Regulatory and Contractual Issues for SNF Medical Directors

David C. Marshall, Esq.
Latsha Davis & Marshall, P.C.

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Presentation Overview

- Explore the evolving responsibilities of Medical Directors in skilled nursing facilities (SNFs), including legal, regulatory, and ethical dimensions.
- Review federal requirements under 42 CFR Part 483, focusing on compliance with CMS regulations.
- Examine key contractual elements such as scope of services, performance expectations, and risk mitigation strategies.
- Discuss common challenges and real-world compliance issues through case studies and practical examples.
- Align Medical Director roles with organizational goals, standards of care, and quality improvement initiatives.

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The Role of a Medical Director in SNFs

- What is a Medical Director?
  - A licensed physician designated by a nursing home to oversee and coordinate medical care.
- Medical directors are responsible for
  - the implementation of resident care policies; and
  - the coordination of medical care in the facility
- Medical Directors should
  - supervise the “medical staff” at the facility
  - inform the “medical staff” of relevant policies and procedures
  - organize, coordinate, and monitor the activities of the “medical staff” and help ensure that the quality and appropriateness of services meets community standards
- The Medical Director is central to ensuring high-quality, resident-centered care in nursing homes.
  - Ensures that resident care policies reflect current professional standards.
  - Provides clinical oversight to support residents’ physical, mental, and psychosocial well-being.
  - Plays a key role in administrative decisions, quality assurance, and coordination of physician services.

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Medical Director Presence in U.S. Nursing Homes (2023)

- 36.1% of nursing homes reported zero medical director presence.
- Presence fluctuated from 2017 to 2023, with a decline over the past 4 years.
- Average time on payroll: 36 minutes/day or 4.2 hours/week per facility.
  - Less than 1 minute per resident day.
- Significant variation by ownership type and state.
  - For-profit: 61.4%
  - Non-profit: 71.3%
  - Government: 66.5%
- For-profit homes reported less time spent by medical directors.
- Regulatory deficiencies for medical director requirements are rare (0.2%).

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Federal Requirements Applicable to SNF Medical Directors

- 42 CFR 483.70(g)
  - (1) The facility must designate a physician to serve as medical director.
  - (2) The medical director is responsible for –
    - (i) Implementation of resident care policies; and
    - (ii) The coordination of medical care in the facility
- Other regulations do not explicitly address medical director services, but relate to responsibilities that the medical director may influence, support or oversee:
  - 42 CFR 483.35 – Nursing Services
  - 42 CFR 483.40 – Behavioral Health Services
  - 42 CFR 483.45 – Pharmacy Services
  - 42 CFR 483.75 - Quality Assurance and Performance Improvement

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State Operations Manual

- Guidance from the State Operations Manual (SOM) – F841 - Very detailed in expectations of Medical Director
- In March 2025, CMS issued revised interpretive guidance for F841, which further clarifies what is expected of medical directors during facility inspections and surveys.
  - Assist facility in the development and implementation of policies and procedures and that these are based on current standards of practice
  - Interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the residents
  - Be available to surveyors to clarify clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the nature and scope of the facility's deficiencies, and help the facility draft corrective actions.
  - Be involved in facility level issues, even if working at a multi-facility organization with corporate or regional offices.

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State Operations Manual

- Medical directors are expected to take an active role in the facility's assessment and quality improvement processes.
  - Includes participating in the development and approval of resident care policies and being involved in the facility's Quality Assurance and Performance Improvement (QAPI) program.
- Medical directors must intervene when clinical practices deviate from accepted standards.
  - Example, if residents are being diagnosed with psychiatric conditions like schizophrenia without proper documentation, or if psychotropic medications are being prescribed inappropriately, the medical director is expected to step in and address the issue.
- Overall, the updated guidance reflects a shift toward holding medical directors more accountable for the quality of care provided in nursing facilities and ensuring that their role is both meaningful and compliant with federal regulations.

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Physician Contract Issues

- STARK
  - Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies.
    - "Referral" includes signing a Plan of Care which includes DHS
  - Prohibits the designated health service entity from submitting claims to Medicare for those services resulting from a prohibited referral.
  - No intent standard for overpayment (strict liability), intent required for civil monetary penalties for knowing violations.
  - Penalties:
    - civil: overpayment/refund obligation, FCA liability, CMP and program exclusion for knowing violations, potential CMP for each service, and civil assessment of up to three times the amount claimed.
  - A SNF/Medical Director relationship triggers the Stark law, and must be structured consistent with the Personal Services Exception.

