

**Legal and Regulatory
Considerations: Selected Issues**

Presented by:
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National Hospice and Palliative Care
Organization
**Creating the Future of Palliative Care
Legal and Regulatory Considerations:
Selected Issues**

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What Will We Cover?

1. Compare Hospice with Palliative Care Programs (PCP)
2. Define key terms in Hospice and Accountable Care Organizations
3. Describe six Organizational Design Options for PCP
4. Explain eight Legal Issues to examine when creating a PCP
5. Describe New York State laws:
 - a. Palliative Care Information Act
 - b. Medicaid Redesign Team #109
 - c. Palliative Care Access Act
 - d. Pediatric Palliative Care



Palliative Care vs. Hospice Care

1. Both defined by Federal and State laws
2. Hospice Eligibility requirements
3. Hospice Election requirements
4. Reimbursement streams for Hospice are routine, continuous, respite and inpatient Hospice care per diem rates.

42 C.F.R. § 418.302 and § 418.306



Revenue Streams for Palliative Care

5. Revenue streams for Palliative Care
 - a. Medicare Part A – Hospital, Outpatient Hospital services, Certified Home Health Agency services
 - b. Medicare Part B – Physicians, Physician Assistants, Nurse Practitioners, Psychologists, Therapists (PT/OT), DME suppliers
 - c. Medicare Part C – Managed Care
 - d. Contract relationships between providers
 - e. Private pay, and third party insurance



Federal Definitions of Hospice and Palliative Care

Hospice Care means a comprehensive set of services described in 1861(dd)(1) of the Social Security Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care. 42 C.F.R. § 418.3

Palliative Care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative Care throughout the continuum of illness involves addressing physical, intellectual, emotional, social and spiritual needs to facilitate patient autonomy, access to information, and choice. 42 C.F.R. §418.3

Six Organization Design Options for Palliative Care Program

- I. Physician Part B Group
- II. Hospice/Hospital or LTCF Contract
- III. Hospice/PC Nurse Liaison in Hospital
- IV. Managed Care Payment Opportunities
- V. Certified Home Health Agency (CHHA)
- VI. Accountable Care Organization (ACO) Provider or Medical Home Team



Eight Complex Rules Require Expert Health Care Legal Analysis

- I. State License Laws
- II. State Corporate Practice of Medicine Laws
- III. Anti-Kickback – Federal and State Laws
- IV. Physician Self Referral – Federal (Stark) and State
- V. Patient Inducement or Solicitation Laws
- VI. Fee-Splitting Rules – State
- VII. Cost Reporting Rules – Medicare and Medicaid
- VIII. Complex Medicare/Medicaid Reimbursement Rules



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I. Organization: Part B Physician Practice

1. Corporate Practice of Medicine Rules Impact
2. Create a separate entity
Professional Corporation or Professional Limited Liability Company
3. Apply for Part B “supplier” number from local Medicare fee for service contractor
4. Medicare Applications CMS-855B, 855I, 855R, Participating Provider Agreement & Electronic Funds Transfer



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I. Legal Issue: State License Laws

1. Federal requirements - CMS Program Memorandum A-02-102

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/a02102.pdf>

2. Is there “wobble room” for Hospice to provide Palliative Care to patients who are not terminally ill and/or who have not elected Hospice care?
3. Example: NY Public Health Law § 4012-b definition of Hospice Care



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II. Legal Issue: Corporate Practice of Medicine Laws

1. Some state laws prohibit a business corporation or lay person from controlling the medical decisions of a physician and professional staff.
2. A business corporation may:
 - a. not employ licensed professionals (physicians, and nurse practitioners);
 - b. have limited contracting opportunities with physicians to provide medical services; and
 - c. not own a Part B physician practice
3. “Captive Professional Corporation” – Management Agreement
4. Safe Harbor for Personal Services – Anti-Kickback 42 C.F.R. § 1001.952(d)



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II. Organization: Hospice Contracts with Hospital or LTCF to Provide PC Specialists

