National Hospice and Palliative Care Organization

Regulatory Alerts

NHPCO
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Regulatory Alert Update – REVISED

Regulatory Relief Final Rule: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

To: NHPCO Provider Members
From: Regulatory Team
Date: October 31, 2019 *(Posted online 11/01/19)*

Summary at a Glance

On September 30, CMS published a final rule on regulatory burden relief which:

1. Defers hospice aide training and competencies to state licensure requirements. If there are no state requirements, hospices will still be required to ensure that their hospice aides meet Federal standards for hospice aide training.
2. Removes requirements to have a person on the hospice staff that has specialty knowledge of hospice medications.
3. Follows the statutory requirement in the SUPPORT Act that the hospice must share the written policies and procedures for drug disposal in the home with patients, families and caregivers. However, CMS encourages hospices to develop easily understood materials that explain safe storage, use, and disposal of controlled drugs to patients, their families, and caregivers in addition to meeting the statutory requirement.
4. Removes requirements for hospices to explicitly coordinate with SNF/NF and ICF/IID staff for orientation of facility staff.
5. Changes in emergency preparedness requirements for hospice inpatient facilities and home-based hospice care.

On September 30, 2019, CMS published a final rule detailing regulatory relief for Medicare providers. NHPCO responded to the proposed rule in November of 2018. **The final rule is effective November 29, 2019.** The changes are detailed below.

Changes in Medicare Hospice Conditions of Participation to Reduce Regulatory Burden

1. Changes to Hospice Aide Requirements in § 418.76

In the final rule, CMS removed the specific training and competency requirements for hospice aides in § 418.76(b) and (c), deferring to State licensure requirements. NHPCO supported this change.

If there are no state requirements, hospices will still be required to ensure that their hospice aides meet Federal standards for hospice aide training. As CMS states: "Hospices in all states will continue to be required to comply with the existing requirements that hospice aides may only perform those skills that are consistent with the training that the aide has received (§418.76(g)(2)(iv)), and that, if an area of concern is verified by the hospice during an on-site aide supervision visit, then the hospice must conduct, and the hospice aide must complete, a competency evaluation in accordance with §418.76(c) and (h)(1)(iii)."

Revised COP language:

§ 418.76 Condition of participation: Hospice aide and homemaker services.

All hospice aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section. Homemaker services must be provided by individuals who meet the personnel requirements specified in paragraph (j) of this section.

(a) *Standard: Hospice aide qualifications.*

(1) A qualified hospice aide is a person who has successfully completed one of the following:

(i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) A State licensure program. ~~that meets the requirements of paragraphs (b) and (c) of this section~~.

Members should consider the following:

(a) Review of internal policies/procedures and State requirements for hospice aide onboarding, training and education, to ensure compliance.
(b) Ensure that documentation regarding hospice aide training, education, and competencies meet State requirements. If no state requirements exist, ensure compliance with federal standards.

2. ***Hospice requirements for medication management in § 418.106 and comments on requirements for communication with the patient, family and caregiver for the safe storage, use, and disposal of controlled substances***

In the final rule, CMS finalized the proposal by removing the procedural requirement that hospices be required to have IDG consultation with **"an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice, to ensure that drugs and biologicals meet each patient's needs."** In many hospices, this review has been completed by a pharmacist. CMS also noted that this pharmacist discussion is frequently occurring as part of the hospice's contract with the pharmacy benefit management (PBM) company.

NHPCO recognizes the importance of ongoing medication review and management. Having this procedural language removed from the COP **does not relieve the hospice of ongoing IDG review and documentation regarding safe, appropriate, and effective use of medications**. According to § 418.54 (a) through (d) and § 418/56 (b) through (d), hospices are still required to comprehensively assess patients on a regular and as needed basis and assure that the patient's plan of care is developed and updated to continually meet the patient's identified needs. complete a drug profile as part of the patient's comprehensive assessment. This will be included as part of the IDG's ongoing assessment and plan of care update for the patient. Discussions with the patient and family would be in a manner and language that the patient and family understand.

NHPCO was strongly opposed to this proposal and made substantive comments about the proposal in the NHPCO comment letter.

Revised COP language for managing drugs and biologicals*:*

§ 418.106 Condition of participation: Drugs and biologicals, medical supplies, and durable medical equipment.
Medical supplies and appliances, as described in § 410.36 of this chapter; durable medical equipment, as described in § 410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

(a) *Standard: Managing drugs and biologicals.*

~~(1) The hospice must ensure that the interdisciplinary group confers with an individual with education and training in drug management as defined in hospice policies and procedures and State law, who is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs.~~

(1) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed

pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

(2) Reserved

COP Language Requiring Drug Profile Review (Added to the Medicare Hospice Conditions of Participation in June 2008. See yellow highlighted area as a reminder for the drug profile requirements.)

§ 418.54 Condition of participation: Initial and comprehensive assessment of the patient.

