Regulatory Primer- Part II

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Session objectives

1. Identify location of Subparts C & D of the Federal Hospice Conditions of Participation
2. Interpret the requirements for key regulatory requirements for Subparts C & D
3. Demonstrate compliance with the requirements for all regulatory requirements for Subparts C & D

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Important Reminder!

- **Today's material is specific to the content of the Medicare Hospice Benefit**
- **Each state has its own licensing rules — you need to review and follow the more stringent of the rules**

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Hospice Regulations-Subparts

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Why are Regulations So Important?

- Set a standard for care
- Ensure consistency in broad care concepts
- Ensure quality to constituents
  - Patients/families
  - Colleagues in health care, internal/external payers
- Required to receive Medicare revenue to fund operations

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Regulations

Requirements published which provide details for compliance with the law

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Hospice Regulations

Where are the federal regulations?

Title 42 – Public Health

- Chapter IV- Centers for Medicare and Medicaid Services
- Department of Health and Human Services
- Part 418 – Hospice Care

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Subpart C—Condition of Participation—Patient Care

- **§418.52 Condition of participation: Patient's rights.**
- **§418.54 Condition of participation: Initial and comprehensive assessment of the patient.**
- **§418.56 Condition of participation: Interdisciplinary group, care planning, and coordination of services.**
- **§418.58 Condition of participation: Quality assessment and performance improvement.**
- §418.60 Condition of participation: Infection control.
- §418.62 Condition of participation: Licensed professional services.
- **§418.64 Condition of participation: Core services.**
- §418.66 Condition of participation: Nursing services waiver of requirement that substantially all nursing services be routinely provided directly by a hospice.
- §418.70 Condition of participation: Furnishing of non-core services.
- §418.72 Condition of participation: Physical therapy, occupational therapy, and speech-language pathology.
- §418.74 Waiver of requirement—Physical therapy, occupational therapy, speech language pathology and dietary counseling.
- **§418.76 Condition of participation: Hospice aide and homemaker services.**
- **§418.78 Condition of participation: Volunteers.**

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Hospice Interpretive Guidelines

- **What they are and what they are used for**
  - Written guidance for surveyors about the Medicare Hospice Conditions of Participation
  - Additional interpretive detail and probing questions for the surveyor to determine compliance with each regulation
  - Promotes consistency in the survey process.
  - Hospice providers have access to the hospice interpretive guidelines and can use them to help ensure a compliant hospice program

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Hospice Interpretive Guidelines

- **What they are not and what they are not used for**
  - Do not establish requirements that must be met by hospices
  - Do not replace or supersede the law or regulations
  - May not be used alone as the sole basis for a citation

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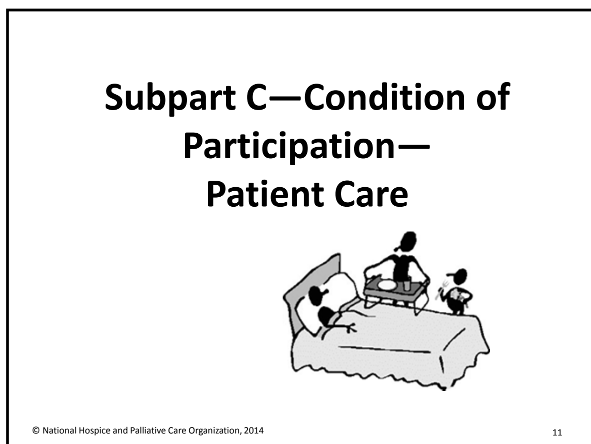
Subpart C—Condition of Participation—Patient Care



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418.52 Patient's rights

- **Advance directives**
  - Hospice must provide advance directive information as needed/ per patient request
  - Cannot refuse service based on advance directive content
  - Hospice must provide a statement of limitation if advance directive cannot be honored on the basis of conscience
    - Policy

