



## Palliative Care Resource Materials

---

### PALLIATIVE CARE CHECKLIST: SELECTED REGULATORY AND RISK MANAGEMENT CONSIDERATIONS<sup>1</sup>

Mary H. Michal, J.D.  
Meg S.L. Pekarske, J.D.  
Reinhart Boerner Van Deuren s.c.  
22 East Mifflin Street, Suite 600  
Madison, WI 53701-2028  
(800) 728-6239  
[mmichal@reinhartlaw.com](mailto:mmichal@reinhartlaw.com)  
[mpekarsk@reinhartlaw.com](mailto:mpekarsk@reinhartlaw.com)

Before initiating a palliative care program<sup>2</sup>, hospices are encouraged to consider the following and visit the NHPCO website at [www.nhpc.org](http://www.nhpc.org) for forms, sample documents and sample additional palliative care resources:

- **The services the hospice wishes to offer are clearly defined.**

Some hospices wish to offer the full IDT model of care. Others contemplate a physician (and perhaps nurse practitioner) providing direct care consultation visits in the hospital, nursing facility, home or clinic. Still others conduct one-time assessments upon the order of an attending physician. When reviewing regulatory issues, it is critical to review the precise model of non-hospice palliative care being considered.

---

<sup>1</sup> These considerations are not legal advice and should not be relied on in lieu of legal advice. Development of a palliative care program is complex and should include a careful analysis of all of the unique facts and circumstances.

<sup>2</sup> Palliative care programs based solely on volunteer support may be treated differently.

- **State licensing laws and regulations, as well as other state laws<sup>3</sup>, have been reviewed to determine whether they permit a hospice to provide the desired palliative care services.**

State hospice licensure laws may limit the ability of a hospice to serve non-hospice patients by narrowly defining key terms such as "palliative care," "terminal illness" or "hospice". **Given that state laws and their interpretations are varied, individual hospices are urged to work with their state hospice organizations to develop a consistent approach to deal with these issues.**

- **If state licensing laws do not allow a hospice to provide non-hospice palliative care, consider a joint venture relationship.**

Under federal regulations, it is permissible for a hospice to unbundle its services and provide non-hospice palliative care to another licensed entity, such as a hospital, home health agency, nursing facility or physician practice.<sup>4</sup>

**Example:** A local hospital wishes to furnish palliative care to its patients. The hospital may contract with the hospice to provide direct care to hospital patients and/or the clinical expertise necessary to establish the program, develop policies, etc.

**Sample Agreement:**

- "Sample Palliative Care Services Agreement" drafted by Mary H. Michal and Meg S.L. Pekarske, Reinhart Boerner Van Deuren s.c. (April 2006).

**Additional Resources:**

- "Palliative Care Services: Selected Legal and Regulatory Considerations" by Mary H. Michal, J.D., Reinhart Boerner Van Deuren s.c. (April 2006).
- NHPCO Newslines Article: "Legislative and Regulatory News; Hospice And Palliative Physician Group: Examining the Issues"

---

<sup>3</sup> There are a number of state law issues that may impact a hospice's ability to provide care, including palliative care. Among them are corporate practice of medicine provisions that limit employment of physicians, state fraud and abuse laws, fee-splitting prohibitions that make certain fee arrangements with physicians impermissible and scope of practice limitations for nurses and nurse practitioners. These are general legal considerations, not limited to palliative care. Once again, it is important that individual hospices work with their state organizations to develop consistent interpretations of the state laws that impact the provision of both hospice services and non-hospice palliative care.

<sup>4</sup> Program Memorandum Intermediaries, Transmittal A-02-102, Medicare Certified Hospices-Clarification of Acceptable Parameters for Some Contractual Arrangements (October 25, 2002); <http://www.cms.hhs.gov/transmittals/downloads/A02102.pdf>.

by Connie A. Raffa, J.D., LL.M. and Mark B. Langdon, J.D. (August 2004).

- Arent Fox Health Care Alert: "Palliative Care: Legal and Regulatory Requirements (Parts 1 and 2)" by Connie A. Raffa, J.D., LL.M. (December 22, 2003).
- "Hospital-Hospice Partnerships in Palliative Care: Creating a Continuum of Service" by the National Hospice and Palliative Care Organization and the Center to Advance Palliative Care (December 2001)
- Excerpt of "Hospital-Hospice Partnerships in Palliative Care: Creating a Continuum of Service: The Antikickback Law and Hospital-Hospice Relationship" by Hogan & Hartson, L.L.P., Washington, D.C. (December 2001).
- Program Memorandum Intermediaries, Transmittal A-02-102, "Medicare Certified Hospices-Clarification of Acceptable Parameters for Some Contractual Arrangements" (October 25, 2002);  
<http://www.cms.hhs.gov/transmittals/downloads/A02102.pdf>.

- **For hospices that are part of a system, consider providing palliative care through other licensed entities within the system with the help of hospice staff.**

Hospices that are system or home health agency-based may find, depending on state law and business considerations, that it is preferable to operate the palliative care program under the auspices of another licensed health care provider within the system, drawing upon the hospice's expertise as necessary.

- **If direct care by physicians and nurse practitioners is contemplated, explore the creation of a Medicare Part B "clinic" or a joint venture with a physician group.**

It is permissible for a hospice program to become a Medicare Part B provider and many hospices have successfully obtained this certification. It is not necessary to establish a separate "clinic" although the hospice should consider where visits will be made (e.g., hospital, nursing facility, clinic, personal residence). If state corporate practice of medicine doctrine prohibits the hospice from employing its physicians, a joint venture with a physician group may be considered.