1. Hospital contracts for Hospice physicians, nurses, social workers, counselors or for Palliative Care training
2. Nurse Practitioners jointly funded
3. Contract issues apply, *i.e.*, kickbacks, safe harbors, Stark, costs allocation on cost report



III. Legal Issue: Anti-Kickback Laws

1. Federal Criminal Law and some States
2. Broad prohibition of offer, solicitation, payment or receipt of anything of value (direct or indirect, overt or covert, in cash or in kind) intended to induce referral of patient for items or services reimbursed by all federal programs, including Medicare, Medicaid, and programs covering veterans' benefits. Social Security Act (SSA) § 1128B.
3. "One Purpose Test" – Kickback if one purpose is to induce referrals.



III. Legal Issue: Anti-Kickback Law

4. Both the offeror and recipient violate statute
5. Safe Harbors 42 C.F.R. § 1001.952
26 business arrangements; Fair Market Value, Reasonable Business Purpose etc.
6. OIG – Advisory Opinion – failure to meet Safe Harbor not automatic kickback.
7. Felony
 - a. Maximum \$25,000 fine.
 - b. Imprisonment up to 5 years.
 - c. Automatic exclusion.
 - d. Civil Money Penalties fines: \$10,000 for each false claim, \$15,000 for each individual to whom false or misleading information was given & \$50,000 for each false record or statement plus damages of 3 times the amount of each item or service.



IV. Legal Issue: Stark Law - Physician Self-Referral

1. Federal Civil Statute and some States
2. Federal Physician Self Referral Law:
A physician may not refer Medicare or Medicaid patients for designated health services (“DHS”) to an entity with which the physician or an immediate family member has a financial relationship unless an exception applies.
3. An entity may not present a claim for reimbursement from Medicare or Medicaid for services provided as a result of a prohibited referral. SSA § 1877



IV. Legal Issue: Stark Law

4. Physician: MD, DO, dentist, podiatrist, optometrist, chiropractor
5. Immediate Family Member: Husband, wife, parent (step), child (step), sibling, in-laws, grandparents or grandchild and spouses
6. Financial Relationship:
 - a. Direct or indirect
 - b. Ownership or investment interest by a physician or immediate family In an entity that furnishes DHS
 - c. Compensation arrangement



IV. Legal Issue: Stark Law

7. Designated Health Services are:
 - a. Clinical laboratory services;
 - b. Physical therapy services;
 - c. Occupational therapy and speech pathology services;
 - d. Radiology and certain other imaging services;
 - e. Radiation therapy services and supplies;
 - f. Durable medical equipment;
 - g. Parenteral and enteral nutrients, equipment, and supplies;
 - h. Prosthetics, orthotics, and prosthetic devices and supplies;
 - i. Home health services;
 - j. Outpatient prescription drugs; and
 - k. Inpatient and outpatient Hospital services.



IV. Legal Issue: Stark Law



8. Federal Stark Law contains exceptions to the general self referral prohibition. Referral is not prohibited if exception is met.
9. Stark Law is strict liability statute. If exception is not met, the arrangement is unlawful.
10. Exceptions apply to:
 - a. Both Ownership/Investment Interests and Compensation Arrangements. (*i.e.*, physician services, in-office ancillary services, intra-family referrals)
 - b. Only Ownership/Investment Interests.
 - c. Only Compensation Interests. (*i.e.*, bona fide employment, rental of office space/equipment, personal services arrangements)

IV. Legal Issue: Stark Law



11. Three-Step Analysis under Stark:
 - ❖ Is there a **referral** from a physician for DHS?
 - ❖ Does the physician (or an immediate family member) have a **financial relationship** with the entity providing the DHS service?
 - ❖ Does the financial relationship fit in an **exception**?

