SUBJECT: Revisions to - Chapter 2 – The Certification Process

I. SUMMARY OF CHANGES: The purpose of these revisions is to include current CMS policy, delete material and make changes within §2080B & §2085. In addition, we have included a new Exhibit 289 and titled it “Model Reciprocal Agreement”.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 20, 2006
IMPLEMENTATION DATE: January 20, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

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<td>N</td>
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

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*Unless otherwise specified, the effective date is the date of service.
Hospice care is an approach to caring for terminally ill individuals that stresses palliative care (relief of pain and uncomfortable symptoms), as opposed to curative care. In addition to meeting the patient’s medical needs, hospice care addresses the physical, psychosocial, and spiritual needs of the patient, as well as the psychosocial needs of the patient’s family/caregiver. The emphasis of the hospice program is on keeping the hospice patient at home with family and friends as long as possible.

Although some hospices are located as a part of a hospital, SNF, and HHA, hospices must meet specific CoPs and be separately certified and approved for Medicare participation. (See Exhibit 129 for “Hospice Survey and Deficiencies Report,” Form CMS-643 and Exhibit 72 for “Hospice Request for Certification in the Medicare Program,” Form CMS-417.)

Services and Items Provided

Substantially all core services must be provided directly by hospice employees on a routine basis. The following are hospice core services and must be provided directly by hospice employees:

- Nursing care (on a 24-hour basis) provided by or under the supervision of an RN functioning within a medically approved plan of care;

- Medical social services under the direction of a physician; and

- Counseling (including dietary and bereavement counseling) with respect to care of the terminally ill individual and adjustment to death.

A hospice may use contracted staff for core services only under extraordinary circumstances (i.e., to supplement hospice employees in order to meet patients’ needs during periods of peak patient load.) If contracting is used, the hospice must continue to maintain professional, financial, and administrative responsibility for the services in accordance with 42 CFR 418.56.

Qualifying for an “Extraordinary Circumstance” Exemption

During the time period from October 1, 2002 – September 30, 2006, in order to qualify for an “extraordinary circumstance” exemption, a hospice must notify the state agency responsible for licensing and certification that it intends to elect an exception under the “extraordinary circumstance” authority. This may be accomplished by providing written notification to the state survey agency when it believes that the nursing shortage has become an “extraordinary circumstance” in its ability to hire nurses directly, and it must estimate the number of nurses that it believes it will currently need to employ under
contract. Notification may be made prior to September 30, 2006, and should address the following:

- An estimate of the number of patients that it has not been able to admit during the past three months due to the nursing shortage and provide the current and desired patient/nurse ratio for the agency;

- Evidence that the hospice has made a good faith effort to hire and retain nurses, including:
  - Copies of advertisements in local newspapers that demonstrate recruitment efforts;
  - Copies of reports of telephone contacts with potential hires, professional schools and organizations, recruiting services, etc.
  - Job descriptions for nurse employees;
  - Evidence that salary and benefits are competitive for the area;
  - Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs, educational institutions, health care facilities, and contacts with nurses at other providers in the area); and
  - Ongoing self-analyses of the hospice’s trends in hiring and retaining qualified staff.

- The hospice must also demonstrate that it has a training program in place to assure that contracted staff is trained in the hospice philosophy and the provision of palliative care prior to patient contact.

- The hospice must assure that contracted staff is providing care that is consistent with the hospice philosophy and the patient’s plan of care.

- Contracted nurses are used to supplement the hospice nurses employed directly. Contracted nurses should not be used solely to provide the continuous nursing level of care or on call service.

The hospice is expected to continue its recruitment efforts during the period that it is contracting for nurses.

**Monitoring the Need for Exemption**

The state survey agency will maintain copies of each exception notification and validate the hospice’s stated need for an exemption during complaint and re-certification surveys. Of particular importance will be the extent to which the hospice nurses have been trained
in the hospice philosophy and are able to effectively provide care to the patient that is consistent with the plan of care established by the attending physician, the medical director or physician designee and interdisciplinary group.

**Medicare Drug, Improvement and Modernization Act of 2003 (MMA)**

Legislation enacted December 8, 2003, by Section 946 of the Medicare Drug, Improvement and Modernization Act of 2003 (MMA), modified the hospice core services requirements as follows:

1. **Waiver of Certain Staffing Requirements**

   Section 1861 (dd)(5) of the Social Security Act has been modified to permit a hospice program to enter into arrangements with another hospice program for the provision of nursing services, medical social services, and counseling in extraordinary, exigent, or other non-routine circumstances. Examples of such extraordinary circumstances might include unanticipated periods of high patient loads, staffing shortages due to illness, or other short term temporary events or temporary travel of a patient outside the hospice’s service area. The hospice that contracts with another hospice for services must maintain professional management responsibility for all services provided under arrangement or contract at all times and in all settings. Existing regulations at 42 CFR 418.56 discuss the professional management of the hospice for services provided under arrangement.

   Hospices must maintain evidence of the extraordinary events that required them to contract for the core services and comply with the following:

   (a) The hospice must assure that contracted staff is providing care that is consistent with the hospice philosophy and the patient’s plan of care; and

   (b) Hospices may not routinely contract for a specific level of care (e.g., continuous care) or during specific hours of care (e.g., evenings and weekends).

2. **Contracting for Highly Specialized Services**

   A hospice program may contract for the services of a registered professional nurse if the services are highly specialized and are provided non-routinely and so infrequently that the provision of such services directly would be impracticable and prohibitively expensive. Highly specialized services are determined by the nature of the service and the nursing skill level required to be proficient in the service. Continuous care is not a highly specialized service, because while time intensive, it does not require highly specialized nursing skills.

