Compliance Issues For Multi-Provider Collaborations: How To Spot & Avoid Potential Pitfalls

LeadingAge New York’s Financial Managers Annual Conference
Wednesday, August 31, 2016
Saratoga Hilton,
Saratoga Springs, New York

LAURIE T. COHEN, PARTNER

FACTORs IMPACTING BUSINESS — MARKET CHANGES

- Affordable Care Act
  - Hospital readmission penalties
  - Bundled care payments
  - Accountable Care Organization (ACO)
  - Value-based purchasing
  - I-SNP
  - Other alternative payment models – Enhanced Care and Coordination Providers (ECCPs)

- NYS MRT/DSRIP
  - Managed Long Term Care (MLTC)
  - Reduction in facility admissions
  - Emphasis on community and home based care
  - MCO requirement to shift to value-based contracting
  - Medicare Alignment Proposal
IMPACT ON SKILLED NURSING

- Significant pressures on “cost” effectiveness
- Attention on outcomes
- Loss of census due to:
  - Shorter length of stay (LOS)
  - Patients bypassing skilled nursing to home health
  - Lack of alignment with payor (ACO, convener, insurance company)

WHAT SENIOR CARE PROVIDER CAN OFFER TO A MCO, ACO OR A MULTI-PROVIDER NETWORK

1. Cost effective and efficient (reduced-unit cost);
2. Lower-cost workbench and lower-unit cost services;
3. Focus on readmission protocols;
4. Well-managed care (Continuing Care Retirement Communities (CCRC)) senior settings (attributable lives for ACO);
5. Home care;
6. Rehab care;
SENIOR CARE PROVIDER (CONT’D)

7. Sub-acute Medicare services;
8. Care and case management services;
9. Information technology knowledge;
10. Shared savings (risk and reward); and
11. Tie-in and coordination of doctors, nurses, etc. servicing its seniors’ covered lives.

POTENTIAL COMPLIANCE ISSUES
THE STARK LAW

The Stark Law is a strict liability statute that prohibits physicians from referring Medicare or Medicaid patients to any entity with which the physician (or an immediate family member) has a financial relationship for the provision of designated health services (“DHS”), unless an exception applies. The Stark Law also prohibits any entity from billing any individual, third party payor or other entity for any DHS provided pursuant to a prohibited referral. Under the Stark Law, a financial relationship includes both an ownership or investment interest and a compensation arrangement.

STARK AND NURSING FACILITY

- Nursing facility services are not designated health services (“DHS”) covered by the physician self-referral or federal Stark law.
- Other services that a nursing facility may bill for are DHS including laboratory and therapy services.
- Nursing facilities need to review arrangements with physicians who order therapy, laboratory tests or other DHS and who have a financial relationship with the facility (e.g., ownership interest, medical director, consulting physician).
ANTI-KICKBACK STATUTE (AKS)

- AKS provides that whoever knowingly and willfully solicits or receives any remuneration (including a kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind: (i) in return for referring an individual to a person for the furnishing or arranging of any item or service for which the payment may be made in whole or in part under Medicare or Medicaid or a State health care program; or (ii) in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under Medicare or Medicaid or a State health care program, shall be guilty of a felony.

ANTI-KICKBACK STATUTE (CONT’D)

- Unlike the Stark Law, AKS does not impose strict liability.

- A determination of whether AKS is violated turns on whether even one purpose of an arrangement is to induce or reward referrals of federal healthcare program business.
ANTI-KICKBACK AND NURSING FACILITY

- The exchange of something of value between collaborating providers, one purpose of which is to induce referrals between the parties, can be found to violate the AKS.
- Ideally, arrangements between providers/referral sources are structured to satisfy the elements of an AKS safe harbor such as the space or personal services safe harbors.
- Nursing facilities need to review arrangements with physicians who receive remuneration from the facility (e.g., medical director, consulting physician) and determine that payment is FMV for specific services and commercially reasonable.

ANTI-TRUST – MULTI-PROVIDER NETWORKS

- Compliance - Absent substantial clinical and/or financial integration, a messenger model or modified messenger model must be used to promote contracting.
- The defining characteristic of a messenger model arrangement is that the messenger serves as a conduit used by providers participating in a network to make individual determinations about their prices and participation in a particular contract offered by a payor. A messenger model must not be used with the intent of increasing provider price leverage through collective negotiation strategies.
- “Traditional Messenger Model”, the messenger goes back and forth between the payor and providers to convey to providers any contract offer made by payor. Then, each provider makes a separate, independent and unilateral decision to accept or reject a payor’s offer.
ANTI-TRUST – MULTI-PROVIDER NETWORKS (CONT’D)

- “Modified Messenger Model”, a messenger collects minimum fees or fee ranges from each individual network provider. Providers may then grant the messenger advance authority, on an individual basis, to agree to offers by payors who meet or exceed the price that the provider has designated as an acceptable price. The messenger then conveys the offer to the remaining providers whose minimum terms were not met for their individual determination whether to opt-in or opt-out of the proposed contract.

- If the network providers will be sharing financial risk (e.g., through capitated payments, holdbacks, or other risk-sharing reimbursement methodologies), the messenger model may not be necessary, and joint negotiation would be permissible.

