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Palliative Care – Palliative Care Services: Selected Legal and Regulatory Considerations

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Introduction

Hospices offer palliative and supportive care to the terminally ill, focusing on managing pain and other symptoms instead of seeking curative treatment for an illness. Recently, the concept of palliative care has expanded beyond the boundaries of hospice care to include care and services provided to patients suffering from progressive, incurable illnesses, who may or may not be eligible for hospice care, depending on whether their life expectancy is greater than six months.

Palliative care focuses on symptom control and supportive care early in a patient's illness and is designed to both improve the quality of life for patients while they fight their disease and potentially increase life expectancy. Palliative care includes consultation, activities, and services offered to patients located in a variety of settings, including acute care units, inpatient or outpatient clinics, nursing homes, or patient homes. In addition to providing care in a variety of settings, palliative care may be separately incorporated into the services offered by medical practices and physician corporations. Palliative care services may also be offered as professional medical educational opportunities, such as fellowships or residencies focusing on hospice and/or palliative care services.

One of the major difficulties with offering palliative care services independent of a hospice is identifying and accessing funding. Palliative care providers typically attempt to fund services through existing reimbursement streams for hospice, home care, hospital, and physician services. Alternatively, palliative care providers may supplement lacking reimbursement with grants, donations, hospital subsidies and other diverse funding sources. Financing issues have significantly contributed to the struggle to offer palliative care services in the United States. However, as people begin to understand palliative care and its benefits, reimbursement may become less problematic.

The Anti-Kickback Statute

1. A. **Prohibitions Under the Anti-Kickback Statute**. The Anti-Kickback

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Statute is a federal law that makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration (*i.e.*, anything of value) to induce referrals of items or services for which payment may be made under a federally-funded health care program. 42 U.S.C.§ 1320a-7b(b). Civil monetary penalties may be imposed for violations of the Anti-Kickback Statute, and for offering incentives to a Medicare or Medicaid eligible patient that a provider knows, or should know, is likely to influence the patient to use a particular provider. 42 U.S.C. § 1320a-7a(a)(7), (5). The Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services (the "DHHS") has promulgated "safe harbors", federal regulations that describe practices or arrangements that will not be considered violations of the Anti-Kickback Statute. 42 C.F.R. § 1001.952. Failure to fit within the requirements of a safe harbor does not necessarily mean that an arrangement is in violation of the Anti-Kickback Statute. However, the safe harbors do provide helpful OIG interpretation of the kinds of actions constituting Anti-Kickback violations and necessary actions to avoid such an inference.

In applying the Anti-Kickback Statute and safe harbors, palliative care services should refrain from engaging in the following activities:

1. Offering inducements to potential referral sources. It is a violation of the Anti-Kickback Statute for a palliative care service to provide remuneration (e.g., additional staffing) to a hospital, skilled nursing facility, or other provider in exchange for the provider's future referral of patients to the hospice. Collaborative arrangements, such as inpatient hospice care units, palliative care consultation services, or hospital-hospice liaison nurses, raise Anti-Kickback concerns because such arrangements are funded by two different health care providers and are high-risk for potentially unlawful inducements for referrals. Such arrangements should be structured under an Anti-Kickback safe harbor, such as the "personal services and management contracts" safe harbor. 42 C.F.R. § 1001.952(d). Under the personal services and management contracts safe harbor, unlawful remuneration does not include payments made by a principal (nursing home) to an agent (hospice) as long as:
    1. the agreement is set out in writing, specifies the services covered and that the services are being provided for the term of the agreement;
    2. the agreement specifies the schedule, length, and exact charge for intervals of services, if not for full-time services;

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3. the term of the agreement is not less than one year;
4. the compensation paid under the agreement is set in advance, consistent with fair market value in an arms-length transaction, and does not take into account the volume or value of services that may be paid by a federally-funded health care program;
5. (v) the services do not counsel or promote violation of a state or federal law; and
6. (vi) the services do not exceed those necessary to accomplish a commercially reasonable business purpose.

Because it is difficult to meet the safe harbor requirement for specifying the schedule, length, and exact charge for intervals of services, the hospice or palliative care provider may use an hourly rate for services provided. This approach may be analogized to the interpretation that "per-use" charges for certain services, such as use of a radiology machine are permitted. However, this interpretation requires that the compensation for such services does not take into account the volume or value of referrals, is based on fair market value, and remains unchanged throughout the term of the arrangement.

2. Offering inducements to Medicare beneficiaries and Medicaid recipients. The Anti-Kickback Statute prohibits the offer or transfer of remuneration to Medicare beneficiaries and Medicaid recipients as an inducement to use a particular provider. Unless carefully reviewed by legal counsel and properly structured, it may be an Anti-Kickback violation for a palliative care provider to offer free programs or services to patients qualifying for government reimbursement. By doing so, the palliative care provider is influencing the patient's selection of a provider, which raises quality and cost concerns.