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Physician Contract Issues

- STARK
  - Personal Services Exception – to satisfy it must:
    - be in writing, be signed by the parties to the agreement, and specify the services covered by the agreement;
    - cover all of the services to be furnished by the physician under the agreement;
    - cover aggregate services that do not exceed those that are reasonable and necessary for the legitimate purposes of the arrangement;
    - be for a term of at least one year;
    - provide for compensation to be set in advance. not to exceed fair market value and not be determined by the volume or value of any referrals or other business generated between the parties; and
    - not involve counseling or promotion of a business arrangement or other activity that violates any state or federal law, such as the federal Anti-Kickback Statute.

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Anti-Kickback Issues

- Basic Prohibition
  - Prohibits offering, paying, soliciting, or receiving anything of value to induce ore reward referrals or generate Federal health care program business.
  - Referrals can be from anyone, for any items or services.
  - Intent: knowing and willful (i.e. specific intent)
  - Penalties
    - criminal: fines up to $25,000 per violation, up to a 5 year prison term per violation
    - civil/administrative: FCA liability, civil monetary penalties and program exclusion, potential $50,000CMP per violation, civil assessment of up to three times amount of kickback.

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Anti-Kickback Issues

- "Any One Purpose" Test
  - The third Circuit has held that the Anti-Kickback Statute is violated when any one purpose of a transaction is prohibited, regardless of other legitimate motivations the parties may have.
    - See United States v. Gerber, 760 F.2d 68 (3rd Cir. 1985).
- Personal Services Safe Harbor
  - Agreement set out in writing
  - Agreement covers all services provided
  - Term of agreement is not less than 1 year
  - Compensation is set in advance, consistent with FMV and not determined by volume or value of business/referrals
  - Services do not exceed those which are reasonably necessary for the purpose

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Contractual Issues for Medical Director Arrangements

- Improper Compensation Structures: Payments that are tied to the volume or value of referrals are a major red flag. Compensation must reflect fair market value and be for actual services rendered
- Lack of Documentation: Agreements without proper documentation—such as time sheets, meeting minutes, or performance evaluations—can be construed as sham arrangements
- Ghost Positions: Some facilities have paid physicians for medical director roles without requiring them to perform any duties, which can lead to allegations of kickbacks
- Non-Compliance with Federal Laws: Violations of the Stark Law and AKS can result in severe penalties. For example, Bridgeport Hospital settled for $10.78 million over allegations of excessive and undocumented payments

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United States of America ex rel. Trilochan Singh v. Paksn, Inc. et al.

- DOJ announced a $45.6 million consent judgment involving Prema Thekkek, Paksn Inc., and six California SNFs to settle False Claims Act allegations.
- They allegedly paid physician's monthly kickbacks ($1,500–$10,000) to induce Medicare patient referrals from 2009 to 2021.
- Contracts lacked documentation of services and were not enforced.
- Physicians were paid based on referral volume; non-performing doctors were terminated, removed for low referral numbers.
- Payments exceeded fair market value and were not commercially reasonable.
- Violated Anti-Kickback Statute and submitted false claims to Medicare and Medicaid.
- Settlement includes a 5-year Corporate Integrity Agreement with HHS-OIG.
- Case initiated under the False Claims Act's qui tam provisions and originated from a whistleblower complaint by a former Paksn executive.

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United States of America ex rel. Neyiris Orozco v. Shlomo Rechnitz et al.

- Alta Vista Healthcare and Rockport Healthcare Services paid $3.825M to settle False Claims Act allegations.
- Allegedly provided physicians with monthly stipends ($2,500–$4,000) and lavish gifts to induce patient referrals.
- Gifts included luxury dinners, golf trips, massages, and gift cards up to $1,000.
- Payments were not supported by documentation of services rendered.
- Compensation exceeded fair market value and lacked commercial justification.
- Violated the Anti-Kickback Statute and resulted in false claims to Medicare and Medicaid.
- Settlement includes a Corporate Integrity Agreement with HHS-OIG.
- Case initiated by a whistleblower under the False Claims Act's qui tam provisions.

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United States ex rel. Goldsholl v. Covenant Healthcare System, et al.

- Covenant Healthcare System and two physicians paid over $69 million to settle False Claims Act allegations.
- Covenant allegedly maintained improper financial relationships with eight physicians and a physician-owned investment group.
- Violations included:
  - Medical director contracts that failed to meet exceptions under the Stark Law and Anti-Kickback Statute (AKS).
  - Employment and rental arrangements with physicians that constituted unlawful remuneration for referrals.
  - Forgiveness of rent and non-arm's-length equipment lease deals to induce referrals.
- Resulted in false claims submitted to Medicare, Medicaid, TRICARE, and FECA.
- Covenant paid $67.2M to the U.S. and $1.8M to the State of Michigan.
- Case initiated by a whistleblower under the False Claims Act's qui tam provisions.