IV. Legal Issue: Stark Law

12. Sanctions and Penalties under Stark:

- a. Denied claims
- b. Return reimbursement to Medicaid/ Medicare for paid claims for DHS
- c. Civil Money Penalties up to \$15,000 for each claim a person “knows or should know” was provided in violation of Stark
- d. Exclusion for attempting to circumvent Stark
- e. Civil Monetary Penalties up to \$100,000 for each arrangement or scheme



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III. Organization: Hospice/PC Nurse Liaison

1. Contract between Hospice and Hospital or LTCF for liaison nurse
2. Rules for Intake Coordination vs. Discharge Planning (D/P) activities apply 42 CFR § 482.43 & handout
3. Potential Kickback, Cost Report, and False Claim issues. 42 U.S.C. § 1320a-7b(b)(2). Free discharge planning services and allocation of liaison's salary and fringe benefits on cost report



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III. Organization: Hospice/PC Nurse Liaisons

4. **Intake Coordination** – manage and facilitate transfer of patients from Hospital to Hospice or PCP. Occurs only after patient referred by physician to Hospice or PCP.



- a. Explain Hospice or PCP policies to patients and family after referral
- b. Establish plan of care prior to Hospital discharge
- c. Communicate and coordinate post-discharge care

III. Organization: Hospice/PC Nurse Liaisons

5. **Discharge Planning** – Review Hospital files, individually or during staff discharge planning rounds, to determine level of care patient will require upon D/C. Discharge planning is hospital's responsibility Medicare Conditions of Participation, and part of DRG.



<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Discharge-Planning-Booklet-ICN908184.pdf>

IV. Organization: Managed Care Contract

Hospice contracts with managed care plans to provide comprehensive palliative care services under a capitated negotiated rate to covered patients.

More under Affordable Care Act



V. Organization: CHHA Palliative Care Program

1. CHHA contracts with Hospice for nurses and social workers to provide care to CHHA patients. Team approach
2. Hospice paid by CHHA for contracted personnel through negotiated rate, *i.e.*, per visit.
3. Contract anti-kickback safe harbor for personal services
42 C.F.R. § 1001.952(d)



V. Organization: CHHA Palliative Care Program

4. PPS based on Home Health Resource Groups (HHRGs). OASIS score - clinical severity, functional status (ADLs), service utilization (PT, OT, Speech), and Metropolitan Statistical Area.
5. Medicare eligible: home-bound, physician's care, skilled services on part-time or intermittent basis, plan of care signed by physician.
42 C.F.R. § 409.42.
6. Medicare requires at least one qualifying service (skilled nursing, PT, ST, OT, or home health aide) be provided directly by CHHA employees. CHHA must not contract for Hospice service that is qualifying service. 42 C.F.R. § 409.44 & Part 484



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VI. Organization: ACO & Different Models to Improve Extended Community Based Services

1. SSA § 1899 Accountable Care Organizations, part of the Medicare Shared Savings Program
2. Effective Jan. 1, 2012.
3. Regulations 42 C.F.R. Part 425
Contract with ACOs to provide services and become an ACO provider. Contract should comply with safe harbor against Kickbacks for personal services.



<http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>

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VI. Organization: Shared Savings Program a/k/a ACO's Goals



1. Accountability and better health care for a patient population.
2. Better individual care by coordinating services and items under Medicare Part A & B.
3. Encourage investment in infrastructure, *i.e.*, electronic medical records.
4. Redesign Care Processes for high quality and efficient service delivery, thus lowering growth in expenditures.

VI. Organization: So What do ACO & Medical Homes Have In Common With PCP & Hospices?

- ★ Better care for individuals
- ★ Better health for populations
- ★ Lower growth in expenditures



These goals are same as ACO. PCPs and Hospices employ interdisciplinary approach to care, which engages the patient and family, and the receipt of capitated payments in Hospice encourages efficiency, while maintaining quality care.

VI. Organization: ACO Definitions 42 C.F.R. § 425.20

Accountable Care Organization is a legal entity authorized under State, Federal or Tribal law , identified by a Tax Identification Number (TIN), and comprised of Medicare eligible providers and suppliers that work together as an ACO to manage and coordinate care for Medicare fee-for-service beneficiaries (Part A & B).

