STARK PROVISIONS IN THE FINAL PHASE III RULE

HCCA Teleconference

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Background and Scope

- Why the two rulemakings?
- Phase III effective date, including transition provision for applying “stand in shoes” to current contracts that qualify as indirect compensation.
- Status of physician fee schedule proposed changes
§411.350 - Scope

- Phase III changes
  - Add section clarifying relationship to reassignment, purchased diagnostic rules, and other Medicare rules and regs
§ 411.351- Definitions

- Entity
- Fair Market Value
- Incident to services
- Physician in the group
- Physician organization
- Radiology and other imaging services
- Referral
Fair market value – Phase III
72 FR 51015

- Phase III change - eliminates the compensation safe harbor
- Phase III comments
  - Reiterates that FMV is based on facts and circumstances
  - Observes that FMV for physician services “may differ” from FMV for administrative services
Incident to services - Phase III

Phase III makes no changes but clarifications.

Emphatic that incident to services are limited to services without a separate benefit (imaging, clinical labs).

Elsewhere in regulation CMS deletes confusing parenthetical in §411.355(a)(3) that suggested diagnostic tests were “incident to”
Physician related definitions - Phase III
72 FR 51017, 51027-28

- Physician in the group -
  - clarified that contract must be “directly” with group practice

- Physician Organization
  - Used in definition for expansion of “stand in shoes”
  - Discussed later, but very important
No change in regulation but clarifications

Personally performed DHS limited for DME. Physician must be supplier and personally perform the services in supplier standard. – specifically mentions CPAP
Radiation oncology exclusion limited to services personally performed or supervised by the referring rad oncologist or personally supervised by a radiation oncologist in the same group. Same analysis for pathologists and diagnostic radiology.

No walk ins

Protects the technical component of DHS ordered by hospital based radiologists and pathologists ordered pursuant to a consultation but not anesthesiologists.
§411.352 Group Practice - Phase III
72 FR 51021-24

- Profit splits and productivity bonuses
  - Phase III changes –special rule for productivity bonuses and profit shares - §411.352(i)
  - Clarifies that direct “incident to” credit is only permissible for productivity bonuses
  - Profit splits can only reward value or volume of referrals, including “incident to” services, using an indirect methodology
  - Reverses prior position as contrary to statutory language
Group Practice – Phase III

- Medical foundations
  - Comment suggests that medical foundations that contract with physician group and bill for the services will make it unlikely that group can qualify as “group practice” for Stark b/c of billing requirement
§411.354 - Financial relationship, compensation, etc

- “Stand in shoes”
- Set in advance
- Physician security interest in equipment
“Stand in the Shoes”
72 FR 51026-29

- Phase III extends “stand in shoes” provision to deem remuneration to group practices or physician organizations as direct remuneration to physicians in such group or organization
- Provision for transition
- Recognition that other intervening entities still trigger indirect analysis but caution on AKS compliance
“Set in advance” provision
72 FR 51030-31, 51062-63

- No text changes
- Clarification that percentage based compensation is “set in advance” but may still improperly take into account the value or volume of referrals or other business generated.” The V/V deeming provisions only apply to unit-based compensation
- Clarification that, for purposes of set in advance requirement, agreements between DHS entity and physicians can be modified during the term so long as the amendment is not related to volume or value of referrals or other business generated between the parties. Specific exceptions may have other requirements on amendments.
Other Changes

- Phase III changes regulation text to provide that a physician security interest in equipment sold to hospital and secured with a loan is a compensation arrangement and not an ownership interest. [411.354(b)(3)(v)] 72 FR 51027
- Phase III comment reiterates that fixed compensation can still “take into account” the value or volume of referrals.
§411.355 - General Exceptions to Ownership and Compensation

- Academic Medical Center
- In office ancillaries
- Intra-family rural referrals
- Medicaid ???
Academic Medical Centers

72 FR 51036-38

- Clarifies that each component of compensation must be set in advance and not take into account volume or value of referrals or other business generated.
- Clarifies that only aggregate compensation from all components must be FMV for services.
- Clarifies that affiliated hospitals must count faculty in a uniform manner depending on class of staff privileges.
In office ancillaries
72 FR 51032-35

- Strong comment that shared ancillary services don’t comply unless block lease
- Considering limiting types of services that might qualify for in office ancillary protection
- Hospital employed physicians cannot qualify for IOA unless billed by physician
- Billing entity must be owned by group, not individuals in mirror entity
Other Changes

- Phase III modifies the Intra-family rural referrals to add an alternative “no other provider within 45 minute transit” option. 72 FR 51039-40

- Medicaid – Are we waiting for Phase IV?
§411.356 - Ownership exceptions

72 FR 51041-43

- Rural –
  - Confirm that Micropolitan Statistical Areas are rural
  - No grandfathering for DHS entities owned by physicians in rural areas that become urban
  - Adds definition to §411.351 confirming statutory definition
§411.357
Compensation Exceptions

- Space & equipment rentals
- Personal services
- Physician recruitment & retention
- Payments unrelated to DHS
- Payments by a physician
- Non-monetary comp
- Fair market value comp Compliance training
- Indirect comp exception
- Professional courtesy
- Community wide information services
Space and Equipment Rentals

