Florida Hospice & Palliative Care Association

Palliative Care Legal Issues

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Webinar

“A wish you’d called me sooner, Mrs. Moodie.”
Palliative Care vs. Hospice Care

1. Hospice Care, defined by 42 CFR § 418.3, means a comprehensive set of services described in 1861(dd)(1) of the SSA, 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, and delineated in a specific patient plan of care.

Palliative Care vs. Hospice Care

2. Palliative Care, defined by 42 CFR § 418.3, 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 and to facilitate patient autonomy, access to information and choice.
Palliative Care vs. Hospice Care

3. Hospice Eligibility requirements – six months or less if illness runs its normal course. § 418.3
4. Hospice Election requirements – waiver of any Medicare services for terminal illness except hospice care, and services of attending physician, if not employee or volunteer of hospice. § 418.24

5. Reimbursement streams for hospice.
   a. Hospice per diem reimbursement for routine, continuous, respite and inpatient hospice care. § 418.302 and §418.306. Payment for physician and nurse practitioner services. § 418.304
   b. No reimbursement per se for palliative care. Revenue streams depend on how palliative care is provided and type of entity. Apply regular reimbursement rules.
Palliative Care vs. Hospice Care

6. Revenue streams for palliative care.
   a. Medicare Part A – hospital, outpatient hospital services, certified home health service
   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.

Why Have a Palliative Care Program (PCP)?

1. Clinical Imperative – Need for better quality of care for persons with serious and complex illnesses:
   a. Relieves physical and emotional suffering.
   b. Improves patient-physician communication and decision-making.
   c. Coordinates continuity of care across settings.
   d. Improves quality of life, satisfaction for patients and their families.

Source: www.capc.org
Why Have a PCP?

2. **Compliance With Patient and Family Wishes** – What do patients with serious illness want?
   
a. Pain and symptom control.
b. Avoid inappropriate prolongation of the dying process.
c. Achieve a sense of control.
d. Relieve burdens on family and caregivers.
e. Strengthen relationships with loved ones.
   
   **Source:** Singer et al., *JAMA* 1999;281(2):163.169.

Why Have a PCP?

3. **The Demographic Imperative** – Providers need PCP to effectively treat the growing number of persons with serious, advanced and complex illness from the day of diagnosis.
   
a. People deserve better care throughout the **multi-year** course of advanced illness.
b. Additional approaches for chronic, progressive illness, disease-modifying therapies.
c. Create an integrated continuum of high-quality palliative and hospice care.
Why Have a PCP?

4. The Educational Imperative
   a. Improve skills, knowledge, and attitudes towards palliative care, and end of life issues.
   b. Medical school and residency curricula are offering palliative care courses.
   c. Hospice & Palliative Nurse Association offers certification for RN’s and NP’s.
   d. Board Certification in Hospice and Palliative Care offered by the American Board of Medical Specialties (ABMS)
   e. Also certification is offered by ABMS if certified by American Boards of Medicine, Anesthesiology, Family Medicine, Physical Medicine and Rehabilitation, Psychiatry, Neurology, Surgery, Pediatrics, Emergency Medicine, Radiology and Obstetrics and Gynecology with specialty in hospice and palliative care.

Why Have a PCP?

The Fiscal Imperative

Population aging + growth in number of patients in need + effective new technologies.
   a. Under DRG system long, high-intensity hospital stays = fiscal crisis for hospitals.
   b. Palliative care lowers costs for hospitals and payors by reducing hospital and ICU length of stay, and some direct costs.
   c. Palliative care improves continuity among hospice/homecare/nursing home settings by supporting appropriate transition management.

Source: www.capc.org
Organization Design Options

A. Physician Part B Group
B. Hospice/Hospital Contract to Provide PC
C. Hospice/PC Nurse Liaison in Hospital
D. Managed Care Payment Opportunities
E. Certified Home Health Palliative Care Program
F. Hospice Contract with Hospital or Skilled Nursing Home for Inpatient Hospice Care

Complex Rules Require Expert Legal Analysis

Creating a Palliative Care Provider Involves:

A. State License Laws
B. State Corporate Practice of Medicine Laws
C. Anti-Kickback – Federal and State Laws
D. Physician Self Referral – Federal and State Stark
E. Patient Inducement or Solicitations Laws
F. Fee-Splitting Rules – State
G. Cost Report Rules – Medicare and Medicaid
H. Complex Medicare/Medicaid Reimbursement Rules
A. Organization Design – Part B Physician Group

1. Physician Part B Palliative Care Practice
2. Hospice Owned Captive Model – Corporate Practice of Medicine Rules
3. Create a separate entity PC or PLLC.
4. Apply for Part B "supplier" number from local Medicare fee for service contractor.
5. National Provider Identification Number.

6. CMS-855 B Medicare Enrollment Application for Medical Group Practice or Clinic that will bill for Medicare Part B services.
7. CMS -855I Medicare Enrollment Application for Physician and Non-Physician Practitioner
8. CMS-855R Medicare Enrollment Application for Reassignment of Medicare Benefits.
B. Organization Design – Hospital Contract

Hospice Contracts With Hospital To Provide Palliative Care 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.

C. Organization Design – Nurse Liaison

Hospice/ PC Nurse Liaison in Hospital or Nursing Home
1. Contract between hospice and hospital or nursing home to provide a liaison nurse in the facility.
2. Rules for Intake Coordination and Discharge Planning Activities apply.
C. Organization Design – Nurse Liaison

3. 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. Explaining 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.

4. Discharge Planning Type Activities – Screen and review hospital files, individually or during staff or discharge planning rounds, to determine level of care patient will require upon discharge.