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Best Practices for Compliance

- Ensure Commercial Reasonableness: Contracts should serve a legitimate business purpose and be reassessed regularly to ensure services are still needed.
- Maintain Detailed Records: Time sheets, service logs, and compensation assessments should be reviewed and validated by compliance officers.
- Implement Multi-Level Review Processes: Contracts should be reviewed by service-line managers, compliance/legal teams, and senior leadership before approval.
- Avoid Referral-Based Compensation: Compensation must not be linked to the volume or value of referrals. Use objective metrics and fair market value assessments

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Basic Contractual Provisions

- Parts of a (binding) contract
  - Offer
  - Acceptance
  - Consideration
  - No Defense
    - mutual mistake
    - misrepresentation or fraud
    - capacity
    - Unconscionability
- Services
  - Specifically list the obligations of both parties and the services to be provided, including:
    - Duty to act in accordance with law and facility policies
    - Recordkeeping requirements
    - Licensure/certification requirements
    - Criminal Background checks

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Basic Contractual Provisions

- Compensation and Billing
  - Contract must specifically spell out all forms of compensation to be provided in exchange for services
    - Fair Market Value for services rendered
    - Compliance issues Contract should explicitly address which party has the responsibility for billing any residents, third party payors, governmental agencies
    - Federal regulations require for SNFs in order to avoid “duplicate billing” issues

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Basic Contractual Provisions

- Term and Termination
  - Establish a timeframe – 1 year minimum (per AKS)
    - This doesn't mean that the services owed can't be completed in less than 1 year
  - Will the contract automatically renew?
    - If so, make sure to calendar dates, to meet any notice of termination deadlines
  - How can the parties "get out" of the agreement?
    - While we have the best of intentions entering a relationship, it is wise to plan for the eventual end of the arrangement.

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Basic Contractual Provisions

- Term and Termination
  - Terminations with and/or without cause
    - Termination without cause is the "cleanest" way to get out of an arrangement
    - What constitutes "cause?"
  - Breach issues
    - Notification to breaching party
    - Is there an opportunity to "cure" the breach and continue?
    - Who gets to determine whether the breach is cured?
    - Parties can easily find themselves in litigation over whether a breach has occurred which authorizes termination of the agreement

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Basic Contractual Provisions

- Indemnification
  - Means of being made whole because of other parties' actions.
  - At a minimum, should be reciprocal.
  - Should contain notice requirements
  - Limitations on liability
  - What standard –
    - "gross negligence" – higher standard
    - acts or omissions
    - breach of duty
    - Fraud provision
    - must be clear and unambiguous

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Basic Contractual Provisions

- Other Issues to Address
  - Appeal Issues
  - Arbitration
  - Independent Contractor
  - Confidentiality/HIPAA
    - if applicable, business associate addendum
  - Nondiscrimination
  - Miscellaneous Terms
    - Assignment
    - Governing Law
    - Notice

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Practical Examples/Issues

- Will the physician act as Medical Director for the SNF alone? Will he/she have any responsibilities in the CCRC/IL or PCH/Assisted Living components of the campus?
  - Ex. Need for medical determination that a resident requires a higher level of care and can no longer meet the conditions of occupancy
- You should incorporate the SOM guidance into the Agreement, and carefully review the expectations from the SOM with the physician.
- Will the Medical Director also be a treating physician for residents?
  - Should be no compensation for professional services – paid by Medicare Part B or resident

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Practical Examples/Issues

- Will physician provide own liability insurance, or will that be covered by the facility?
- Include all required reporting obligations of physician within the Agreement (e.x. Elder Justice Act, etc.)
- Physician should present an invoice for the Medical Director services performed, as this will help to demonstrate that the physician is an independent contractor and not a facility employee

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Conclusion

- Imperative that those with contracting authority understand the compliance issues that overlay these relationships
- Goal is to enter into contractual relationships that are beneficial from a service and business perspective, while achieving compliance with governing law.
- Advice – develop a contract policy and checklist to ensure achievement of these goals

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Contact Information

David C. Marshall, Esq.
Latsha Davis & Marshall, P.C.
1250 Camp Hill Bypass, Suite 110
Camp Hill, PA 17011
Phone: (717) 620-2424
Email: dmarshall@ldylaw.com

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