2. **Tools for Avoiding a Violation of the Anti-Kickback Statute**
    1. Compliance Guidance. The OIG has issued Compliance Program Guidance for Hospices (the "Compliance Guidance") to assist hospice providers in structuring health care arrangements to avoid violating the Anti-Kickback Statute. 64 Fed. Reg. 54031 (Oct. 5, 1999). The Compliance Guidance includes a notice published in the Federal Register that specifically identifies hospice incentives to actual or potential referral sources as a high-risk area for an Anti-Kickback

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violation. The Compliance Guidance suggests that hospices address the issue with policies and procedures aimed at minimizing the potential risk of such a violation. 64 Fed. Reg. 54031, 54040 (Oct. 5, 1999). The Compliance Guidance suggests that hospices take the following actions: carefully review contracts with referral sources to ensure compliance with hospice policies and procedures; refrain from submitting claims for patients referred through arrangements structured to induce referrals; and refrain from offering or providing free gifts or services to individuals or entities that may potentially be a source of referrals. The Compliance Guidance specifically emphasizes careful review of potentially suspect arrangements between nursing homes and hospices. For example, the Compliance Guidance notes that hospices should have policies in place that prevent the hospice from paying nursing homes an amount above fair market value for services provided in addition to those services considered part of the nursing home's standard charge. It is highly recommended that tools like the Compliance Guidance become part of the hospice's strategy for addressing compliance issues and that training for paid staff and volunteers becomes part of the overall hospice/palliative care Corporate Compliance Program. In addition, hospice policies should be clear that patients receive the same level of care regardless of payor source, insurance status, and the presence or absence of other health care providers.

2. OIG Advisory Opinions. OIG Advisory Opinions ("Advisory Opinions") are OIG interpretations of particular arrangements or situations issued at the request of private parties. Although Advisory Opinions may only be formally relied upon by the requesting party, they do state the position of the OIG regarding whether the OIG would sanction a particular arrangement for violating the Anti-Kickback Statute. Therefore, Advisory Opinions are useful guidance for understanding the OIG's interpretation of certain arrangements. The following Advisory Opinion summaries provide examples of the kinds of issues addressed in the Opinions that may affect palliative care service providers. Advisory Opinion 00-3 discusses whether a hospice may provide free services to terminally ill individuals who are not eligible for hospice care because they have a life expectancy over six months or have elected to seek curative treatment. The Opinion concluded that although the free services could generate prohibited remuneration if intent to induce referrals were present,

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the arrangement would not be subject to Anti-Kickback sanctions based on the facts presented. The OIG's reasoning included that the services were to be provided by unpaid volunteers; benefits of the program were primarily intangible; the program provided a substantial benefit to a vulnerable patient population; and substantial barriers existed to the beneficiary's election of hospice care. This interpretation is helpful for determining how the OIG will evaluate certain free hospice and/or palliative care services. Advisory Opinion 02-4 discusses whether a durable medical equipment ("DME") company may place portable oxygen systems on-site at certain hospitals, clinics, and physician offices (collectively, the "Distributors") for distribution to patients being discharged to home. Based on the facts presented, the OIG approved continuation of this activity. The OIG's reasoning included the fact that the DME company did not pay for use of the "consignment closet" and, therefore, the Distributors did not receive any remuneration under the arrangement. According to the OIG, because the Distributors did not receive any remuneration under the arrangement, the Anti-Kickback Statute is not implicated. Advisory Opinion 01-20 discusses an arrangement whereby a hospice was paying a nursing facility 100% of the Medicaid daily nursing facility rate for non-hospice patients for residents that are eligible for both the Medicare hospice benefit and Medicaid even though the State Medicaid program only typically pays the hospice 95% of the daily nursing facility rate for these residents. In addition, although the nursing facility rate includes pharmaceutical services, the hospice was also paying the nursing facility the fair market value for medications related to the resident's terminal condition. The OIG determined that although the payment of 100% of the daily nursing facility rate does not raise Anti-Kickback concerns, additional payment for pharmaceutical services already covered by the daily nursing facility rate does implicate the Anti-Kickback Statute. The OIG concluded that more information was needed to evaluate the benefit to the nursing facility and the appropriateness of the separate payments.

3. Fraud Alerts and Special Advisory Bulletins. The OIG frequently issues Fraud Alerts and Bulletins to address areas of concern. In August 2002, the OIG issued a Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (the "Bulletin"). The Bulletin stated that it is acceptable for hospices to give patient's

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"inexpensive" gifts that are worth less than $10 per gift or $50 in the aggregate annually per patient. For example, a holiday gift of a free television is not permissible because it is likely over the $50 annual limit. More expensive items or services are only acceptable under the following five statutory exceptions:

1. waivers of cost-sharing amounts based on financial need;
2. properly disclosed copayment differentials in health plans;
3. incentives to promote the delivery of certain preventive services;
4. any practice permitted under the federal Anti- Kickback Statute; or
5. waivers of hospital outpatient copayments in excess of minimum copayment amounts.