5. Discharge planning is hospital’s responsibility pursuant to Medicare conditions of participation for hospitals and paid for in DRG payment. COPs – 42 C.F.R. § 482.43.
C. Organization Design – Nurse Liaison

6. Problem: If hospital discharge planner involves liaison before the patient referred to hospice or PCP, the liaison is performing discharge planning. Two issues:

   a) Potential Kickback – hospital is receiving in-kind contribution of discharge services, thereby being relieved of costs incurred, to induce hospital to make referrals to the hospice or PCP.
   42 U.S.C. § 1320a-7b(b)(2).

b. Cost report issue for hospice because hospital discharge planning activities are not costs related to patient care of a hospice or PCP patient, and subject to disallowance. Including all of liaison’s salary on hospice or PCP cost report could be false claim.
C. Organization Design – Nurse Liaison

7. Solution
   a. Does State Law permit delegation of discharge planning functions?
   b. Liaison leased to hospital for discharge planning services. Contract must meet the Personal Services and Management Contract Safe Harbor under Kickback statute. 42 C.F.R. § 1001.952(d). In writing, describe services and schedule, term one year or more, FMV, no link to amount of referrals from hospital, not promote violation of federal law, and reasonable business purpose.

7. Solution (cont’d.)
   c. Cost report issue – liaison keeps time records on discharge planning activities vs. intake activities to allocate allowable and non-allowable salary and related costs.

   Pub. 15, Section 2113 et al., home health care coordinators.
C. Organization Design – Nurse Liaison

9. Education and Liaison Activities
are allowable hospice costs if necessary
for patient care and do not duplicate services
which hospital should supply.
Educational resource to hospital concerning
hospice and palliative care, training for hospital
staff, and consultant to hospital for hospice or
palliative care policies and practices. Educate
physicians on available hospice/palliative care
services.

D. Organization Design – Managed Care
Payment Opportunities

Hospice contracts with
managed care plans to
provide comprehensive palliative
care services under a capitated
negotiated rate to covered patients.
E. Organization Design – CHHA

CHHA Palliative Care Program

1. CHHA contracts with hospice for nurses and social workers to provide care to CHHA patients. Team approach.


3. CHHA reimbursed under PPS based on Home Health Resource Groups (HHRGs). Reimbursement level depends on patient’s OASIS score assessing clinical severity, functional status (ADLs), and service utilization (PT, OT, Speech Language Pathology).

4. HHRG rates depend on geographic location, where patient is treated.
E. Organization Design – CHHA

5. Patient must be eligible for home health services under Medicare: confined to home, under physician’s care, in need of skilled services on part-time or intermittent basis, pursuant to plan of care signed by physician, and services provided by CHHA or under arrangement.

42 C.F.R. § 409.42.

6. Medicare requires at least one qualifying service (skilled nursing, physical, speech, continuing occupational therapy, medical social services 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 and 484.14(a)

7. Hospice/CHHA contract should meet safe harbor for personal services against anti-kickback laws, because hospice and CHHA may refer patients to each other.

42 C.F.R. § 1001.952(d)
F. Organization Design – Inpatient Hospice Unit

1. Hospitals or Nursing home contracts with hospice to provide inpatient hospice care. Hospice inpatient unit at hospital may also be part of the hospital’s palliative care program.

2. Admission is for pain control, acute management of symptoms that cannot be managed elsewhere; or inpatient respite care for no more than five consecutive days.

3. Hospice pays hospital negotiated per diem rate. Usually Hospitals won’t contract for Inpatient Respite Care because rate is too low.

4. Hospice still involved in providing services required in plan of care.

5. Cap total number of inpatient days for 12 months can’t be more than 20% of total number of hospice days.
F. Organization Design – Inpatient Hospice Unit

6. Requirements for Inpatient Hospice Care, § 418.108(a), for symptom management and pain control must be provided in a Medicare certified hospice that meets the requirements of § 418.110; or a hospital or SNF that meets § 418.110(b) and (e), i.e. 24-hour nursing services and patient areas.

7. For Inpatient Respite Care – 24-hour RN is no longer required if patients needs are met. § 418.108(b)

8. Per 42 C.F.R. § 418.108(c), contract must at minimum state:
   a. Hospice gives inpatient provider a copy of the patient’s plan of care, and specifies inpatient services to be furnished;
   b. Inpatient provider has policies consistent with hospice’s, and agrees to abide by hospice palliative care patient care protocols;
   c. Hospice inpatient clinical record includes all inpatient services and events: copy of discharge summary given to hospice; and if requested, medical record provided to hospice;
F. Organization Design – Inpatient Hospice Unit

d. The inpatient facility identifies one of their staff who is responsible for implementation of contract terms;
e. Hospice retains responsibility to ensure appropriate training of inpatient personnel who provide care pursuant to contract. Description of training and those giving the training are documented;
f. Both Parties agree on a method for verifying that requirements of 8a to e are met.

Complex Rules Require Expert Legal Analysis

Creating a Palliative Care Provider Involves:

A. State License Laws
B. State Corporate Practice of Medicine Laws
C. Anti-Kickback – Federal and State Laws
D. Physician Self Referral – Federal and State Stark
E. Patient Inducement or Solicitations Laws
F. Fee-Splitting Rules – State
G. Cost Report Rules – Medicare and Medicaid
H. Complex Medicare/Medicaid Reimbursement Rules
A. Complex Rules – State License

1. What is state definition of hospice care?
2. Is there “wiggle room” for hospice to provide palliative care to patients who are not terminally ill and/or who have not elected hospice care?
3. Does state law define palliative care?
5. Regulator’s interpretation, i.e., NY Pub Health Law § 4012-b.

B. Complex Rules – Corporate Practice

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 group.
B. Complex Rules – Corporate Practice

3. Reason for the rule is to ensure that medical decisions are only made based on what is best for the patient.

4. Some states have a clear prohibition, i.e., New York. Some states don’t follow rule. Some states law is unclear and case decisions must be reviewed.

