Memorandum to Physician Clients and Advisors
January 1, 2022 Deadline to Amend Physician Compensation Plans
for New Stark Law Changes

The following article is based upon our understanding of hundreds of pages of regulations, preambles and explanations.

There is a good chance that something we say in this article will not be absolutely correct. We will be updating this article in the future (stay tuned!).

As most physicians and physician advisors relating to group medical practices are aware, the Stark Law was amended in 2020 to change how compensation arrangements within group medical practices must be arranged in order to be able to bill Medicare for Designated Health Services (DHS).

The newly promulgated rule described below will not be effective until January 1, 2022.

The primary focus and impact on the Stark Law for group medical practices is the way that doctors working in the practice can be compensated with reference to their referrals or work on Designated Health Services.

For example, a doctor in a practice that bills Medicare cannot be compensated, directly or indirectly, based upon his or her referrals of patients to receive such Designated Health Services, except to the extent attributable to a reading fee or physician service that may be billed globally with the Designated Health Service.

Designated Health Services are as follows:

a. Clinical laboratory services

b. Physical therapy, occupational therapy, and outpatient speech-language pathology services

c. Radiology and certain other imaging services.

d. Durable medical equipment and supplies.

e. Parenteral and enteral nutrients, equipment, and supplies.

f. Prosthetics, orthotics, and prosthetic devices and supplies.

g. Home health services.

h. Outpatient prescription drugs.

i. Inpatient and outpatient hospital services.

The new rule will apparently apply to DHS income from services that are performed after 2021. For example, in January of 2022 practices will receive payment for many 2021 DHS, which may be distributed based upon the prior rules, while revenues received from 2022 DHS can be distributed under the new rules. It is somewhat difficult to draft documents and administer monies based upon the year that services were rendered, but some practices may elect to do so, while most will likely apply the new rules to all 2022 revenues, regardless of what year services were rendered.

Under the new rules, which will be effective on January 1, 2022, the main changes reflect that:

Change #1: Overall profits from DHS can be shared, not a percentage of revenues.

Doctors can be compensated based on overall profits from DHS when properly arranged, but not gross revenues.

Some practices currently have compensation arrangements where each doctor in the practice receives a certain percentage of all revenues derived from one or more DHS, such as each doctor in a five doctor practice receiving 10% of revenues derived from ultrasounds given in the practice.

Effective January 1, 2022, the doctors will only be able to be compensated for DHS based upon net "overall profits" attributable thereto. These profits must be divided in a reasonable and verifiable manner not directly related to the volume or value of a physician's referrals for DHS.

Additionally, these profits must be aggregated prior to any payment to physicians (doing away with the practice's ability to allocate distributions differently for each kind of DHS).

Regulations are surprisingly sparse for what the definition of "overall profits" will be. Comments to the proposed rule even identified the lack of direction to which the response again identified the necessity for calculation of overall profits to not be based on volume or value.

There are entire textbooks and graduate schools courses on the concept of "cost accounting" and how direct and indirect costs are allocated to separate and related businesses and endeavors.

The entire treatment of the term "overall profits" in the new regulations is as follows:

§ 411.352 - Group Practice. ...

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

The entire treatment of "overall profits" under the preamble and explanation is as follows:

> ...overall profits means "the profits derived from all the designated health services." Thus, the profits from all the designated health services of any component of the group that consists of at least five physicians...must be aggregated before distribution. To illustrate, suppose a physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients in a centralized building ... or a location that qualifies as a ''same building''.... If the practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians.
>
> We are cognizant that under the requirement...the overhead expenses of, and income from, a practice must be distributed according to methods that are determined before the receipt of

payment for those services giving rise to the overhead expenses or producing the income.

This new rule will cause a significant hardship for many practices, because the definition and calculation of "overall profits" can be somewhat complicated, especially since the compensation arrangements are typically planned prospectively.

Most medical practices develop compensation arrangements yearly, which is why the final rule does not go into effect until January 1, 2022, even though it was issued January 19, 2021.

For example, an ultrasound machine may be owned by the practice, but can be depreciated whereby its cost is amortized over a period of time, such as seven years.

Alternatively, an ultrasound machine might be leased from an unrelated third party, so that the lease payment would be a cost of operation.
An ultrasound technician might spend 35% of his time doing ultrasound work in the practice, and 65% of his time doing other things.

The ultrasound tech's compensation costs includes not only salary, but employment taxes, insurances, Workers' Compensation and pension contributions.

The ultrasound machine may occupy a room in the practice that uses air conditioning and electricity, so rent, electricity, office insurances and janitorial expenses would need to be allocated as costs in the determination of net profit.

In addition, the billing department of the practice bills and tracks receipts and does follow-up work that must also be taken into account.