The limitations set forth in this Special Advisory Bulletin present a strong implicit cautionary message to hospices and palliative care programs that "free care" may be carefully scrutinized. The OIG is considering several additional exceptions and will continue to consider other requests for Advisory Opinions related to this issue.

Other Regulatory Issues

1. **The False Claims Act**. The False Claims Act ("FCA") allows the government and private citizens to file a claim against an individual or entity that submits a false bill or request for payment. False claims are typically charges for items or services that are substantially in excess of the provider's usual charges for such items or services, without a finding of good cause by the DHHS Secretary. 31 USC § 3729-3731. Possible damages for a violation of the FCA include civil fines up to $11,000 per claim and three times the amount for damages ("treble" damages). 28 C.F.R. § 85.3(a)(9). The elements of a FCA claim include the following:
    1. A defendant submits, or causes another to submit, a claim for payment or approval to the federal government;
    2. The claim submitted is false or fraudulent; and
    3. The defendant's acts are "knowingly" undertaken or the defendant acts in reckless or deliberate disregard for the truth. See United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051, 1054 (W.D. Mo. 2001) citing United States v. NHC Health Care Corp., 115 F. Supp. 2d 1149, 1152-53

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(W.D. Mo. 2000).

A defendant "knowingly" submits a false claim when a defendant has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required to find a FCA violation. 31 U.S.C. § 3729(b)(1-3).

Under the FCA, it is a risk for hospices to provide free palliative care services to non-hospice-eligible patients, but then charge hospice patients for the same services simply because reimbursement is available. Such activities may be viewed as attempts to obtain government reimbursement at levels substantially in excess of what is ordinarily charged for the same services. Hospices should have policies laying out eligibility requirements, such as financial hardship, for a patient to qualify for free care/sliding scale fees, which will decrease the risk of a potential FCA violation.

2. **Medicare Conditions of Participation**. The Medicare Conditions of Participation for hospices, or any other health care provider considering expanding services to include palliative care services, should be reviewed before expanding services to ensure that the expansion does not jeopardize eligibility for reimbursement by federally-funded health care programs.

   Specific to hospices, the Medicare Conditions of Participation for hospices define "hospice" as "a public agency or private organization or subdivision of either of these that– is primarily engaged in providing care to terminally ill individuals." 42 C.F.R. § 418.3. Section 42 C.F.R. § 418.50(b) similarly states that "a hospice must be primarily engaged in" providing covered hospice services. The Centers for Medicare and Medicaid Services has interpreted this requirement to allow hospices to provide palliative care services because, although hospices must be "primarily" engaged in providing hospice care, it is not required that hospice care be the exclusive service of hospices. A hospice's decision to expand services to offer palliative care may be impacted by the Medicare Conditions of Participation for hospices, such as those conditions addressing quality assurance and the role of the interdisciplinary group in care management. 42 C.F.R. § 418.66, 68. Although the hospice should already be providing hospice services in compliance with these conditions, expanding services to palliative care appears to require that the palliative care services meet the same standards required for the hospice.
3. **Insurance Liability**. If a hospice or other health care provider decides to

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expand the services it offers to include palliative care services, it should inform its insurance carrier that it will be expanding care to include such services. It is advisable for the provider to request that the insurance carrier verify in writing that the insurance policy covers the provision of palliative care separately from other services that may be provided as a part of another benefit, such as the hospice benefit. Obtaining documentation of coverage provides an additional insurance safeguard for palliative care services.

4. **State Licensure for Palliative Care Services**. State licensure laws differ dramatically and may include specific requirements that are either inapplicable to palliative care services or that palliative care providers are unable to meet. For example, a state license to provide hospice services may limit the services that may be provided to "hospice services" only. This raises a question as to whether a hospice may provide palliative care services under the hospices state licensure. In this case, a hospice may request clarification from the department or agency issuing the hospice licenses to ensure that it is permissible for the hospice to expand its services to non-hospice palliative care. As palliative care expands, licensure to provide such services may evolve in some states to require a separate palliative care license to provide such services in health care settings.
5. **Corporate Practice of Medicine**. Many states have provisions governing the corporate practice of medicine that prevent the control of medical decisions by anyone other than physicians. Under these provisions, it may be impermissible for a corporation to employ physicians or otherwise control licensed professionals in the provision of medical services. A hospice that is interested in establishing a clinic, for example for the provision of palliative care, must have its legal counsel carefully review state law with regard to corporate practice of medicine. The structure of the entity must take into consideration any such provisions. In some states, for example, it is necessary for the hospice to contract with the clinic, as opposed to taking an ownership interest in it.

Conclusion

In structuring palliative care services, a provider should consider its mission and commitment to provide access to palliative care services, the potential impact of the services being offered on federal spending, the potential for inappropriate referrals, the public benefit in offering such services, the barriers to receipt of palliative care, and the needs of a vulnerable group of individuals. Although there

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are many risks associated with the expansion of services to include palliative care, careful structuring, in accord with available regulatory guidance, makes expanding services to include palliative care a necessary and valuable venture.

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