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418.52 Patient's rights

- Exercise of rights and respect for property and person
  - Surveyors will look at documented complaints for last 12 months and outcomes of the complaint
  - 5 working days from becoming aware of complaint to investigate
    - If verified, report to state/local bodies within those 5 days
  - All alleged and real violations reported to hospice administrator
  - Surveyors will look at documented complaints for last 12 months and outcomes of the complaint
  - 5 working days from becoming aware of complaint to investigate
  - If verified, report to state/local bodies within those 5 days

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418.52 Patient's rights

- Pain management & symptom control
  - Hospice response to patient's request for pain management 24/7
- Patient/ family involvement in developing plan of care
  - How do they participate?
  - How does hospice staff facilitate?
- Refusal of service is a right
  - Are there trends?
  - How do you introduce services?

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418.54 Initial & comprehensive assessment

Initial assessment

- Completed by RN
- 48 hours from the effective date of the notice of election
- Not a "meet and greet" visit
- Must be completed in the location where the hospice services are being delivered
- RN begins to develop the plan of care
- Focus is on meeting immediate needs of patient/ family

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418.54 Initial & comprehensive assessment

Comprehensive assessment

- 5 calendar days after the effective date of the election of hospice care
- Plan of care is not formed by RN in a vacuum
  - IDG participation
  - Attending physician
- Guidelines:
  - Heavy focus on pain assessment
  - Medication review
    - Are current medications achieving the outcome wanted by the patient?

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418.54 Initial & comprehensive assessment

Initial bereavement assessment

- Initial assessment of bereavement services must be included in comprehensive assessment
  - Bereavement services can be offered prior to a patient's death
  - Patient plan of care must address bereavement issues

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418.54 Initial & comprehensive assessment

Update of the comprehensive assessment

- Minimally every 15 days or as the patient's condition requires
- Assessment updates should be easily identified in the clinical record
- Required to document if there were no changes in the condition of the patient/family needs
- Evidence that IDG is actively involved in evaluating patient care

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418.54 Initial & comprehensive assessment

Patient outcome measures

- Must be include data elements in assessment that would allow for the measurement of outcomes
- Suggested:
  - Pain
  - Dyspnea
  - Nausea
  - Vomiting
  - Constipation
  - Emotional distress
  - Spiritual needs

§ 418.56 IDG, care planning, and coordination of services

Approach to service delivery

- Documentation that verifies participation of all core IDG members in written plan of care
- Process for developing plan of care with IDG and attending physician
- Assessment – plan of care link
- Needs of patient unrelated to terminal illness
  - Document awareness of needs and who is addressing them

RN coordinates plan of care

- How does the RN assure that IDG kept informed of patient/family status and coordination of care?

§ 418.56 Care planning

Plan of Care

- Individualized plan of care
- Development was collaborative
  - Signatures on plan of care not necessary, but documentation of collaboration must be evident
- Include complimentary/ alternative therapies if provided to patient/ family
- Medications
  - Proactive anticipation of side effects
  - Preventative measures implemented
  - Hospice response to patient needs for pain/ symptom management

§ 418.56 Care planning

Content of the plan of care

- **Scope and frequency of services**
  - Visit ranges acceptable
    - Small intervals (1-3/week)
  - PRN visits acceptable as an accompaniment to an established visit frequency
    - **PRN may not be a standalone visit frequency**
  - Standing orders must be individualized and signed by patient's physician

§ 418.56 Care planning

Content of the plan of care

- **Measurable outcomes**
  - Outcomes should be a measureable result of the implementation of the plan of care
  - Data elements should be used as part of the plan of care to see if they are meeting the goals of care
  - Are outcomes documented and measurable?