5. Why does it matter? If license law permits hospice to have a palliative care program, but you are in a corporate practice of medicine state, the Part B Physician Palliative Care Group cannot be a division of hospice or owned by hospice.

B. Complex Rules – Corporate Practice

7. Possible solution, if state law has corporate practice of medicine requirements, Part B Palliative Care Group (PCP) set up as a “Captive” Professional Corporation. Hospice enters Management Service Contract with Part B PCP.

8. Management agreement hospice provides:
   - Administrative staff
   - Space / Lease
   - Purchasing Equipment, Supplies
   - Payroll, Bookkeeping, Budget
   - Arrange for Legal and Accounting Contracts
   - Medical Records and HIPAA
   - Data Analysis
   - Computer – IT
   - Compliance
   - Billing
   - Human Resources – recruiting, hiring, credentialing
   - Policies and forms
B. Complex Rules – Corporate Practice

9. Fair Market Value (FMV) fees for management services.

10. Safe Harbor for personal services and management contract because hospice and Part B PCP can refer patients to each other. 42 C.F.R. § 1001.952(d)

11. Role of Hospice Medical Director and Part B Group.

12. If hospice management agreement restricts physician’s professional judgment, physician could be sanctioned for “unprofessional medical conduct.”

13. Evaluate degree to which hospice management controls money flow to Part B PCP. The more control exercised by hospice through, i.e., budgetary constraints, the more likely the arrangement will violate corporate practice of medicine rules, applicable under some states.
B. Complex Rules – Corporate Practice

14. Organization documents such as articles of incorporation and bylaws, should be reviewed by health care counsel to ensure physician has sufficient control. Bylaws limiting physician shareholder’s ability to receive distribution from the PC or PLLC may violate corporate practice laws.

C. Complex Rules – Anti-Kickback Law

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.
C. Complex Rules – Anti-Kickback Law

3. “One Purpose Test” – Kickback exists if one purpose of payment is to induce referrals, regardless of legitimate purposes.
4. Remuneration is anything of value, money, bribes, rebates, free services.
5. Both the offeror and recipient violate statute.

6. Felony
   - Maximum $25,000 fine.
   - Imprisonment up to 5 years.
   - Automatic exclusion.
   - Civil Money Penalties up to $50,000 and damages up to 3 times the amount of the illegal kickback.
C. Complex Rules – Anti-Kickback Law

7. Statutory and Regulatory Exceptions or Safe Harbors are voluntary.
8. Safe Harbors describe minimum requirements for different business relationships that, if fully met, assure no criminal or civil sanctions.
9. Failure to Meet a Safe Harbor is not automatically a kickback. Arrangement evaluated on specific facts.

10. Safe Harbors, 42 C.F.R. § 1001.952. There are 25, including:
   - Discounts
   - Bona fide employment
   - Space rentals
   - Personal service and management contracts
   - Co-insurance and deductible waivers
   - Price reductions for eligible managed care organizations
   - Electronic health record items and service
C. Complex Rules – Anti-Kickback Law

11. Fair Market Value generally means price paid in arm’s length transaction, and does not take into account the volume or value of any referrals or business paid by Federal or State.

12. Reasonable Business Purpose.

13. OIG – Advisory Opinion.

D. Complex Rules – Stark Law

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
D. Complex Rules – Stark Law


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.
   c. By a physician or immediate family.
   d. In an entity that furnishes DHS.
D. Complex Rules – 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.

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.
D. Complex Rules – Stark Law

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).

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?
D. Complex Rules – 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 service a person “knows or should know” was provided in violation of Stark.
   d. Exclusion.
   e. Civil Monetary Penalties up to $100,000 and exclusion for attempting to circumvent Stark.

13. Health Care Attorney should analyze business relationships, and referral streams of Palliative Care Programs to ensure all these “Legal Minefields” are safe.

14. Most common safe harbors against kickback are Personal Services Management Contract and Lease.
E. Complex Rules – 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).

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.
E. Complex Rules – Patient Inducement or Solicitation

4. OIG states 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.

5. Special Advisory Bulletin on Gifts and Other Inducements to Medicare or Medicaid Patients issued 8/30/02.
http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandinducements.pdf

6. Patient Protection and Affordable Care Act (PPACA) § 6402 amends §1128A(a)(i)(6), definition of remuneration under CMP, to exclude “certain charitable and other innocuous programs.”
   a. Remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs;
E. Complex Rules – Patient Inducement or Solicitation

b. The offer or transfer of items or services for free or less than FMV if:
   i. Coupons, rebates, or other rewards from retailer;
   ii. Items offered on equal terms to general public regardless of health insurance status; and
   iii. Offer or transfer is not tied to provision of care reimbursed by Medicare or Medicaid.

6. PPACA § 6402 cont’d.

c. Offer or transfer of items or services for free or less than FMV by a person to an individual in financial need if not part of an ad or solicitation; not tied to care paid for by Medicare or Medicaid; and there is a reasonable connection between the item or service and the medical care being provided.

d. Effective March 23, 2010

e. Effective January 1, 2011, waiver of certain co-pays under Part D for first prescription under certain circumstances.
E. Complex Rules – Patient Inducement or Solicitation

7. Application to Palliative Care Program if complimentary support services are offered to patient in order to induce patient to use entity’s palliative care or hospice services. Each fact pattern needs to be legally analyzed by healthcare attorney.

OIG Advisory Opinions

42 C.F.R. § 1008.1 et. seq. describes process to obtain a legal opinion from OIG on whether a potential business arrangement or activity is a kickback, 42 U.S.C. § 1320a-7b, and whether sanctions will be imposed such as Civil Money Penalties or Exclusions

- fee
- opinion is only applicable to parties and facts presented
- no opinion as to False Claims Act, improper billing, claims submission, cost reporting or related conduct.
F. Complex Rules – 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. NY Educ. Law § 6531.

