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Directed Referrals: New Stark Rules

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Under the federal Stark law, hospitals and other healthcare employers may require that employed or contracted physicians refer items or services to the hospital or another designated provider subject to certain limits. (42 CFR § 411.354(d)(4); *see* https://www.hollandhart.com/requiring-referrals-from-employees-and-contractors). Effective January 19, 2021, CMS modified the rules for such directed referral requirements in physician agreements. If they have not done so, hospitals and other providers will need to update their physician agreements if they want to require employed or contracted physicians to refer designated health services to the employer.

1. Conditions for Directed Referrals. The new rules changed the regulatory safe harbors for employment agreements, personal services arrangements, recruitment agreements, group practice arrangements with hospitals, fair market value, indirect compensation arrangements, obstetrical malpractice insurance subsidies, academic medical centers, and the new safe harbor for limited compensation under $5,000. (42 CFR §§ 411.355(e) and 411.357(c), (d), (e), (h), (l), (p), (r), and (z)). Now, if the employer requires that the contracted physician make referrals to the employer or other identified provider, the arrangement must satisfy the following additional conditions:

> If a physician's compensation under a bona fide employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.
>
> (i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.
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> (ii) The compensation is consistent with the fair market value of the physician's services.
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> (iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at §411.355 or §411.357.
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> (iv) The compensation arrangement complies with both of the following conditions:
>
> > (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and

signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(*Id.* at § 411.354(d)(4)).

2. Key Changes. Most of the requirements for directed referrals existed under the former rules; however, the new rules added the following two conditions:

a. Compensation Set in Advance. Unlike the Stark safe harbors applicable to contractor arrangements (42 CFR § 411.357(d) and (l)), the Stark safe harbor for employment contracts generally does not require that the compensation be set in advance; accordingly, employers may change a physician employee's compensation at any time, retroactively or prospectively, so long as the compensation is fair market value. (Id. at § 411.357(c)). But now, if the employer will require the employed physician to make referrals to a particular provider, the physician's compensation (or the formula for determining the compensation) must be “set in advance for the duration of the arrangement,” i.e., “[a]ny changes to the compensation (or the formula for determining the compensation) must be made prospectively.” (Id. at § 411.354(d)(4)(i)). The net result is that employers must choose between the flexibility of making retroactive changes to physician compensation (e.g., retroactive bonuses or compensation adjustments) or requiring employed physicians to refer designated health services to

the employer.

The semi-good news is that the new Stark rules made it somewhat easier to change the compensation prospectively:

> [C]ompensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is "set in advance" if all of the following conditions are met:
>
> (A) All requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).
>
> (B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.
>
> (C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified….

(*Id.* at § 411.354(d)(1)).

b. Not Contingent on the Number of Value of Referrals. In addition to the other requirements for directed referral requirements, "neither the existence of the compensation arrangement nor the amount of the compensation [may be] contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier." (42 CFR § 411.354(d)(4)(vi)). For example, a hospital employer may not require that an employed or contracted physician meet certain quotas as a condition of his or her continued employment or the amount of compensation received, i.e., the hospital may not require that an employed or contracted physician refer x number of cases or $y in revenue. (85 FR 77550). The CMS commentary to the new rule offered the example of a hospital reviewing a physician's past performance when considering a contract extension:

> if, for example, the hospital increases the physician's compensation in the renewal term only if the physician made a targeted number of referrals for diagnostic testing to the hospital or the designated wholly owned providers and suppliers in the current term, the compensation would not meet the condition at § 411.354(d)(4)(vi). Similarly, if, for example, the hospital refuses to renew the employment arrangement (or terminates it in the current term) unless the value of the physician's diagnostic testing referrals generates sufficient profit to the hospital (or its wholly owned providers and suppliers), the existence of the compensation arrangement would be contingent on the value of

> the physician's referrals in violation of § 411.354(d)(4)(vi).
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> (85 FR 77548). On the other hand, the regulation specifically states that "[t]he requirement to make referrals to a particular provider … may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier." (42 CFR § 411.354(d)(4)(vi)). Thus, according to CMS:
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> > [If] the directed referral requirement … provided for termination of the compensation arrangement if the physician failed to refer 90 percent, for example, of his or her patients to a particular provider, practitioner, or supplier, it would not run afoul of the special rule at § 411.354(d)(4) or jeopardize compliance with the requirement of the applicable exception.
>
> (85 FR 77550). Even in such cases, however, the directed referral requirement must satisfy or account for other conditions in § 411.354(d)(4), including that a physician is not required to direct the referral to the employer if "the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment." (See id at § 411.354(d)(4)(iv)(B)).

3. Next Steps. Given these changes, hospitals and other providers that require or want to require their employed or contracted physicians to make referrals should review the and implement the new rules. Among other things, they should:

> a. Review and, as necessary, amend their existing agreements to ensure that they track the requirements in § 411.354(d)(4). Employers may not require directed referrals unless "[t]he requirement to make referrals to a particular provider … is set out in writing and signed by the parties." (42 CFR § 411.354(d)(4)(iv)(A)).
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> b. Re-evaluate compensation programs for employed physicians to ensure that (as with contractor physicians) any compensation changes are made prospectively only, not retroactively.
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> c. If appropriate, consider including a percentage-based referral requirement, but do *not* include target numbers or quotas or otherwise condition either continued employment or the amount of compensation on the number or dollar value of referrals.
>
> d. Monitor ongoing compensation arrangements. Any changes to compensation must be made prospectively only, not retroactively, if you want to require directed referrals. Although this has been the rule for independent contractor physicians, it is a change for employed physicians.