

Legislative and Regulatory News

Hospice And Palliative Physician Group: Examining The Issues

By CONNIE A. RAFA, J.D., LL.M., AND MARK B. LANGDON, J.D.

A recent trend in palliative care is for hospices to create other entities as part of an effort to advance the concept of palliative care and reach a broader population, who are either not yet eligible for hospice care or choose not to elect hospice care. This article provides a brief discussion of various structures that a hospice might consider in setting up a separate entity, such as a clinic or professional medical corporation, to provide palliative care services.

An increasingly frequent approach involves a palliative care organization, such as a hospice, assisting physicians in establishing a medical group or clinic that contracts with the palliative care organization for management and administrative services. The management agreement could be a comprehensive and long-term agreement that provides compensation to the palliative care organization for supplying staff, equipment, and space, and general administrative services. Such administrative services could include budgeting and bookkeeping services, arranging for legal and accounting services, purchasing inventory and supplies, assisting in the recruitment of practitioners, maintaining files and records, and assisting in strategic planning. Because the non-physician palliative care organization exerts some control over the physician practice through a management services agreement, this model is often referred to as a "captive" professional corporation.

Another possible approach is for the hospice—consistent with state law and the requirements of the local Medicare contractor—to enroll in the Medicare program as a Part B supplier, or clinic, and bill for non-hospice palliative care services. We discuss this model in more detail below.

While both options can be highly beneficial to patients, there are some critical legal issues a hospice must consider when contemplating the development and implementation of a business plan. The laws set forth below are highly technical and might seem daunting, but this article will help you structure palliative care programs within the confines of these laws.

I. The Federal Anti-Kickback Statute

One of the most significant laws you need to be familiar with when developing a palliative care program is the Federal Anti-Kickback Statute. This law is a broad prohibition of the offer, solicitation, payment, or receipt of anything of value that is intended to induce the referral of a patient for an item or service that is reimbursed by most federal programs, including Medicare and Medicaid. The law has been interpreted broadly by several courts to apply to situations where only *one* purpose of a payment is to induce referrals, even if there may be other legitimate purposes for which the payment is made. As a result, virtually any financial relationship between a health care provider and a referral source has potential anti-kickback implications.

This original law is very broad, so several exceptions have been added to it by Congress and by regulations adopted by the Office of Inspector General of the Department of Health and Human Services. Full compliance with one of these exceptions—referred to as "safe harbors"—is an absolute defense to an anti-kickback law prosecution by the OIG. Therefore, it is advisable to structure a transaction within a safe harbor whenever possible. To qualify for safe harbor protection, however, *all* of the requirements specified in the applicable statute or regulation must be met.

Most relevant for purposes of an arrangement between a hospice and a palliative care organization is the "personal services and management contracts" safe harbor. The requirements of this safe harbor are:

1. The agreement must be in writing and signed by the parties;
2. The agreement must cover all of the services to be provided for the term of the agreement and specify the services to be provided;
3. If the agreement is intended to provide for services on a part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;

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4. The term of the agreement must be for not less than one year;
5. The aggregate compensation paid over the term of the agreement must be set in advance, be consistent with fair market value in arms-length transactions, and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health care program;
6. The aggregate services contracted for must not exceed those which are reasonably necessary to accomplish the commercially-reasonable business purpose of the services; and
7. The services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law. 42 C.F.R. § 1001.952(d).

In summary, any management or administrative services agreement between a hospice and a palliative care clinic or physician group practice has to meet all of these safe harbor requirements for that arrangement to be immune from prosecution under the Anti-Kickback Statute. However, it is important to note that, even if all the requirements of the safe harbor cannot be met, the arrangement would not automatically be considered illegal. In fact, some of the requirements—such as that the total compensation be set in advance—can be very difficult to satisfy. Rather, the determination of the legality of the arrangement depends on the intent of the parties. To that end, as long as the compensation reflects fair market value for legitimate and necessary services, such services are actually provided, and the payments do not vary based upon the volume or value of referrals generated between the parties, the risk of a violation would probably be low.

Note also that the requirements of the personal services safe harbor would similarly apply to any medical director relationships involving the hospice, the palliative care clinic, and physicians. Further, any equipment and space rental arrangements between the hospice and the palliative care clinic should, to the extent possible, be structured to comply with the requirements of the “equipment rental” and “space rental” safe harbors. The requirements for these safe harbors are very similar to the requirements listed above, but apply to the lease of equipment and space. The most notable requirement of those safe harbors is that the fees must represent fair market value, and the

total fee must be set in advance. Thus, a fee fluctuating in any manner based upon hours or another basis would not comply with this standard. Again, however, the failure to fully qualify for a safe harbor does not necessarily mean that an arrangement is illegal.