   NOTE: Since the hospice conditions of participation have not yet been revised to reflect the changes of the MMA, a hospice should not be cited for a deficiency at
Role of the Hospice Medical Director

The medical director is required by regulation to assume overall responsibility for the medical component of the hospice’s patient care program. In addition, the hospice physician(s), including the physician members of the IDG must also meet the general medical needs of the patient to the extent that these needs are not met by the attending physician. Hospice physician involvement in the plan of care must be evident in the clinical record documentation. Medical directors and physician members of IDG may work “under contract” with the hospice. The requirements at 42 CFR 418.56 and 418.86 are still applicable to hospice, as well as all other responsibilities under the hospice conditions of participation. Hospices retain professional management responsibilities for the services under contract and must ensure that qualified persons furnish them in a safe and effective manner.

Role of the RN Team Coordinator

The hospice is required by 42 CFR 418.68(d) to designate a registered nurse to coordinate the implementation of the plan of care for each patient. There is no requirement that this person work full time, but there must be assurances that the plan of care is coordinated on a 24 hour basis so the patient receives the necessary care and services required in the plan.
2085 - Operation of Hospice Across State Lines

(Rev.17, Issued: 01-20-06, Effective: 01-20-06, Implementation: 01-20-06)

When a hospice provides services across State lines each respective state agency must be aware of and approve the action. Each SA must verify that applicable state licensure, personnel licensure, and other state requirements are met in its respective state.

The provision of services across State lines is appropriate in most circumstances. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of hospice services.

When a hospice provides services across State lines, it must be certified by the State in which its provider number is based, and its personnel must be qualified in all States in which they provide services. Certification activities within a particular state are completed by the appropriate SA for that state. The involved States should have a written reciprocal agreement permitting the hospice to provide services in this manner. The reciprocal agreement must indicate that both States are aware of their respective responsibilities for assessing the hospice’s compliance with the CoPs within their state. The agreement should assure that home visits are conducted to a sample of all patients served by the hospice in all states served by the hospice.

The CMS RO will review the required reciprocal agreement between the states to assure that the SA where the practice location resides is assuming responsibility for any necessary surveys of the location. If the SAs are unable to come to a reciprocal agreement on assuring the necessary surveys of the location, the location should not be approved as a part of the hospice. The provision of interstate service without a written reciprocal agreement could severely undermine the state’s ability to fulfill its statutory responsibilities under §1864 of the Act to enforce Medicare’s health and safety requirements. It is at the discretion of the states to decide whether entering into reciprocal agreements is in the best interest of their residents, provider markets, and quality assurance and oversight systems.

Exhibit 289 contains a model reciprocal agreement document for states to use to assist them in fulfilling their statutory responsibility to enforce Medicare’s health and safety requirements when a hospice provides services across state lines.

In States that have a reciprocal agreement in place, providers are not required to be separately approved in each state; consequently, they would not have to obtain a separate Medicare provider agreement/number in each state. Providers residing in a state that does not have a reciprocal agreement with a contiguous state are precluded from providing services across state lines.
In the event that the hospice operates in two CMS ROs, the RO responsible for the state in which the hospice provider agreement/number is based should take the lead in assuring that the required survey and certification activities are met.

The hospice must receive approval from CMS to provide services across state lines before it can bill Medicare for any covered services provided to these patients.
Exhibit 289

Model Reciprocal Agreement

(Rev.17, 01-20-06)

The State of _______ and the State of ________, in order to more effectively administer their survey and certification responsibilities relating to providers/suppliers that provide services across state lines, agree as follows:

GENERAL

The State of _______ and ________ will coordinate the administration of the responsibilities under section 1864 of the Social Security Act with respect to providers/suppliers that are approved to provide services across state lines under a single Medicare agreement and/or number. In general, the States of _______ and ________ agree to cooperate and conduct their respective responsibilities related to these providers/suppliers in a coordinated manner in order to promote streamlined operations and minimize unnecessary burdens on beneficiaries, providers/suppliers, survey personnel of the states and the Centers for Medicare & Medicaid Services (CMS).

PROCEDURES

The State of ________, where the approved provider/supplier issued the agreement/number is located, shall be referred to as the Primary State. The Primary State maintains the overall responsibility for coordinating all surveys, including initial surveys, re-surveys, revisits, and complaint surveys of providers/suppliers providing services across state lines with the State of ________. The Primary State will also report the survey results and the certification recommendations to the CMS regional office responsible for the Primary State.

The Primary State and the State of_______ have agreed that the State of_______ will be responsible for conducting any necessary surveys of a practice location in State of_______. The Medicare survey findings of the practice location will be incorporated into the findings of the Medicare survey of the approved provider/supplier. The Primary State will notify the approved provider/supplier of the survey findings. It will also process any necessary termination or denials or other recommendations resulting from surveys by either state.

Both the State of _______ and the State of ________ will use CMS forms, guidelines, policies and instructions in processing surveys of providers/suppliers that practice in more than one state.
STATE LICENSURE

1. The States of ________ and ________ will be responsible for ensuring that their respective state licensure laws including those related to licensure of personnel, certificate of need and any other applicable requirements relating to (TYPE OF PROVIDER/SUPPLIER) are met.

2. The State of ________ and the State of ________ will use survey funds allocated by CMS as compensation for their costs related to a particular survey, re-survey, revisit or complaint survey of a particular provider/supplier.

TERMS OF AGREEMENT

This agreement will remain in effect until terminated by mutual consent of the parties.