§ 418.56 Care planning

Review of the plan of care

- Minimally every **15 days** or as the patient's condition requires
- All IDG members participate whether actively providing care or not
- Communication with attending may be through phone calls, electronic methods, orders received, or other means
  - Define in policy

§ 418.56 Coordination of services

Coordination of services

- What systems are in place to facilitate exchange of information and coordination of services between:
  - Hospice staff
  - Non-hospice staff
- Is there documentation in the clinical record of information sharing between:
  - Hospice staff
  - Non-hospice staff

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§ 418.58 Quality assessment and performance improvement (QAPI)

- Organization self assessment
- QAPI plan – written
- Program scope
  - Adverse patient events
- Program data
- Program activities
- Performance improvement projects
- Governing body involvement

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§ 418.58 QAPI

- Patient-focused and outcome (or results) oriented
- Goal
  - To monitor quality/performance
  - Find opportunities for improvement
  - To improve care
- Focus is on achieving patient/family desired outcomes or results
- Tied to other regulations

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§ 418.64 Core services

- Hospice must routinely provide **substantially all** core services directly by hospice employees
  - Nursing
  - Medical Social Services
  - Counseling
    - Bereavement
    - Spiritual
    - Dietary
- May use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances
  - Continuous home care may not be routinely contracted out

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§ 418.76 Hospice Aide

- **Qualifications and competency requirements**
- **A registered nurse must make an on-site visit to the patient's home:**
  - No less frequently than every 14 days to assess the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs
  - The hospice aide does not have to be present during this visit
  - If state regulation is more stringent, follow it

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§ 418.76 Hospice Aide

Hospice aide written instructions:

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- Hospice aides are assigned to a specific patient by a registered nurse that is a member of the interdisciplinary group
- Written patient care instructions for a hospice aide must be prepared by a registered nurse who is responsible for the supervision of a hospice aide
  - Written by the RN (RN is responsible for the supervision of the aide)
  - Must be patient specific and not genetic

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§ 418.78 Volunteers

Role and activities:

- Used in day to day administrative and/ or direct patient care roles
  - Office activities
  - Direct patient care services
  - Non-administrative patient care activities (may not use these hours for 5% level of activity)
- Direct patient care services must be evident in patient plan of care
- There should be documentation of time spent and the services provided by volunteers

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Subpart D— Administration

- **§418.100 Condition of participation: Organization and administration of services.**
- **§418.102 Condition of participation: Medical director.**
- **§418.104 Condition of participation: Clinical records.**
- **§418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.**
- **§418.108 Condition of participation: Short-term inpatient care.**
- **§418.110 Condition of participation: Hospices that provide inpatient care directly.**
- **§418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/MR/IID.**
- **§418.114 Condition of participation: Personnel qualifications.**
- § 418.116 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

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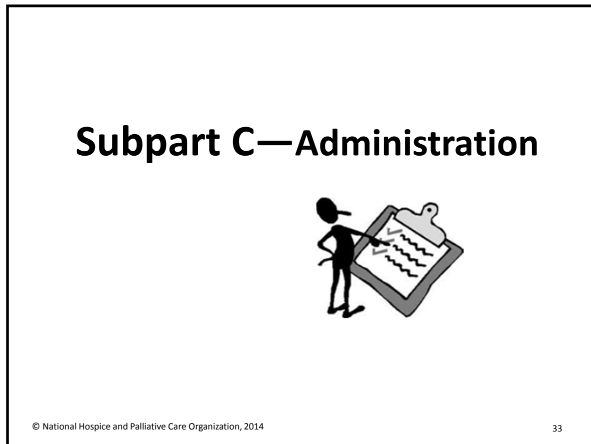

§ 418.100 Organization and administration of services

- **Standard: Services:** Nursing services, physician services, and drugs and biologicals must be made routinely available on a 24-hour basis 7 days a week.
- **Standard: Professional management responsibility:** A hospice that has a written agreement with another agency, individual, or organization to furnish any services under arrangement must retain administrative and financial management, and oversight of staff and services for all arranged services, to ensure the provision of quality care.
- **Standard: Hospice multiple locations**
- **Standard: Training**