G. Complex Rules – Cost Report Issues

1. Actual reimbursement not determined by cost report because of per diem hospice rates, but must comply with cost reporting regulations. Provider “attestation” on cost report that all regulations have been met.
2. False Claims Act exposure.
G. Complex Rules – Cost Report Issues

3. Shared employees or office space between hospice and palliative care programs must be allocated.
4. Allocation method requires prior approval from hospice fiscal intermediary.
5. Salary and fringe benefits allocated based on approved time sheets, or costs, or revenue of each entity.

6. Costs of renting or maintaining shared office space allocated based on square footage and time.
8. Related Party Rules apply if, i.e., palliative care program purchases nursing or aide services from hospice and de-minimus exception not met. 42 C.F.R. § 413.17
H. Complex Rules – Medicare & Medicaid Reimbursement Rules

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

H. Complex Rules – Medicare Billing Rates

   a. Use Evaluation and Management Codes.
   b. Use AI modifier for Principal Physician of Record.
   c. Reason – CMS increased the work relative value units (RVUs) for new and established office visits, initial hospital and nursing facility visits and increased use of these visits in calculations for practice expense and malpractice.
   d. Source – Pub. 100-04 and Medicare Learning Network Q&A at:
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?
Choosing A Good Death: Palliative Care Options & Legal Requirements

Connie A. Raffa, JD, LLM

Four years ago, when family came to visit my dying mother at the hospital, they asked the clerk where is the palliative care unit? The clerk responded: what is the patient’s name? “Palliative?”

The term “palliative” is not as foreign as it used to be. Palliative Care Programs (PCP) are sweeping the country. The Center to Advance Palliative Care (CAPC) reports that the number of hospitals that offer PCP has more than doubled from 632 in 2000 to 1,300 in 2007, approximately one in five hospitals.

My first involvement with PCP was in June 2002 when CAPC invited me to present on legal issues impacting palliative care at their health systems conference. That presentation in Seattle had a long and boring title: “Meeting the Legal and Regulatory Requirements for Reimbursement Under Medicare and Medicaid for Palliative Care.” Six years later my presentation is now called “Choosing A Good Death: Palliative Care Options and Legal Requirements.” Although many of the legal issues remain the same, my experience with PCPs is now personal. My mother, Anna Raffa, died in the PCP at a major New York hospital, and my Aunt Ann died in the hospice inpatient house of the Visiting Nurse Service & Hospice of Suffolk. They both experienced a “good death,” and I share their stories in my presentations. They both received the comfort and dignity of palliative care; the same care but in two different provider settings.

Different or the Same? What are the Revenue Streams?

What I wrote in 2003 for Caring remains true today: all hospice care is palliative care, but not all palliative care is hospice. Palliative care and hospice care embrace the same holistic approach of comfort, pain management and symptom control, addressing the spiritual and psychological needs of the patient, and providing support to the family. The difference is not in the care provided, but in the hospice election and eligibility requirements. A palliative care patient can still pursue curative treatment, and need not be terminally ill with a life expectancy of six months or less if the illness runs its normal course. Hospice is a defined benefit reimbursed under Medicare, almost all Medicaid programs and private insurance. There are four levels of Medicare reimbursement. Although a Medicare benefit called “palliative care” does not yet exist, palliative care is provided in many different settings and the reimbursement requirements for palliative care depend on whom, how and where it is provided. The current reimbursement revenue streams available for palliative care are: Medicare Part A for inpatient and outpatient hospital setting, skilled nursing home, and certified home health agency; Medicare Part B for physician, physician assistant, nurse practitioner, psychologists, physical and occupational therapists, social workers (with limitations), and durable medical equipment suppliers; Medicare Part C managed care; Medicaid, private insurance, private pay and contract relationships with other providers. For example, services provided by a palliative care consult team in a hospital composed of a physician specializing in palliative care and pain management, a nurse practitioner, and social worker are reimbursed for hospital services under the appropriate DRG for inpatient care, and Part B for the physician and nurse practitioner, and grant or contributions for the social worker, unless the care is for the treatment or diagnosis of mental illness.
Palliative Care Organization Design Options

Although there may be other organization design options for a PCP, I have identified the following six.

1. Physician Part B Group
2. Contract between Hospital and Hospice creating a PC Team
3. Contract between Hospital and Hospice PCP for Nurse Liaisons to assist with discharge planning functions, if permissible under state law.
4. Contract between Hospice PCP and Managed Care Plan
5. A PCP of a Certified Home Health Agency (CHHA)
6. Hospice Contract with Hospital or Nursing Home for Inpatient Hospice Care

The most popular model for a PCP is the physician and/or nurse practitioner consultation visits for patients in hospitals and nursing homes. The hospital or nursing home may have their own PCP using their own professional staff, or they may contract with a hospice to provide a joint PCP. My original articles describing these different PCPs were published in Caring magazine, and can be found at my firm’s website www.arentfox.com by searching palliative care.