Consideration of the Anti-Kickback Statute is also important when evaluating the overall structure of the arrangement and assessing whether legitimate reasons support entering into the transaction. For example, the government could conceivably question the propriety of a hospice setting up a wholly owned subsidiary that would focus on the provision of palliative care services to patients outside of the traditional hospice program. That is, the government could assert that such a transaction serves merely as a mechanism to funnel referrals back and forth between the hospice and the palliative care organization, with the hospice capturing revenue from the Medicare program that it would otherwise not receive. Such arguments can be rebutted, however, to the extent that bona fide reasons support this structure, and all pertinent Medicare coverage and billing requirements are satisfied.

II. The Stark Law

In addition to the Anti-Kickback Law, it is also important to consider the implications of any arrangement involving the provision of palliative care services under the Stark Law. The Stark Law prohibits a physician who has a financial interest with an entity, or a physician whose immediate family member has such an interest, from referring a patient to the entity for the furnishing of certain “designated health services” reimbursable by Medicare or Medicaid, unless an exception applies. The designated health services covered by the law include the following: clinical laboratory services; physical therapy services (including speech-language pathology); occupational therapy services; radiology and certain other imaging services; radiation therapy; durable medical equipment; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and hospital services. Penalties for violating the Stark Law include forfeiture of any reimbursement for services rendered based on an unlawful referral, civil fines, and exclusion from the Medicare and Medicaid programs.

Notably, Medicare-covered hospice services, including the specific designated health services listed above, that are reimbursed *under the hospice composite rate* are specifically excluded from the reach of the Stark Law.

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However, the Stark Law still might be relevant to the extent that physicians associated with the hospice or the palliative care clinic refer any of the services outlined above to the hospice or the clinic, and such services are reimbursable outside of the composite rate. In such an instance, the financial relationship between the physician and the hospice or the clinic would have to meet an exception to the Stark Law. And, unlike the Anti-Kickback Law, an arrangement that does not meet an exception to the Stark Law automatically violates the law. Notably, there is an exception for certain referrals that occur within a physician's office, so it is possible that a physician's referrals to the palliative care clinic would be protected.

III. State Anti-Kickback and Self-Referral Laws

In addition to the federal health care fraud and abuse laws discussed above, many states have their own kickback and self-referral laws that apply regardless of whether the patient is a Medicare or Medicaid beneficiary. Sometimes these laws are much broader in scope than the federal laws; sometimes they are narrower. It is probably safe to assume that compliance with the federal laws discussed above will reduce your risks under most state laws. However, before proceeding with any business plan, you should engage in a thorough review of the laws in the state(s) where you anticipate doing business.

IV. Corporate Practice Of Medicine Doctrine

Another significant issue to consider when assessing the development of a palliative care program is whether the relevant state has a "corporate practice of medicine" doctrine that might prohibit, or limit the ability of, a hospice setting up a palliative care clinic. In short, several states have laws that prevent a business corporation or layperson from controlling the medical decisions of a physician and his or her professional staff. With the rise of the physician practice management company over the last decade, many physician practices have ceded aspects of their control of the day-to-day business affairs to business corporations. Such a prohibition would be implicated to the extent that the hospice exercises any control over the medical judgment or professional decision-making of a licensed practitioner.

Accordingly, in those states with a relevant corporate practice of medicine law, care must be taken to make certain that the hospice does not exert any control over the professional decisions that are made and executed through the professional corporation. That is, medical decisions made for patients seeking services through the

palliative care clinic should be made strictly by licensed professionals practicing through that entity. To the extent that such professional medical decisions and judgments are actually controlled or influenced in any way by the hospice, a risk exists that a state regulatory body could challenge the arrangement as involving the unauthorized practice of medicine by the hospice.

In assessing whether the development of a palliative care clinic is viable from a corporate practice of medicine perspective, the first step would be to determine whether the relevant state has a corporate practice of medicine doctrine. If it does not, then you likely will have more flexibility in how you set up the palliative care entity, who the owners are, etc. If the state does have a corporate practice of medicine doctrine, the next question is whether that state's law would apply to a hospice setting up a palliative care clinic, and, if so, how. In addition, you would need to assess whether that state actively enforces its corporate practice of medicine law. That is, although some states have corporate practice of medicine laws on their books, not all of them actively enforce those laws. Considering this issue usually entails contacting the appropriate regulatory officials from the relevant states.

V. State Fee-Splitting Prohibitions

Some states also have laws that prohibit physicians from splitting their professional fees with non-physicians. In those states, care would need to be taken when structuring any management fee to be paid by the palliative care clinic to the hospice. In addition to being commensurate with the fair market value of the services provided, in certain states the fee may not be based upon a percentage of revenues or collections of the clinic. In all instances, the hospice must maintain appropriate documentation of the services provided, and the fees paid for these services.

VI. A Hospice Enrolling As A Part B Supplier

While it is not impermissible for a hospice to become a Medicare Part B Supplier in order to bill for non-hospice palliative care for Medicare beneficiaries, take care to review the viability of this approach under the state and federal laws outlined above. Also, the hospice should communicate with its Part B contractor to determine what additional requirements might apply. Last, the hospice must make certain there are no state licensure laws that might serve as an impediment to employing this type of structure.