- If there is no financial risk sharing, joint negotiations of price may be possible to the extent reasonably necessary to support clinical integration.

ANTI-TRUST – MULTI-PROVIDER NETWORKS (CONT’D)

- Clinical integration cannot be a mere fig leaf for price fixing. Joint negotiations with payors must promote the goals to be achieved through clinical integration (i.e., the complement of activities described in further detail below, including collective standard setting, enforcement of performance against standards, significant investment in infrastructure, etc.). If not, the antitrust enforcement agencies and/or the courts may condemn the arrangement under the antitrust laws.

- The network resulting from clinical integration efforts cannot have monopoly power in any market in which it participates.

- Monopoly power is the power to raise prices in a properly defined market unimpeded by competition.

- If the resulting network will have monopoly power in any market, clinical integration may not save it from condemnation under the antitrust laws.
CO-LOCATION OF SERVICES

To the extent that provider collaborations may lead to providers being located in the same facility, there are state and federal rules regarding co-location or shared space.

- Nursing homes are generally required to use their licensed space for the benefit of their residents.
- Under 10 NYCRR Section 415.26(b)12(i), a nursing home may “enter into a written contract for the purpose of leasing unneeded space and equipment on the premises of the facility to a health care practitioner licensed by the State Education Department, or to a provider licensed under the Public Health Law, Mental Hygiene Law, or Social Services Law to provide health care services to residents”

CO-LOCATION OF SERVICES (CONT’D)

- Further, such arrangements are subject to prior written approval of the Health Commissioner and such arrangements cannot result in any diminishment of resident care or services, or adversely affect the cost of delivering nursing home services.
- Fraud and abuse rules require arms-length, fair market value, commercially reasonable lease arrangements.
REGULATORY WAIVER AUTHORITY

PHL Section 2807(20)(e) and (21)(e) authorize the waiver of regulatory requirements for DSRIP projects and capital projects that are associated with DSRIP projects by:

- The Department of Health (DOH),
- The Office of Mental Health (OHM),
- The Office of Alcoholism and Substance Abuse Services (OASAS),
- The Office for People with Developmental Disabilities (OPWDD).

A waiver may be issued:

- as necessary to allow applicants to avoid duplication of requirements and to allow the efficient implementation of the proposed projects;
- Only if the waiver would not jeopardize patient safety; and
- Only for the life of the projects.

MSSP WAIVERS

- October 29, 2015, CMS released a Final Rule finalizing several waivers of federal prohibitions against fraud and abuse including the Physician Self-Referral Law (the “Stark Law”), the Federal Anti-Kickback Statute (“AKS”), and certain civil monetary penalties (“CMP”) law provisions.

- CMS viewed these waivers as necessary for MSSP ACOs to successfully facilitate quality improvement and improve care coordination. All waivers were made effective as of October 29, 2015.
MSSP WAIVERS (CONT’D)

1. A “pre-participation” waiver of the Stark Law and the AKS applies to ACO-related start-up arrangements in anticipation of participating in the MSSP. **Essentially, the pre-participation waiver enables an ACO participant or provider, like a hospital, to fund ACO development, such as infrastructure creation, for the benefit of the ACO participants, including referring physicians, without the risk of liability under the Stark Law or the AKS.**

2. An “ACO participation” waiver of the Stark Law and the AKS applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the MSSP and for a specified time thereafter. **The ACO participation waiver is a very broad waiver. A NY hospital system sponsored ACO has used this waiver for payment of monthly care management fees to SNFs which would not otherwise meet personal service safe harbor or professional service exceptions**

MSSP WAIVERS (CONT’D)

3. A “shared savings distributions” waiver also waives the Stark Law and the AKS for distributions or use of shared savings earned by an ACO. **The shared savings distribution waiver allows for shared savings received by the ACO to be applied in virtually any manner, including distributions to outside parties.**

4. A “compliance with the physician self-referral law” waiver waives the AKS with respect to any financial relationship between or among an ACO, its participants and its providers/suppliers that implicates the Stark Law. **In essence, the compliance with Stark Law waiver protects arrangements meeting a Stark Law exception from liability under the AKS.**
MSSP WAIVERS: (CONT’D)

5. A “patient incentive” waiver waives provisions of the beneficiary inducements CMP law and portions of the AKS with respect to items or services provided by an ACO, its participants or its providers/suppliers to Medicare beneficiaries for free or below fair market value. The patient incentive waiver allows an ACO to offer to its beneficiaries certain non-monetary preventive items or services, including transportation.

ACO WAIVERS

- The waivers only apply to the MSSP. The waivers do not apply when an ACO operates outside of the MSSP for commercially insured patients.

- Stark and AKS do not apply to commercial ACO contracts, but in effect these fraud and abuse laws must be analyzed given that there is typically a Medicare and/or Medicaid referral nexus between the physicians participating in the ACO and other providers, and as such any direct or indirect financial relationship could implicate these laws even if the relationship only covers commercial patient matters.

- In essence, a provider can inappropriately pay under a commercial deal to reward and induce government reimbursed patienterrals. CMS has expressed that performance-based payments received by an ACO from a commercial health plan do not necessarily implicate fraud and abuse laws, but a thorough analysis of all facts should be completed.