Legal Requirements

Unlike other industries, normal business practices in the health care industry may be considered kickbacks for referrals or inducements to patients to choose your PCP. To best demonstrate my point: in the beverage industry, if you want to get your product on a shelf in a supermarket, you must pay for “shelf space.” Paying for referrals in health care may land you in jail. When creating a new service line or product in any industry there are legal considerations to address. Health care is no different. However, the impact of existing laws should not be a barrier to innovation. With the correct legal advice your PCP can be created in a manner that does not violate existing laws. Business relationships among providers usually involve parties that can refer patients to each other for healthcare services or items. Many of the rules are federal and have parallel state laws. The main areas of concern are:

1. State License Laws
2. State Corporate Practice of Medicine Laws
3. Anti-Kickback – Federal and State Laws
5. Patient Inducement or Solicitations Laws
6. Fee-Splitting Rules – State
8. Complex Medicare/Medicaid Reimbursement Rules

This minefield of federal and state regulations can be navigated by a health care attorney, with expertise in these areas. The stakes are too high to use an attorney without health care experience. The press is always reporting about overnight millionaires as a result of whistleblower or relator lawsuits. In this environment, it is wise to protect your business and yourself from corporate and personal liability. The following is a brief explanation of each of these areas of laws.
1. **State License Laws**

The first place to start is state license laws. Are there state license requirements for a PCP? Is the term palliative care defined by state law? If the PCP is a division of your hospice, does the state licensing law permit a hospice to provide palliative care to nonhospice patients? Look for wiggle room. Medicare defines hospice as a program "primarily engaged" in providing hospice care. This wiggle room in the Medicare definition permits a hospice to provide palliative care to patients who have not elected hospice care. CMS Program Memorandum A-02-102 entitled "Medicare Certified Hospices-Clarification of Acceptable Parameters for Some Contracted Arrangements" describes different contract relationships where another provider, such as a hospital or CHHA, purchases some of the "highly specialized staff time or services of a hospice" for their patients. These services are not hospice services, but become part of the package of the palliative care services offered by the contracting provider.

A good example in the PM is a patient receiving skilled services from a CHHA. The beneficiary is diagnosed with a terminal illness but refuses to elect hospice care because he wants to pursue curative treatments. The patient is in pain. The CHHA purchases from the hospice “specialized pain control services” and “specialized nursing services.” The hospice bills the CHHA pursuant to the terms in its contract, and the CHHA pays the hospice directly. Neither provider bills Medicare for the contracted services. Instead, those services are reimbursed to the CHHA in its episode payment under the Medicare prospective payment system for CHHAs. The amount of Medicare reimbursement to the CHHA depends on which Home Health Resource Group (HHRG) applies to the patient. Its selection depends on how the patient scores on the OASIS evaluation. OASIS questions assess the patient’s clinical severity domain, functional status domain (Activities of Daily Living) and service utilization domain will determine the HHRG. Also, where the patient lives and is treated determines the geographical code applied to the Medicare payment. Since this patient remains a CHHA patient in its PCP, the CHHA must maintain the patient’s medical record, including documentation from the leased hospice staff.1

State licensing laws that restrict a hospice to care for only terminally ill patients who have elected hospice care have no wiggle room. In New York we originally had this problem. The state regulators prohibited a hospice from contracting with CHHAs to lease a hospice nurse to the CHHA PCP. Such an arrangement was beyond the hospice license and the hospice was engaging in private duty nursing, a service for which it was not licensed. This problem was fixed by amending the license laws for hospice, Public Health Law § 4012-b. The amendment permits a hospice to act alone or contract with another provider to provide palliative care services to patients “with advanced and progressive disease and their families.” The bottom line is you must find out what the state regulators’ interpretation is of your state’s hospice license laws.

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1 The patient must be eligible for home health services under Medicare pursuant to 42 C.F.R. §409.42. He must be confined to the home, under the care of a physician, in need of skilled services on a part-time or intermittent basis pursuant to note plan of care signed by a physician, and the services must be provided by a CHHA or under arrangement.

Medicare also requires that at least one of the qualifying services be provided directly by CHHA employees. These include skilled nursing, physical, speech or occupational therapy, pursuant to 42 C.F.R. §409.44, §409.45, and §484.14(a). Therefore, the CHHA must make sure that the contracted service from the hospice for its palliative care program is not the one qualifying service. So, if nursing is the CHHA’s qualifying service, the CHHA cannot contract with the hospice for nurses, unless the CHHA decides to choose another service to be provided directly by CHHA employees.
2. Corporate Practice of Medicine

Some states prohibit a business corporation or lay person from controlling the medical decisions of a physician. These states require that all the owners of a physician group hold the same professional license. This legal concept is called the “corporate practice of medicine” rule. The policy enforced is to ensure that medical decisions are not influenced by nonphysicians, and that decisions are made based on what is best for the patient. Some states have a clear prohibition against the corporate practice of medicine, such as New York and California. Some states don’t follow the rule at all, such as Florida and Kentucky. In some states, the law is unclear. In a state that does not have or enforce this rule, the hospice may apply to be a physician group, or own the group as a separate entity.

In a corporate practice of medicine state, the physician group must be a separate entity, such as a professional corporation or a professional limited liability corporation. It cannot be a division of the hospice. The physician group must apply to be a Part B supplier. Each physician applies for a National Provider Identification Number, and, if they are an employee of the group, reassignment of their Medicare reimbursement to the group. What role does hospice play? The typical arrangement is for the hospice to serve as a Management Service Organization (MSO) by entering into a management and administrative services contract with the physician group. The MSO typically provides administrative staff, equipment, space, budget, bookkeeping, payroll, arranging for legal and accounting services, purchasing, inventory, medical records, data analysis, computer support, compliance, human resources, recruiting, hiring, credentialing, and billing. The hospice must charge FMV fees for the management services. The MSO contract should comply with the safe harbor against kickbacks for personal services and management contract. The risk is that the physician group will pay the hospice more than FMV for its management services in return for the hospice referring palliative care consultations to the physicians.

This model is called the “captive physician group” and is used in states like New York and California, which enforce their corporate practice of medicine laws. Note this is not a Medicare or federal law. Therefore, if you are a hospice in a state that enforces a corporate practice of medicine rule, and the hospice applies for a Part B supplier number, Medicare will issue it to the hospice. However, the physicians may be at risk with the state regulators. A physician’s participation in a group that violates the state corporate practice of medicine rule may be viewed as “unprofessional medical conduct,” and subject the physician to sanction under the professional conduct rules of the state.