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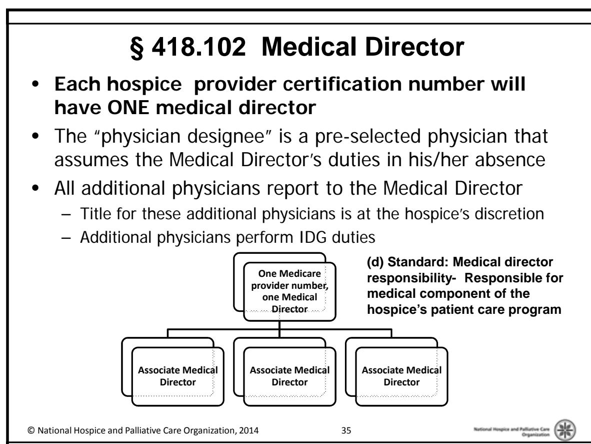

§ 418.104 Clinical records

(b) Standard: Authentication

- Must have a policy for authentication
  - Must be able to explain system and method to identify the author of each entry
  - Electronic authentication = user ID and password
- Acceptable identifiers:
  - Handwritten
  - Electronic
  - Faxed handwritten
  - NO stamped signatures allowed unless notarized evidence of physician debility
- Hospice must provide equipment to surveyors to view electronic records and provide a paper copy upon request

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§ 418.106 Drugs and biologicals, medical supplies, and durable medical equipment

(a) Standard: Managing drugs and biologicals

- Ensure that IDG confers with individual with education and training in drug management to ensure that drugs and biologicals meet each patient's needs
  - Individuals may include:
    - Licensed pharmacist
    - Board certified physicians in palliative medicine
    - RN's certified in palliative care
    - Physicians, RN's, NP's who complete a specific hospice or palliative care drug management course

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§ 418.106 Drugs and biologicals, medical supplies, and durable medical equipment

(d) Standard: Administration of drugs and biologicals

- IDG must determine patient/family ability to safely administer drugs
- Must be identified in patient plan of care

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§ 418.106 Drugs and biologicals, medical supplies, and durable medical equipment

(e) **Standard: Labeling, disposing, and storing of drugs and biologicals**

- **Provide a copy of written policies and procedures** for managing and disposing of drugs in patient's home, ad discuss with patient and family at the time when controlled drugs are first ordered, document discussion in clinical record
- Note! NHPCO recently provided written comments to EPA's proposed rule regarding drug disposal.

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§ 418.106 Drugs and biologicals, medical supplies, and durable medical equipment

(f) Standard: DME

- The instruction given to the patient/family on the use of the DME and supplies must be documented in the patient's clinical record, as well as the patient/family's understanding of the safe use of the DME and supplies.
- **Surveyor probes:**
  - Ask the patient to describe instructions received regarding the use of durable medical equipment and supplies.
  - Has the patient/family had any problems with the equipment received?
  - Does the DME function as required and intended?
  - Clinical record documentation should verify/support their responses.

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§ 418.106 Drugs and biologicals, medical supplies, and durable medical equipment

(f) Standard: DME

- **Contract with an accredited DME provider**
- Current contract – no DME accreditation
  - hospice should have a letter their file from the DME stating the DME has applied for and is waiting for accreditation by the September 2009 deadline date.
- Contract with a DME that only serves hospice providers – no DME accreditation
  - hospice will need to make sure same type of letter from DME.
- If the hospice owns its own DME, then no accreditation is needed.

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§ 418.110 Hospices that provide inpatient care directly - Restraints and seclusion

Restraint means:

- Any manual method
- physical or mechanical device
- material or equipment that immobilizes or reduces the ability of a patient to move his or her
  - Arms
  - Legs
  - Body
  - head freely, including devices

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§ 418.110 Hospices that provide inpatient care directly - Restraints and seclusion

Restraint also means:
- A drug or medication when it is used as a:
  - restriction to manage the patient's behavior or
  - restrict the patient's freedom of movement
  - is not a standard treatment or dosage for the patient's condition.

Seclusion means:
- the involuntary confinement of a patient alone in a room or an area from which the patient is physically prevented from leaving. Patients who request private rooms would not be considered in seclusion.