72 FR 51043-45

- Clarifies that parties may amend leases multiple times during or after first year provided that the rental charges are not changed
- If the rental charges are changed, parties must terminate the agreement and enter into new agreement
- Parties can enter into new lease within a year of termination if for new space
- Non-exclusive shared facilities do not fit in exception
- Tenant improvements must be recouped based on whether they are for the benefit of a single tenant or multiple future tenants.
- Higher rates for holdovers permitted if in original contract
Personal Services

72 FR 51045-47

- Phase III changes
  - added a 6 month holdover period on the same terms and conditions
- Phase III comments
  - Gainsharing is now called Rewards Sharing
  - Can be amended on same basis as leases
Physician Recruitment
72 FR 51047

- Basic requirements
- Recruitment into groups
- Rural providers
- Other changes
Basic Requirements

- In writing and signed by all parties (including group practice if any payments to group)
- Not conditioned on referrals other than reasonable credentialing restrictions
- Recruit cannot be on medical staff
- Recruit must relocate from outside the geographic area served by the hospital into the area
- Recruit must move practice location 25 miles or have 75% of new practice revenues from patients not seen in prior three years
No relocation requirement

- Residents, including all training and post-residency fellowships
- Physicians employed for the immediate prior two years by
  - Federal or state bureau of prisons
  - DOD, VA, or Indian Health Services
  - And NO private practice
- Others by advisory opinion where determined not to have a practice with a significant number of patients who are or could become patients of recruiting hospital
Measuring the geographic service area

- Basic rule – the lowest number of contiguous zip codes from which hospital get at least 75% of inpatients

- Clarifications
  - The doughnut
  - Contiguous zip codes < 75% of inpatients
  - Multiple configurations
  - Hospital not health system
Recruitment into Group Practices

- Clarification of “actual recruitment expenses”
- Keeps limit on overhead to “actual, additional incremental costs” except for rural providers
- Permits co-location but with strong cautions
- Permits groups to impose reasonable practice restrictions
  - Moonlighting
  - Solicitation of patients and employees
  - Confidential and proprietary information
  - Treatment of medicaid or indigent
  - Repayment of losses incurred by practice for recruit in excess of any hospital payments
  - Reasonable liquidated damages if recruit leaves practice and stays in area (not reasonable if non-compliant with state and local law)
Special rural provisions

- Applies to rural health clinics, as well as rural hospitals and FQHCs
- Optional 90% test for geographic service area
- Some flexibility on overhead allocation by group practice for recruited physician
  - Practice in rural area or HPSA
  - Recruit is replacement within one year for retired, deceased, or relocated physician
  - Allocation may not exceed the actual incremental costs or the lower of (i) a *per capita* allocation or (ii) 20% of the aggregate overhead
CMS clarifies that indirect compensation exception and fair market value exception do not protect recruitment.

CMS believes that in appropriate circumstances, the AMC exception and employment exception may protect recruitment.
Remuneration Unrelated to DHS
72 FR 51056

- Comments confirm that exception covers next to nothing
- Anything limited to medical staff is related to DHS
Payments by a physician

72 FR 51056-57

- States that, in light of expansion of Fair Market Value exception to include remuneration from physician to DHS entity and limitation in Payments by physician that no other exception applies, routine purchases must meet FMV standards

- Unintended consequences
Non-monetary compensation

72 FR 51058-59

- Adds a “grace” provision permitting repayment of amounts in excess of limit (so long as below 150% of limit) and returned by physician in the same calendar year or 180 days whichever is earlier. Limited to once per doctor every 3 years.

- Adds one staff appreciation event per year that need not be counted toward limit, although any gifts at such events do count.

- Limit is determined by hospital, not by health system.
Fair market value compensation

72 FR 51059-60

- Phase III changes
  - Modified to cover remuneration to or from a physician and entity
  - Specifically excludes rental of office space

- Phase III comments
  - Does not cover physician recruitment
  - No presumption that a transaction is fair market value
Permits CME credit provided that compliance training is the primary purpose of the program
Indirect compensation exception
72 FR 51061-63

- Indirect compensation is the only exception for indirect compensation arrangements
- Percentage of collections arrangements will not satisfy exception b/c of connection to value and volume of referrals or other business
- Structuring arrangements to comply with indirect exception is not per se prohibited
- Stand in shoes!!!
- AKS issues
Reg text modified to limit exception to entities with a formal medical staff and requires a written policy.
Retention Payments in Underserved Areas

72 FR 51065

- Certified offer of employment opportunity from AMC, group, or physician organization
- Expanded retention payments to physicians in medically underserved areas or serving medically underserved populations
- Payments may be made by rural health clinics, as well as hospitals and FQHCs
- Payments equal to a written offer or, if no written offer, the lower of (i) 25% off physician’s annual income, or (ii) the reasonable costs of replacing the physician
Community-wide health information systems

72 FR 51064-65

- Watchful waiting policy for CMS in light of EHR regulations
QUESTIONS?