Obviously, the role of the hospice Medical Director in creating a “captive physician group” is pivotal. This contract relationship is referred to as a “captive” because the hospice or PCP exerts some control over the physician group as a result of the contractual relationship. The relationship created should be analyzed against state corporate practice of medicine laws, fee splitting laws, federal (Stark) and state self referral laws, and safe harbors of anti kickback provisions covering the various contractual relationships, for example personal services, management, lease, and/or equipment rental.
3. State and Federal Anti-Kickback Laws
The next law to consider is the state and federal anti-kickback laws. These laws are a 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. Remuneration is anything of value including money, rebates and free services. Both the offeror and recipient of a kickback violate the law. A kickback can exist if one purpose of the payment is to induce referrals, regardless of the legitimate reason for the payment. Offering or receiving a kickback is a felony punishable by imprisonment, fine, automatic exclusion, and civil money penalties (CMP).

The federal and some state anti-kickback laws are criminal laws, punishable by fines, imprisonment, and/or exclusion. However, there are “safe harbors” that describe different types of business relationships. If you follow the requirements of the safe harbor, i.e., contracting for management or personal services, there is no criminal or civil sanction. Failure to meet the requirements of a safe harbor is not automatically a kickback arrangement. The facts of the business relationship must be evaluated to determine intent.

The 26 business relationships for which there are safe harbors include discounts, bona fide employment, space rentals, personal service and management contracts, co-insurance and deductible waiver, price reductions for eligible managed care organizations, and many more. Fair market value (FMV) payments in business relationship and the reasonable business purpose of the relationship must be evaluated. FMV generally means the price paid in an arm’s length transaction, and does not take into account the volume or value of any referrals or business paid by Medicare, Medicaid or other government funded programs. If your health care counsel is not sure whether a kickback exists, a request for an Advisory Opinion can be made from the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). There is a fee for the opinion.

Under the 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. An entity may not present a claim for reimbursement from Medicare or Medicaid for DHS provided as a result of a prohibited referral. Federal Stark is a civil law which imposes strict liability. The referral is not prohibited if an exception applies. If an exception is not met, the arrangement is unlawful. There are various exceptions that apply to ownership/investment and compensation arrangements, ownership/investment interests, and purely compensation. A Stark analysis consists of three steps:
1. Is there a referral from a physician for a DHS?
2. Does the physician (or his immediate family member) have a financial relationship with the entity providing the DHS service?
3. Does the financial relationship fit an exception?

DHS services include clinical laboratory, physical therapy, occupational therapy, speech pathology, radiology and certain imaging, radiation therapy and supplies, DME, parental and enteral nutrients, equipment and supplies, prosthetics and orthotics devices and supplies, home health, outpatient prescription drugs and inpatient and outpatient hospital services. Although hospice care is not a DHS, palliative care services may be. Sanctions
and penalties for a Stark violation include denied claims, overpayment, CMP and exclusion. Many states have their own prohibition of self referral laws.

5. Patient Inducement or Solicitation
The Anti-Inducement provisions provide for the imposition of CMP against any person who offers or transfers remuneration to any individual eligible for benefits under Medicare or Medicaid that such person knows or should know is likely to influence such individual in order to receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by Medicare or Medicaid. The term “remuneration” under Section 1128A(i)(6) of the Social Security Act is defined to include “transfers of items or services for free or for other than fair market value.” The legislative history to the Health Insurance Portability and Accountability Act of 1996 indicates that Congress did not intend for the Act to preclude “the provision of items and services of nominal value, including, for example, refreshments, medical literature, complimentary local transportation services, or participation in free health fairs.” H.R. Conf. Rep. No. 104-736, at 255 (1996).

Items of nominal value which can be given to patients or potential patients are interpreted as having value of $10 per item or $50 in the aggregate on an annual basis per individual. There are five exceptions of permissible remuneration, which include: 1) nonroutine unadvertised waivers of co-payments or deductible after collection efforts; 2) disclosed differentials in a health insurance plan’s co-payments or deductibles; 3) incentives to promote the delivery of certain preventive care; 4) any business relationship permitted under anti-kickback safe harbors at 42 C.F.R. §1001.952; and 5) waivers of co-payment amounts in excess of the minimum co-payments amount under the Medicare hospital outpatient fee schedule.

The OIG has a “Special Advisory Bulletin on Gifts and Other Inducements to Medicare or Medicaid Patients” issued 8/30/02. How do these rules impact a PCP? If complimentary support services are offered to a Medicare beneficiary or Medicaid recipient to influence the patient to choose your PCP, these rules apply. Each fact pattern must be analyzed against these rules. If health counsel is not sure, she may request an Advisory Opinion from the OIG on whether a proposed business practice is a kickback, inducement or solicitation. OIG Advisory Opinions (AO) are not precedents.

However, the following opinions provide some insight. In OIG AO # 00-7, a hospital providing free transportation between the patient’s home and hospital was not an inducement. In OIG AO # 01-19, a hospital donation of space to an end of life program was not a kickback because the program was run by volunteers and served a bona fide community purpose. In OIG AO # 03-4, free pagers given to home health patients by their CHHA was an inducement, but the OIG choose not to sanction. In OIG AO # 00-3, the foundation for the hospice provided supportive care for free to patients who had not elected hospice care. Volunteers provided friendship visits, transportation, assistance writing and reading the mail, running errands, food preparation, and respite breaks for family. OIG held that the volunteer services were a kickback, but they choose not to impose sanctions because the program was run by a foundation for a non profit hospice.
6. **State Fee-Splitting Laws**
Your PCP must also be examined to ensure that any state fee-splitting law is not violated. Not all states have fee-splitting laws. However, for those that do, usually the physician is at risk. In New York State, the Education Law § 6531 states that a physician’s license may be revoked, suspended or annulled for professional misconduct if a physician requests, receives, participates in, 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.” In the captive physician model, if the hospice contracts with the physician group to provide administrative and billing services, and that fee is determined as a percentage of the physician’s revenue from billing for services, the arrangement may constitute a prohibited fee split. However, the problem may be solved by changing the fee to FMV for the administrative and billing services.

