NYSBA, Health Law Section Annual Meeting

Tackling the Opioid Crisis: Navigating the Regulatory, Legislative and Ethical Maze, Including How-To's on Becoming a Substance Abuse Treatment Center in New York

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Opioid Crisis and Pain Treatment

Evolution of pain management and treatment

- Previously
  - Pain management involved medication management
- Opioid Crisis Era
  - Opioids and Injections are not recommended
  - Consider other options - physical therapy

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Opioid Crisis and Pain Treatment

- Optum: 75% to 90% less likely to have short or long term exposure to opioids if first provider is a physical therapist, chiropractor or licensed acupuncturist
  - Source: *Conservative Therapies for New Onset Low Back Pain and Predictors of Long-term Opioid Use and Misuse*, Lewis Kazis, ScD, et al, Boston University School of Public Health

OPTUM

- Optum focused on plan design and importance of referral timing to increase physical therapy involvement

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Opioid Crisis and Pain Treatment Legal Obstacles Overview

- Legal Obstacles for Addressing the Opioid Problem:
  - Evidence: Physical therapy is more effective for treating pain than opioids
  - Physician must structure their practices in a certain way to incorporate physical therapy and comply with state and federal law

- Demonstrative Example of Legal Obstacle:
  - How can a pain management physician practice engage a physical therapist to provide physical therapy services in light of Stark law and Medicare reimbursement supervision requirements?

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Opioid Crisis and Pain Treatment Legal Obstacles Overview

- Stark Law:
  - In Office Ancillary Services ("IOAS") exception requires physician supervision of individual performing the service.
  - Can a pain management physician supervise a physical therapist for purposes of the IOAS exception?

- Medicare reimbursement:
  - Must physical therapy services in a physician office be billed as incident to the physician?
  - Can the Physical therapist bill directly?
  - What are the supervision requirements requirements?

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

- Prohibits any financial relationship -- including arrangements for compensation -- between a physician (or immediate family member) and an entity with which the physician (or immediate family member) refers patients for designated health services ("DHS"), defined by the statute

- Examples of DHS
  - Clinical laboratory, physical therapy, occupational therapy, outpatient speech language pathology, radiology and other imaging services, Radiation therapy services and supplies

- Note: State self-referral prohibitions

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

- Strict Liability Statute
  - Refund any amounts collected for services provided pursuant to a prohibited referral
- Civil Monetary Penalties ("CMP") if violation is found
  - Improper claims or failure to refund money:
  - Circumvention Scheme - DHS entity knows/should know arrangement has general purpose of assuring referrals to DHS entity that if made directly to DHS entity, would violate Stark
- Exclusion from federal health care programs
- Potential False Claims Act liability
  - Knowingly presenting or causing to be presented a false or fraudulent claim to the U.S. government for payment

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

- **Exceptions**
  - The only circumstance in which a physician and an entity to which the physician refers can escape the prohibition is through meeting an applicable exception to the statute
    - Personal Services
    - Employment
    - Group practice
    - In-office ancillary services

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Group Practice Criteria

- Group practice means a single legal entity of two or more physicians legally organized as a partnership, professional corporation, faculty practice plan or similar association where:
  - Each physician member provides ***substantially*** the full range of services that physician routinely provides (including medical care, consultation, diagnosis or treatment)
  - Professional services provided through joint use of shared office space, facilities, equipment and personnel

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Group Practice Criteria

- *Substantially all* (at least 75%) of each physician member's patient care services are:
  - Provided through group
  - Billed under group's billing number
  - All income is treated as receipts of group
  - Overhead expenses and income from practice are distributed in accordance with previously determined methods

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Group Practice Criteria

- No physician in group may directly or indirectly receive compensation based on the volume or value of referrals by the physician.

- Exception: Group physicians may be paid share of overall profits or productivity bonus (for personally performed or "incident to" services) if not directly related to DHS referrals.

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Group Practice Criteria

- Productivity Bonus
  - Not the same as productivity bonus in the employment context
  - A physician in the group may be paid a productivity bonus based on services that he or she has personally performed, services "incident to" such personally performed services, or both
  - May not be determined in any manner that is directly related to the v/v of DHS referrals by the physicians (except for the "incident to" services)

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Group Practice Criteria

- Productivity bonus will not be considered directly related to volume or value of referrals if one of the following conditions is met:
  - The bonus is based on the physician's total patient encounters or RVUs;
  - The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payor; or
  - DHS revenues for group practice are less than 5% of group practices' total revenue and the allocated portion to each physician in the group is 5% or less of the physician's total compensation from the group

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

- For provision of DHS when ancillary to the office-based practice of medicine (even if not really ancillary)

- Definition of "group practice" is key
  - Fully integrated, not a loose confederation of physicians designed to profit from DHS referrals
  - Financial incentives to make DHS referrals are attenuated

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

- Who may provide services?
  - Referring physician;
  - Physician who is member of same group practice as referring physician;
  - **Individuals who are directly supervised by physician or another physician in same group practice; and**
  - Physicians in the group practice such as employees and independent contractors of group practice

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

Where are services provided?

- Same building where referring physician (or others in group) furnish services unrelated to the furnishing of DHS; must meet one of 3 tests:

1. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week
2. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week
3. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

Where are services provided?