ACO Participants are providers and supplies who establish a mechanism for shared governance whereby each ACO Participant has a proportionate control over ACO's decision-making process, management, clinical and administrative systems.

VI. Organization: CMS Innovative Center – Demonstration Models ACA § 3021, SSA § 1115A

CMS has various demonstration projects underway whereby they are testing models of care delivery for *“defined populations for which there are deficits in care leading to poor clinical outcomes or potential avoidable expenditures.”* Focus on models to reduce costs, while enhancing quality of care.

http://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/34_Office_CMMI.html

PCP should explore opportunities to collaborate in demonstration projects.

VI. Organization: Various Demonstration Models ACA § 3021, SSA § 1115A

Patient Centered Medical Homes –

1. a health care setting that facilitates partnerships between individual patients and their personal physicians, and patient's family.
2. Care is enhanced by information technology.
3. *to provide targeted, accessible, continuous and coordinated care to Medicare beneficiaries with chronic or prolonged illnesses requiring regular medical monitoring, advising or treatment.”*
4. Demonstration project is being conducted in 8 states including urban, rural and underserved areas over a 3 year period.



<http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1199247.html>

V. Legal Issue: Patient Inducement or Solicitation

1. Anti-Inducement Provision:

Section 1128A(a)(5) imposes civil monetary penalties against any person who offers or transfers remuneration to any individual eligible for Medicare or State health care program, that such person knows or should know is likely to influence such individual to order or to receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program. 42 C.F.R. § 1003.102(b)(13).



V. Legal Issue: Patient Inducement or Solicitation

2. **Remuneration** under Section § 1128A(i)(6) includes transfers of items or services for free or for other than fair market value.
3. Congress did not intend to preclude provision of items and services of **nominal value**, including, *i.e.*, refreshments, medical literature, complimentary local transportation services, or participation in free health fairs.
H.R. Conf. Rep. No. 104-736, at 255 (1996).



V. Legal Issue: Patient Inducement or Solicitation

4. OIG nominal value no more than \$10 per item, or \$50 in the aggregate on an annual basis. Frequent rendering of items or services to any individual may preclude such items and services from being classified as nominal in value. 65 Fed. Reg. 24400, 24411 (4/26/00).
5. **Special Advisory Bulletin** on Gifts and Other Inducements to Medicare or Medicaid Patients issued 8/30/02.



<https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandinducements.pdf>

VI. Legal Issue: State Fee Splitting Laws

A physician's license may be revoked, suspended or annulled for professional misconduct if a physician requests, receives, participates, or profits from "*the division, transference, assignment, rebate, splitting or refunding of a fee*" or "*a commission, discount or gratuity*" in connection with providing professional care or services.

Ex.: NY Educ. Law § 6531.



VII. Legal Issue: Cost Report Issues

1. Provider "attestation" on cost report that all regulations have been met. False Claims Act exposure.
2. Shared employees or office space between Hospice and PCP must be allocated based on timesheets or square footage. Method requires prior approval from MAC.
3. Related Party Rules apply if, *i.e.*, PCP purchases nursing or aide services from Hospice and de-minimums exception not met. 42 C.F.R. § 413.17



VIII. Legal Issue: Medicare & Medicaid Reimbursement Rules



1. Palliative Care services must be medically necessary and documented.
2. Physician Billing and Coding Issues.
3. Medicare Reassignment Rules apply for physician employees of the Part B PCP.
4. Nurse Practitioners state rules must be examined.

Final Thoughts



- ❖ Think outside the box.
- ❖ Use Current Reimbursement Streams to fund Your Palliative Care Programs.
- ❖ Change comes through challenge.
- ❖ Complex Federal and State laws require analysis by Healthcare Attorney.
- ❖ Articles: www.arentfox.com.

Questions



Thank you!