Many practices will wonder if it is even worth the expenses of keeping track of "overall profits" when such profits are not required to be distributed to the physicians. However, the vagueness found within these definitions may be good news for medical practices that would like to make the calculation of net profits simpler than what might otherwise apply.

Change #2: Physician compensation on DHS profits must be calculated equally.

Any medical group that bases physician compensation on DHS profits must do so by allocating all DHS profits using the same formula, which must be established

in advance and not take into account the volume or value of referrals. Many medical practices have divided income or revenues for one or more DHS's in different ways.

For example, if one physician in the group produces 65% of the professional service fees and the other physician produces 35% of the professional fees, the ultimate distribution of x-ray revenues for the practice may be based upon 65%/35%, while ultrasound profits might be divided equally.

The new rule would require that all DHS profits (including the above referenced x-ray and ultrasound profits) would have to be allocated based upon one method of determination.

An example applying current practices, revenue from a blood lab might be shared 90% equally among the primary care doctors in a multi-specialty practice, and 10% equally among the surgeons, while physical therapy revenues might be shared 80% among the surgeons and 20% among the primary care doctors.

Under the new rule, this practice will have to share the overall profits from all DHS in the same proportion for each physician within each pod of five or more physicians, or the entire practice if no pods are designated. Pods of five physicians can be designated when the group practice contains ten or more physicians, and each pod may use a different formula or method of determining the DHS profit sharing. An entity may not compensate a physician based directly or indirectly on the volume or value of that physician's referrals.

For medical practices having fewer than ten doctors, this means that the profits of DHS that are shared must all be shared in accordance with the same formula. Referring back to the above example, the surgeons may receive 60% of all DHS overall profits for physical therapy and blood lab in equal shares, and the primary care doctors may receive 40% of all such DHS items in equal shares.

In contrast, if the group practice described above consisted of five surgeons and four primary care doctors, and they add another doctor of any specialty, they can have five doctors who share DHS profits in one way and five doctors who share DHS profits in another way.

If this example group added another surgeon, and therefore had six surgeons and four primary care doctors, they could allow five of the surgeons to share in the DHS profits in one method, and the four primary care doctors and one surgeon to share in the DHS profits another method.

This might mean that the surgeons share equally 80% of the physical therapy and 20% of blood lab DHS profits, and the mixed-physician pod share 20% of the

physical therapy and 80% of the blood lab DHS profits.

Unfortunately, there cannot be a pod of less than five doctors, so one surgeon in the above example will have to be treated differently than the others to comply with these rules.

Pods do not have to be based on any specific criteria, and eligibility standards may be utilized to develop the pods as desired by the medical group. Eligibility standards may be based on whether the physician is an owner, employee or independent contractor, or how long the physician has been with the group.

The above conclusion is based upon the following excerpt from the preamble to the final rule:

> [A] physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not determined in any manner that *is directly related to* the volume or value of referrals by the physician. We have long interpreted "is directly related to" ... to mean "takes into account[.]"

Change #3: Only Medicare DHS profits are subject to Stark Law.

The Stark Law rules do not apply to Medicaid or Medicare Advantage/HMO plans, TRICARE or other federal programs.

It was widely assumed by conservative health care lawyers and other advisors that the Stark Law applied to federal programs other than Medicare, but the new regulations clarify that this is not the case.

This will have a large impact on medical groups located in states that do not regulate compensation for Designated Health Services.

The vast majority of our physician clients are in Florida, subjecting them to Florida's Patient Self-Referral Act, which is very similar to the Stark Law. Florida's act has the same list of Designated Health Services, except that x-ray is excluded from the list.

Florida physician practices may therefore wish to distribute x-ray revenues or profits to the referring physician, if health care counsel is comfortable that such allocation does not breach any Medicare or Florida "anti-kickback" or "patient brokering" rules.

In the preamble to the finalized rule, the above conclusion was explained as follows:

> We believe that the inclusion of this [Medicaid] reference unnecessarily complicates the regulation.... This is because the definition of "designated health services" includes only those services payable in whole or in part by Medicare....
> For consistency with the definitions and regulations we proposed (and are finalizing here), we [are eliminating] the references to Medicaid in the definition of "overall profits."

This explicit shift away from application to all federally funded payor systems will likely cause Florida providers to change their allocation of x-ray technical component revenue or profit from non-Medicare beneficiaries to be allocated to the referring physician in a medical practice.

Change #4: Value-based exceptions may be utilized for innovative group practice arrangements.

Revenues and profits from Designated Health Services rendered for patients under "value-based" activities will not be subject to the Stark Law limitation.

Apparently, there will be some contractual or medical facility or hospital-related cost and quality assurance programs that physician groups may become involved with such as clinically integrated networks, where insurance carriers monitor costs and outcomes, and may share cost-savings with medical groups.

The new regulations recognize that these arrangements present less risk of abuse and will permit doctors who are in these arrangements to be credited with net profits from designated health services that they recommend, under certain circumstance which are not at all well defined.