7. **Medicare and Medicaid Cost Report Issues**
If your PCP involves a provider that files cost reports with Medicare or Medicaid, you must be sensitive to the impact the business relationship will have on the cost report. It doesn’t matter if the provider is paid on a prospective payment basis. Cost reports have an “attestation” that must be signed, which states all laws were complied with. Some cost report rules that may come into play are home office, shared employees and/or office space, related party rules, and prudent buyer rules. For example, if a nurse employed by hospice shares her time caring for hospice and palliative care patients, her salary and fringe benefits must be allocated based on a method that was pre-approved by the Medicare contractor. These rules are set forth in Medicare regulations and the Provider Reimbursement Manual. Medicaid usually follows Medicare principles or they have their own set of rules.

8. **Medicare and Medicaid Reimbursement Rules**
Once you’ve created your PCP you need to identify revenue streams to pay for the services or items. Medicare and Medicaid have complex reimbursement rules applicable to each provider type. For example, physician and nurse practitioner billing and coding rules, and reassignment rules. Palliative care services provided must be medically necessary and documented.

**Conclusion**
Palliative care is here to stay. Many states have definitions of palliative care. Medicare has a definition in the proposed conditions of participation for hospices. PCP address many needs. CAPC has identified several of them: 1) the need for better quality of care for persons with serious and complex illnesses; 2) compliance with patient and family wishes for pain and symptom control and choosing what I call a “good death;” 3) hospitals need PCP to effectively treat the growing number of persons with advanced illnesses; and 4) to relieve hospital financial burdens through cost avoidance savings from PCP. Medical schools have also recognized that palliative care is important with LCME requirements that “clinical instruction must include important aspects of end of life care.” Similarly, residency ACGME requirements for internal medicine and subspecialties require that each resident receive instruction in the principles of palliative care.
Legal Issues to Consider When Creating a Health Care Business Model

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Business practices considered standard in other industries may in the health care industry be considered kickbacks for business or inducements to patients to choose a certain provider. To best demonstrate my point: in the beverage industry, if you want to get your product on a shelf in a supermarket, you must pay for “shelf space.” Paying for referrals in health care may land you in jail. The minefield of federal and state regulations such as licensing, corporate practice of medicine laws, kickbacks, physician self referral (known as Stark), fee splitting, professional misconduct, anti-inducement or solicitation laws necessitate that a health care attorney, with expertise in these areas, counsel the creation, transactions, and business relationships of any health care provider. The stakes are too high to use an attorney without health care experience and expertise.

When creating a new service line or product in any industry there are legal considerations to address. Health care is no different. However, the impact of existing laws should not be a barrier to innovation. With the correct legal counsel and advice the new service line or product usually can be created in a manner that does not violate existing laws. Business relationships among providers usually involve parties that can refer patients to each other for healthcare services or items. Many of the rules are federal and have parallel state laws. The main areas of concern are:

1. State License Laws
2. State Corporate Practice of Medicine Laws
3. Anti-Kickback – Federal and State Laws
5. Patient Inducement or Solicitations Laws
6. Fee-Splitting Rules – State
8. Complex Medicare/Medicaid Reimbursement Rules

The following is a brief explanation of each of these areas of laws.

1. State License Laws
The first place to start is state license laws. Are there state license requirements for the new “entity”? If the new service line or product is to be provided under the existing license of your current entity, is that service or product permissible?
2. Corporate Practice of Medicine
After the license question is resolved, you must consider the type of corporate entity to create. Choices vary depending on state requirements. Should the entity be a corporation – C or S, a limited liability company or a professional corporation. Some states require that all the owners of an entity that will provide professional services, such as physician services or legal services, be owned by individuals who hold the same professional license. The reason for this requirement is that these states prohibit a business corporation or lay person from controlling the medical decisions of a physician or professional staff. This legal concept is called the “corporate practice of medicine.” The policy enforced in corporate practice of medicine states is to ensure that medical decisions are only made based on what is best for the patient. Some states have a clear prohibition against the corporate practice of medicine, such as New York. Some states don’t follow the rule at all, such as Florida and Kentucky. In some states, the law is unclear.

3. State and Federal Anti-Kickback Laws
The next law to consider is the State and Federal Anti-Kickback laws. This law is a 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. See Social Security Act § 1128B.

Remuneration is anything of value including money, rebates and free services. Both the offeror and recipient of a kickback violate the law. A kickback can exist if one purpose of the payment is to induce referrals, regardless of the legitimate reason for the payment.

The federal and some state anti-kickback laws are criminal laws, punishable by fines, imprisonment, and/or exclusion. However, there are “safe harbors” that describe 26 different types of business relationships. If you follow the requirements of the safe harbor, i.e., contracting for management or personal services, there is no criminal or civil sanction. Failure to meet the requirements of a safe harbor is not automatically a kickback arrangement. The facts of the business relationship must be evaluated to determine intent.

The 26 business relationships for which there are safe harbors include discounts, bona fide employment, space rentals, personal service and management contracts, co-insurance and deductible waiver, price reductions for eligible managed care organizations, and many more. Fair market value payment in business relationship, and reasonable business purpose of the relationship are legal concepts which must be evaluated. If your health care counsel is not sure whether a kickback exists, a request for an Advisory Opinion can be made from the Office of the Inspector General (“OIG”) of the U.S. Department of Health and Human Services (“HHS”). There is a charge for the Opinion.

