F.R. § 411.357(c) be updated to remove the contract cross-reference and/or master list requirement. The master list requirement is inconsistent with the recent statutory changes that allow for a “collection of documents” to establish a writing.

Electronic Health Records Items and Services

As a general matter, CHA greatly appreciates the removal of the sunset date for this exception. CHA requests consideration of further modifications to the exception to provide flexibility for providers while continuing to safeguard against abuse.

CMS has requested comments on whether the 15% contribution requirement should be reduced or eliminated, and whether such a reduction or elimination would impact the use and adoption of EHR technology. CHA urges CMS to eliminate this contribution requirement as an unnecessary obstacle to the spread of EHR technology, particularly given all of the other safeguards against abuse contained in the exception. Care teams need ready access to information necessary to make informed decisions about patient care. In today’s world, this requires building and maintaining electronic systems for securely transmitting information and making it available to support those caring for the patient across care settings, among professionals, and over time, including providing electronic health record (EHR) technology and support services to physician practices. The requirement that a recipient contribute 15% of the cost for the donation of EHR technology and related services unreasonable constrains how hospitals finance needed infrastructure to implement new value-based payment models and promote coordination of care, and it is an obstacle to the spread of EHR technology.

Finally, CHA urges CMS to consider deleting 42 C.F.R. § 411.357(w)(8), consistent with the Office of the Inspector General’s proposed revisions to the corresponding safe harbor to the federal anti-kickback statute, to provide additional flexibility regarding replacement technology to protect against physician practices being locked into a vendor that may be providing subpar services. CHA notes that CMS has stated its goal is to ensure as much consistency as possible between this exception and the corresponding safe harbor.

CHA appreciates the opportunity to provide CMS with comments on the proposed rule. If you have any questions, please contact me at akeefe@calhospital.org or (202) 488-4688, or my colleague Jackie Garman, vice president, legal counsel, at jgarman@calhospital.org or (916) 552-7636.

Sincerely,

/s/

Alyssa Keefe

Vice President, Federal Regulatory Affairs