This exemption does not appear to be available to the vast majority of medical groups but may present a good opportunity when the smoke clears on what this really is, and how a doctor would be part of this type of arrangement while treating medicare patients.

The regulations confirm that this situation is complex, as follows:

> For example, a shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings represents the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity (or on the entity's behalf). And, when payments are made to encourage a physician to adhere to a redesigned care protocol, such payments are made, in part, in consideration of the physician refraining from

following or altering his or her past patient care practices rather than for direct patient care items or services provided by the physician.

Value-based arrangements are explained in several definitions that have been added as of the promulgation of the new rule taking effect; these terms might be included by health care lawyers, but they seem very confusing to us, and consist of the following:

a. Value-based activity – an activity that is reasonably designed to achieve the value-based purpose of the value-based enterprise;

b. Value-based arrangement – an arrangement for the provision of at least one value-based activity for a target patient population

c. Value-based enterprise (VBE) – two or more participants that collaborate to achieve a purpose, within a value-based arrangement, having an accountable body or person, and records such arrangement with a "governing document" that describes the moving parts thereto;

d. Value-based purpose – this definition contains many prongs to achieve; coordination and management of care of a target patient population, improving quality of care for that population, reducing costs or growth of expenditures and operational oversight for a value-based enterprise, or transitioning from volume-based care models to quality of care and control of costs care models for a target patient population

e. VBE participant – an individual or entity that engages in one or more value-based activities as a part of a VBE; and

f. Target patient population – an identified population selected by the VBE or its participants based on criteria, set out in writing, that is used to further the value-based purpose(s).

Value-based arrangements share a foundation with value-based healthcare delivery: patient care coordination and management.

For example, if a patient undergoes a surgical procedure that requires follow up after discharge by a physician and the performing surgical center, and the surgical center has a value-based purpose of maintaining coordination of care, then the physician's follow up is considered to be a value-based activity. The compensation the physician receives would be from a value-based arrangement.

In an interest to allow for VBE participants to remain innovative in development of value-based delivery of services, CMS directly states that an activity would qualify as a value-based activity when the activity is "reasonably designed to achieve at least one value-based purpose of the value-based enterprise."

There is not requirement that a value-based purpose be achieved, only a good faith belief that the activity would achieve such purpose, to be protected under the applicable exception.

Change #5: Better guidance on exceptions for "Incident To" services.

An "Incident To" service is a service provided under the direct supervision of a doctor.

The final rule discusses "incident to" services within the § 411.352 as follows:

> [Compensation] may directly relate to the volume or value of DHS referrals by the physician if the referrals are for service "incident to" the physician's personally performed services.

While an "incident to" service might be considered to be a DHS, the regulations recognize that when a doctor has to be intricately involved in supervising a particular procedure, test, or other service performed by another physician or non-physician practitioner (NPP), the supervising physician may be compensated as if the service were not a DHS. An "incident to" compensation payment may relate directly to the volume or value of the physician's referrals.

A physician's compensation for "incident to" services is not calculated in the same manner that any other compensation from DHS is calculated. "Incident to" services are paid to a physician in what is commonly known as a productivity bonus.

"Incident to" services are, therefore, relative to the personal productivity of the physician, and not subject to the regulation under Stark Law.

Examples of "Incident To" services that will not be considered DHS for purposes of the Stark Law (meaning that the doctor can receive a productivity bonus as if this was personal service income generated by him or her) are as follows:

a. Physician assigned supervision of chemotherapy suite (as required by Medicare), even without physician's knowledge, considered "incident to" patient's treatment and physician received compensation for chemotherapy suite coverage. (*U.S. ex. rel. Lockyer v. Hawaii Pacific Health*, 490 F.Supp.2d 1062 (D.Hawaii, 2007).)

b. Physician ordered blood lab work that was completed by another practitioner (or NPP) within the same group, and physician is permitted to receive compensation for remaining in the office to indirectly supervise DHS incident to other care by physician.
c. One physician ordered chemotherapy for a patient; another physician was supervising in the chemotherapy suite during the patient's treatment. The second physician may receive compensation for DHS "incident to" their action in supervision.

There are several other instances of "incident to" services that do not have anything to do with the new Stark Law and issued final rule that have been excluded from our discussion.

The many changes coming into effect on January 1, 2022 after issuance of the final rule on January 19, 2021 may cause group practices to scramble here at year end to develop appropriate formulas and designations for Stark Law compliance.

Main ideas to focus on, as discussed, are the changes in the manner of calculating and allocation of overall profits (as opposed to revenues generally) and the specificity of such within the group(s) of physicians in each practice. This may be offset by the explicit exclusion of non-Medicare government funded payor program (Medicaid, TriCare, etc.).

As previously indicated, this article may contain our interpretation that may not be absolutely correct. We encourage you to check back with us for further updates!

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