Under the 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. An entity may not present a claim for reimbursement from Medicare or Medicaid for services provided as a result of a prohibited referral. Federal Stark is a civil law which imposes strict liability. The referral is not prohibited if an exception applies. If an exception is not met, the arrangement is
unlawful. There are various exceptions that apply to ownership/investment and compensation arrangements 42 CFR 411.358, ownership/investment interests 42 CFR 411.356, and purely compensation 42 CFR 411.357.

A Stark analysis consists of three steps:

1. Is there a referral from a physician for a DHS?
2. Does the physician (or his immediate family member) have a financial relationship with the entity providing the DHS service?
3. Does the financial relationship fit an exception?

5. Patient Inducement or Solicitation

Anti-Inducement Provision, Section 1128A(a)(5) of the Act, provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to any individual eligible for benefits under [Medicare or a State health care program] that such person knows or should know is likely to influence such individual in order 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]. See also 42 C.F.R. § 1003.102(b)(13) “Anti-Inducement Regulations.” The term “remuneration” under Section 1128A(i)(6) of the Act is defined to include “transfers of items or services for free or for other than fair market value.” The legislative history to the Health Insurance Portability and Accountability Act of 1996 indicates that Congress did not intend for the Act to preclude “the provision of items and services of nominal value, including, for example, refreshments, medical literature, complimentary local transportation services, or participation in free health fairs.” H.R. Conf. Rep. No. 104-736, at 255 (1996).

Items of nominal value which can be given to patients or potential patients are interpreted as having value of $10 per item or $50 in the aggregate on an annual basis per individual. There are five statutory or regulatory exceptions of permissible remuneration, which include:

1. Non-routine unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts.
2. Properly disclosed differentials in a health insurance plan’s co-payments or deductibles.
3. Incentives to promote the delivery of certain preventive care. Such incentives may not be in the form of cash or cash equivalents and may not be disproportionate to the value of the preventive care provided.
5. Waivers of co-payment amounts in excess of the minimum co-payments amount under the Medicare hospital outpatient fee schedule.

If needed, your health care counsel can request an advisory opinion on whether a proposed business practice is a “kickback” or inducement or solicitation.
6. State Fee-Splitting Laws
The proposed business venture must also be examined to ensure that any state fee-splitting law is not violated. Not all states have fee-splitting laws. However, for those that do, usually the physician is at risk. For example, in New York State the Education Law § 6531 states that a physician’s license may be revoked, suspended or annulled for professional misconduct if a physician requests, receives, participates in, 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.” For example, if your business model involves a physician paying a fee for administrative and billing services and that fee is determined as a percentage of the physician’s revenue from billing for services, this arrangement may constitute a prohibited fee split. However, the problem may be solved by changing the fee to fair market value for the administrative and billing services. An experienced health care attorney can recognize these issues and address them.

7. Medicare and Medicaid Cost Report Issues
If the proposed business venture involves a provider that files cost reports with Medicare or Medicaid, you must be sensitive to the impact the business relationship will have on the cost report. It doesn’t matter if the entity will be paid on a prospective payment basis. Cost reports have an “attestation” that must be signed, which states all laws were complied with. Examples of cost report rules that may come into play are home office, shared employees and/or office space, related party rules, Prudent Buyer rules, etc. These are set forth in Medicare regulations and the Provider Reimbursement Manual. Medicaid usually follows Medicare principles or they have their own set of rules. Once again, an experienced health care attorney can assist you in navigating these rules with the proper corporate structures, procedures, and prior approvals from applicable fiscal intermediaries.

8. Medicare and Medicaid Reimbursement Rules
Once you’ve created your new business model, you need to identify revenue streams to pay for the services or items. Medicare and Medicaid have complex reimbursement rules applicable to each industry, which are too numerous to mention. For example, physician billing and coding rules, reassignment rules, nurse practitioner billing rules, etc.

Conclusion
A state or federal investigation is very costly to defend. The government has an arsenal of sanctions at the criminal, civil, and administrative level. The criminal laws include making a False Statement, Mail or Wire Fraud, False Claims in Medicare or State Health Programs, failure to disclose and repay an overpayment, and other state and federal sanctions. Civilly, there are the Civil Money Penalties (“CMP”) laws, which impose an $11,000 fine for each claim. Anti-kickback laws impose fines up to $25,000, 5 years imprisonment, automatic exclusion, and CMP up to $50,000 and damages up to 3 times the amount of the illegal kickback. Penalties for violating the physician self referral law – Stark – include denied claims, overpayment, CMP up to $15,000 for each service a person knows or should have known was in violation of Stark, exclusion, and CMP up to $100,000 for attempting to circumvent Stark.

The press is always reporting about overnight millionaires as a result of “whistleblower” or “relator” lawsuits. In this environment, it is wise to protect your business and yourself from corporate and personal liability by using the correct attorney with the correct expertise.
Change comes through challenges. Making an experienced health care attorney part of your strategic team in planning any new health care venture is wise. An experienced health care attorney can help you structure your business relationships without tripping any of these minefields of laws. What is a good health care attorney? I would define a good health care attorney as someone who has extensive experience working in your particular industry. An attorney who also has government regulatory experience is ideal because they know how regulators think and can identify the issues. For most work, the attorney does not have to be admitted in your state. Many of these issues are federal and those that are state are usually regulatory advice, which an experienced health care attorney can address by reviewing the state laws. How should you approach the attorney? Call him or her on the phone. Explain what you want to do. Don’t expect answers immediately. Ask for information about the attorney’s background.