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Legal Alert
Health Care

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Choosing A Good Death: Palliative Care Options & Legal Requirements

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.

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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
4. Physician Self Referral – Federal and State "Stark"
5. Patient Inducement or Solicitations Laws
6. Fee-Splitting Rules – State
7. Cost Report Rules – Medicare and Medicaid
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

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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.

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

[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.

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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,

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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, coinsurance 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.

4. Physician Self-Referral – Federal and State Stark

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)
3. have a financial relationship with the entity providing
4. the DHS service?
5. 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

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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

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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.