- Centralized Building which means all or part of a building that is owned or leased on a full-time basis by a group practice, including a mobile vehicle, van or trailer where some or all of the group practice's DHS is provided:
  1. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week
  2. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week
  3. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

- How are services billed?
  - By physician performing or **supervising** services
  - By group practice of which such physician is member, employee or independent contractor under a billing number assigned to the group practice; or
  - By entity that is wholly owned by such physician or such group practice

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

In-Office Ancillary Services Exception

- Question Presented
  - How can a pain management physician supervise the services of a physical therapist so as to meet the elements of IOAS exception which requires supervision?

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

"A professional association for physical therapists asked the following questions:

1. **If a physical therapist employed by a physician practice furnishes services, bills using the physical therapy provider number, and then reassigns payment to the group practice, are the billing requirements met?**
2. Would a rehabilitation agency, which is owned by physicians, and has its own billing number, be considered a wholly owned entity for billing purposes?
3. Can physicians own a physical therapy private practice office and bill through the provider number of that office?
4. When a designated health service is billed by an entity wholly owned by a group practice, do the Medicare conditions of participation applicable to the wholly owned entity determine the applicable level of supervision or do the supervision requirements related to group practice billing apply."

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Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

- With respect to the first question, we assume it is directed at services provided after March 1, 2003, as prior to that date, services by an employed physical therapist had to be billed as ''incident to'' services.
- **Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act,** which requires that the service be **billed by** the performing physician, the **supervising physician**, the group practice using a number assigned to the group, or an entity wholly owned by the performing or supervising physician or the group practice.
- **However, if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met. . . With respect to the last question, the supervision must meet the requirements applicable to the billing submitted to the Medicare program**.

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

- **Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act,** which requires that the service be **billed by** the performing physician, the **supervising physician**, the group practice using a number assigned to the group, or an entity wholly owned by the performing or supervising physician or the group practice.

Social Security Act, Section 1877

(b) General Exceptions to Both Ownership and Compensation Arrangement Prohibitions.—Subsection (a)(1) shall not apply in the following cases:

(2) In-office ancillary services.—In the case of services—

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

- **However, if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met. . . With respect to the last question, the supervision must meet the requirements applicable to the billing submitted to the Medicare program.**

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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Medicare Benefit Manual Chapter 15

Services Furnished by a Therapist in Private Practice (TPP)

Section 230.4(A)

- "When the therapist who has a Medicare NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the therapist, with the therapist identified on the claim as the supplier of services. However, services of the therapist who has a Medicare NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to therapy services incident to a physician.) In that case, the physician/NPP is the supplier of service, the NPI of the supervising physician/NPP is reported on the claim with the service and all the rules for both therapy services and incident to services (§230.5) must be followed."

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Medicare Benefit Manual Chapter 15

Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service

Section 60(A)

- "Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, **physical therapists** and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services."
- Physical therapy is its own benefit category in the Social Security Act and therefore can also be provided by, and billed by, a physical therapist. In such cases, no physician supervision is required.
- Of course, physician still must certify the need for therapy.

Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

Stark Law Preamble, 69 Fed. Reg. 16054, 16071-16072 (March 26, 2004)

- "As explained in the Phase I preamble (66 FR 885–886), we have concluded that section 1877 of the Act **should not subject physicians to supervision standards that differ from the standards for Medicare payment and coverage for the services provided**. Thus, for example, services billed ''incident to'' will require the level of supervision applicable under the ''incident to'' rules. Services that require only low-level general supervision are subject to that lower level of supervision for purposes of section 1877 of the Act. **As noted above, these regulations under section 1877 of the Act do not, in the first instance, establish the supervision requirements applicable to particular services, nor are they an appropriate vehicle for doing so.**"

Opioid Crisis and Pain Treatment Legal Obstacles Recap

- IOAS Exception requires service to be provided by "Individuals who are directly supervised by physician or another physician in same group practice"
- IOAS Exception requires services to be billed by: "By physician performing or supervising services"

- Stark Law Preamble and Medicare Manual explanation: There is no supervision requirement for PT in private practice to provide services in a physician practice.

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Opioid Crisis and Pain Treatment Legal Obstacles - Conclusion

- Medicare Status: PT in Private Practice
- Payment: PT should reassign payment to physician practice
- Reimbursement: 100% Medicare physician fee schedule
- Supervision: No direct supervision requirement.

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RECOMMENDATIONS

- **Think First** - Providers must be structured to properly account for regulatory considerations
  - Review self-referral and kickback regulatory considerations together with Medicare / Medicaid reimbursement guidelines
  - Identify creative regulatory solutions to legal hurdles allowing room for growth in fighting the opioid epidemic
- **Act Later** - Providers should ALWAYS consult counsel as they modify practice service offerings and locations

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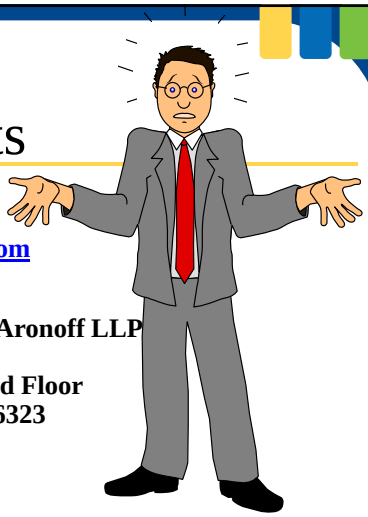
Questions or Comments



Thank you!

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