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Restraint free facility

- If a hospice declares their facility "restraint free"
  – Policy/ procedure that supports
    - States what will happen if the patient needs restraints of seclusion

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Patient death during restraint

- If a patient has an unexpected death that occurs while in restraint or seclusion, or an unexpected death occurs within 24 hours after restraint or seclusion has been discontinued, the death must be reported to CMS Regional Office
- If a death occurs within one week after the use of restraint or seclusion and it is reasonable to assume the death was associated with restraint and/or seclusion, the death should be reported to CMS Regional Office

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§ 418.112 Hospices that provide hospice care to residents of a SNF/NF or ICF/MR

- June 27, 2013 - CMS published the final rule regarding requirements for long term care facilities when they enter into an agreement with a hospice to offer hospice services to residents of the facility.
  – Effective August 26, 2013
  – Side-by-side comparison chart detailing regulatory roles and responsibilities for each provider type
- Greater scrutiny on provision of care for a patient receiving hospice care in a nursing facility for both the hospice and the facility
  – Nursing facility surveyors have been instructed to select at least 1 hospice patient during a facility survey

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§ 418.112 - Professional management

Professional management of the patient's terminal illness
- Professional management involves assessing, planning, monitoring, directing, and evaluating.
- Hospice duties:
  – Ongoing assessment of the patient's terminal illness
  – Care planning
  – Monitoring
  – Coordination and provision of hospice care by IDG
  – Coordination of care with facility

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§ 418.112 Contractual agreement

Agreement must include:
- Communication and documentation strategy
  – The hospice must document that communication has occurred.
- Provision for notifying hospice under certain circumstances
- Hospice responsibility for determining hospice care provided
- Both providers must comply with their applicable conditions/requirements for participation in Medicare/Medicaid

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§ 418.112 Contractual agreement

Agreement also includes:

- Hospice responsibility to provide services to same extent as serving a patient in a private home
- Delineation of hospice responsibilities
- Provision to use facility personnel to assist in implementing the plan of care only to the extent that a hospice would routinely use a patient's family
- Hospice reports to facility all patient rights violations unrelated to the hospice
- Bereavement services

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§ 418.112 Nursing Facility Responsibilities

- Included in the contractual agreement
  - An agreement that it is the SNF/NF or ICF/MR responsibility to continue to furnish 24 hour room and board care, meeting the personal care and nursing needs that would have been provided by the primary caregiver at home at the same level of care provided before hospice care was elected.

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§ 418.112 Nursing Facility Responsibilities

The facility must offer the same services to its residents who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit

- Room and board services
- Care for conditions unrelated to hospice terminal illness
- Core hospice services may not be delegated to facility staff
- Hospice may offer bereavement services to facility staff or residents that fulfill the role of a hospice patient's family as identified in the plan of care

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§ 418.112 Hospice Responsibilities

A delineation of the hospice's responsibilities, which include, but are not limited to the following:

- Providing medical direction and management of the patient's terminal illness.
- Nursing.
- Counseling, including spiritual, dietary and bereavement.
- Social work.
- Provision of medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms.
- All other hospice services that are necessary for the care of the patient/ resident's **terminal** illness and related conditions.

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§ 418.112 Hospices plan of care

- Coordinated and guides both providers
- May be divided into two portions; separately maintained
- Hospice plan of care must identify the provider responsible for each function/ intervention in plan of care for the patient's terminal illness
- Both providers portion of plan of care should reflect identification of:
  - Common problem list
  - Palliative interventions and outcomes
  - Responsible discipline/ provider
  - Patient goals

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§ 418.112 Coordination of Services

- Hospice designates IDG member to provide overall coordination of care
  - May or may not be the hospice RN; (physician, social worker or counselor member of the IDG)
  - Implementation of plan of care with facility representatives
  - Communicates with facility to implement hospice plan of care
- Surveyors will look for evidence of communication, system coordination, outcomes meeting patient goals in both the hospice and the facility charts
  - May talk to facility nursing aide