#### **Enrollment Forms and Information:**

- Visit the CMS website at <http://www.cms.hhs.gov/MedicareProviderSupEnroll/> to obtain a

Medicare Part B enrollment form (Form 855B) and information regarding becoming a Medicare Part B provider.

- Hospices will need to submit their enrollment form to the Medicare carrier for their region. A listing of the Medicare carriers and their regions may be found at <http://www.cms.hhs.gov/MedicareProviderSupEnroll/PSEC/list.asp>.

#### **Additional Resources:**

- "Palliative Care Services: Selected Legal and Regulatory Considerations" by Mary H. Michal, J.D., Reinhart Boerner Van Deuren s.c. (April 2006).
  - NHPCO Newsline Article: "Legislative and Regulatory News; Hospice And Palliative Physician Group: Examining the Issues" by Connie A. Raffa, J.D., LL.M. and Mark B. Langdon, J.D. (August 2004).
  - Arent Fox Health Care Alert: "Palliative Care: Legal and Regulatory Requirements (Parts 1 and 2)" by Connie A. Raffa, J.D., LL.M. (December 22, 2003).
- **Billings to patients are based on fair market value. The decision to provide free care or care at below market rates should be based solely on an individual's ability to pay and subject to a sliding fee scale.**

It is impermissible to provide anything of value to a beneficiary for purposes of inducing the person to elect a Medicare covered service/benefit. One of the most important ways that hospices blunt the inference of an impermissible inducement is to charge patients fair market value for provided services. This means, for example, that care provided to a patient who may later become a hospice patient should be billed at the value of the services, unless the hospice has organized a program to provide uncompensated care to those who are unable to pay for needed care and instituted a sliding fee scale which is based on ability to pay. Such programs and fee scales should be well documented and consistently administered.

#### **Additional Resources:**

- "Palliative Care Services: Selected Legal and Regulatory Considerations" by Mary H. Michal, J.D., Reinhart Boerner Van Deuren s.c. (April 2006).
- NHPCO Newsline Article: "Legislative and Regulatory News; Hospice And Palliative Physician Group: Examining the Issues" by Connie A. Raffa, J.D., LL.M. and Mark B. Langdon, J.D. (August 2004).

- Arent Fox Health Care Alert: "Palliative Care: Legal and Regulatory Requirements (Parts 1 and 2)" by Connie A. Raffa, J.D., LL.M. (December 22, 2003).
  - OIG Advisory Opinion No. 00-3 (April 7, 2000)  
[http://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00\\_3.htm](http://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_3.htm).
- **Billings to other contract health care providers (e.g. hospital systems) reflect fair market value and their structure has been reviewed by legal counsel.**

The federal anti-kickback prohibitions apply to referral sources, and once again, it is impermissible to provide anything of value to a referral source such as a hospital, nursing facility or physician, in order to induce referrals into the hospice program. If the hospice is providing services to a facility such as a nursing home or a hospital, the amount billed must reflect fair market value for the services and must not take into account the volume or value of referrals.

**Additional Resources:**

- "Palliative Care Services: Selected Legal and Regulatory Considerations" by Mary H. Michal, J.D., Reinhart Boerner Van Deuren s.c. (April 2006).
  - NHPCO Newline Article: "Legislative and Regulatory News; Hospice And Palliative Physician Group: Examining the Issues" by Connie A. Raffa, J.D., LL.M. and Mark B. Langdon, J.D. (August 2004).
  - Arent Fox Health Care Alert: "Palliative Care: Legal and Regulatory Requirements (Parts 1 and 2)" by Connie A. Raffa, J.D., LL.M. (December 22, 2003).
- **The hospice's professional liability carrier has been informed of the palliative care program and has confirmed that coverage will extend to the program.**

Keeping in mind that the goals of a palliative care patient may be very different from the goals of a hospice patient, it is critical that the hospice verify with its professional liability carrier that palliative care services are covered. It is important to inform the carrier in writing regarding the specific nature of the program that the hospice is offering and secure confirmation that coverage extends to non-hospice palliative care.

- **There is a clear distinction between the hospice program and the palliative care program. The palliative care program must not be provided as a referral mechanism to the hospice. It must be a separate and distinct service to the community.**

Hospices are advised to examine their mission when considering a palliative care program and assess whether the program can generate sufficient income to be self-sustaining. While many patients will never be admitted into a hospice program, it is important to overcome any inference that a palliative care program loses money in order to induce early referrals to the hospice program. Such an inference can be overcome, in part, by providing information on the full range of hospice choices, including the competitors, to pre-hospice palliative care patients being referred to hospice.

- **Eligibility decisions are based on clinical factors (e.g. prognosis) and patient choice.**

If an individual qualifies for both programs, and chooses palliative care because she or he desires to continue receiving aggressive treatment, the choice should be clearly documented. The documentation should emphasize that the admission decision was based on patient choice, not on the provider's financial considerations.

- **The palliative care initiative is mission-driven and there are sufficient reimbursement streams to fund the initiatives through billing patients and third party payors and/or community donations.**

Revenues generated on the hospice side should not be a rationale for a freestanding hospice program to develop a palliative care program that loses money. On the other hand, a health system with its own hospice and palliative care program may well decide that a hospital-based palliative care program decreases hospital days while increasing the quality of care and may have more flexibility with regard to the structure of its program. Likewise, a managed care program may decide to offer certain palliative care coverage to its enrollees in a manner that does not create an inference of an impermissible inducement. The anti-kickback analysis is very fact specific and cannot be applied equally across all settings. As with all important program enhancements, hospices are encouraged to consult their legal counsel when structuring non-hospice palliative care programs.