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§ 418.112 Orientation and training

- Hospice assures orientation facility staff in:
  - Hospice philosophy
  - Policies and procedures
  - Pain control and symptom management methods
  - Patient rights
  - Forms
  - Record keeping
- Hospices can collaborate for general hospice philosophy and pain management training
- Specific training regarding forms, record keeping and coordination between each hospice and facility needs to be completed individually by the hospice

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§ 418.114 Condition of participation: Personnel qualifications

- *Social worker.* A person who—
  - Has a Master of Social Work (MSW) degree from a school of social work accredited by the Council on Social Work Education; or
  - Has a baccalaureate degree in social work from an institution accredited by the Council on Social Work Education;
  - or a baccalaureate degree in psychology, sociology, or other field related to social work and
  - Is supervised by an MSW if:
    - Baccalaureate degree in psychology, sociology, or other field
    - Has a BSW and was hired by hospice organization after December 2, 2008
  - Has 1 year of social work experience in a healthcare setting

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§ 418.114 Criminal background check

- The hospice must obtain a criminal background check on all hospice employees who have direct patient contact or access to patient records.
- Hospice contracts must require that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.

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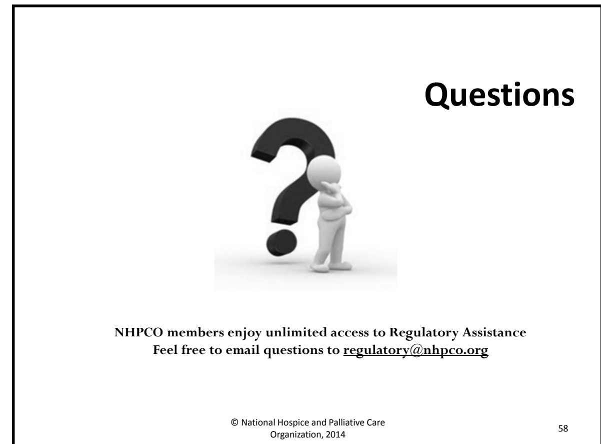

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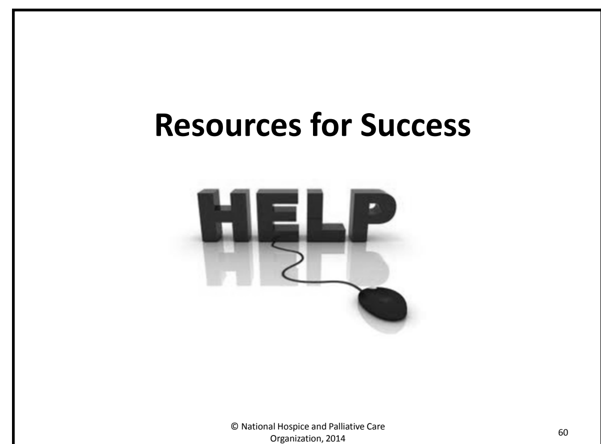

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NHPCO Resources

- **The Medicare Regulations for Hospice Care, Including the Conditions of Participation for Hospice Care (8/7/13)**
- **Medicare Hospice Conditions of Participation Subparts C & D - Member Resources**
  - Subparts C & D CoP tip sheets
  - Discipline CoP Specific Tip Sheets
  - Medicare Hospice CoP Implementation Checklist
- CMS Survey Deficiencies 2010-2012 Comparison Chart (August 2013)
- CMS CY 2012 Top 10 Hospice Survey Deficiency Tip Sheet (August 2013)
- CMS CY 2012 Top 10 Hospice Survey Deficiency Audit Tool (August 2013)

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References

CMS Hospice Center

- http://www.cms.hhs.gov/center/hospice.asp
  - Conditions of Participation Hospice
  - Medicare Benefit Policy Manual; Chapter 9 - Coverage of Hospice Services

NHPCO Regulatory Page

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