The hospice must conduct and document in writing a patient-specific comprehensive assessment that identifies the patient's need for hospice care and services, and the patient's need for physical, psychosocial, emotional, and spiritual care. This assessment includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must identify the physical, psychosocial, emotional, and spiritual needs related to the terminal illness that must be addressed in order to promote the hospice patient's well-being, comfort, and dignity throughout the dying process. The comprehensive assessment must take into consideration the following factors:

(1) The nature and condition causing admission (including the presence or lack of objective data and subjective complaints).

(2) Complications and risk factors that affect care planning.

(3) Functional status, including the patient's ability to understand and participate in his or her own care.

(4) Imminence of death.

(5) Severity of symptoms.

(6) *Drug profile*. A review of all of the patient's prescription and over-the-counter drugs, herbal remedies and other alternative treatments that could affect drug therapy. This includes, but is not limited to, identification of the following:

(i) Effectiveness of drug therapy.

(ii) Drug side effects.

(iii) Actual or potential drug interactions.

(iv) Duplicate drug therapy.

(v) Drug therapy currently associated with laboratory monitoring.

(7) *Bereavement*. An initial bereavement assessment of the needs of the patient's family and other individuals focusing on the social, spiritual, and cultural factors that may impact their ability to cope with the patient's death. Information gathered from the initial bereavement assessment must be incorporated into the plan of care and considered in the bereavement plan of care.

(8) The need for referrals and further evaluation by appropriate health professionals.

Content and form of the controlled drug storage, use, and disposal notice for patients and families: In the proposed rule, CMS proposed to allow hospices to determine the content and form of controlled drug storage, use and disposal notice for patients and families, suggesting that improved patient/family communication, in a manner and language the patient and family can understand, is far superior to the requirement to share agency policies and procedures. NHPCO supported this proposal but also flagged the conflict in the language in the SUPPORT Act and this regulatory relief proposal.

In the final rule, CMS noted that because of the changes outlined in section 3222 of the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), they are not finalizing the proposal to have safe storage, use and disposal of controlled substances education to patients and families in user-friendly formats. The SUPPORT Act **requires** hospices, which permit their employees to dispose of medications in the patient's home, to provide their written policies and procedures to patients, families and caregivers. This provision amends section 302 of the Controlled Substances Act (21 U.S.C. 822).

Members should consider the following:

(a) Review of agency practices to ensure that discussions and documentation are occurring surrounding the safe use, storage and disposal of controlled drugs with the patient or representative, and the family/caregiver(s), in a language and manner that they understand to ensure that effective education has occurred.
(b) IDG discussions and documentation contain updates to patient plan of care that include drug profile reviews.

3. ***Hospice requirements: orientation of skilled nursing facility (SNF) and intermediate care facilities for individuals with intellectual disabilities (ICF/IID) staff***

In order to achieve their original regulatory goal of adding flexibility and reducing hospice costs for this activity, CMS revised existing COP § 418.112(f) to clarify that a hospice must consult with and thus share responsibility with the facility to assure facility staff orientation and training. CMS's intent is not to move the requirements related to facility staff orientation and training from a standalone requirement to a provision in the written agreement. Language was added to COP § 418.112 (c) to include a written agreement that negotiates the mechanism and schedule for the orientation of staff to occur. The goal is for shared responsibility between the facility and the hospice regarding orientation and training of facility staff. NHPCO did not support this change, due to the increased

burden on hospice providers to renegotiate contracts to more clearly specify orientation responsibilities.

Revised COP language:

§ 418.112 Condition of participation: Hospices that provide hospice care to residents of a SNF/NF or ICF/IID. (See language in red below)
In addition to meeting the conditions of participation at § 418.10 through § 418.116, a hospice that provides hospice care to residents of a SNF/NF or ICF/IID must abide by the following additional standards.

(f) *Standard: Orientation and training of staff*. Hospice staff, in coordination with SNF/NF or ICF/IID facility staff, must assure orientation of such staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

Members should consider the following:

(a) Review your agency's current process for orientation and training of facility staff caring for your hospice patients.
(b) Communicate with facility providers regarding the update to the COP.
(c) If a plan is not in currently in place, work with your facilities to develop a joint plan for facility staff orientation and training.
(d) Ensure that your record keeping regarding facility staff orientation exists and is current.

4. ***Emergency Preparedness Changes at § 418.113***

a. Annual Review of Emergency Preparedness Program

All providers and suppliers will be required to update their emergency preparedness plan biennially. This is the minimum requirement for non-LTC facility providers and suppliers; providers and suppliers are encouraged to review and update their emergency preparedness plan more frequently if needed.

b. Documentation of Cooperation Efforts

The requirement to document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials and facilities' participation in collaborative and cooperative planning efforts is eliminated. Collaboration and cooperation is encouraged, but the documentation of efforts is not required.

c. Emergency Preparedness Training Program

The CMS final rule requires **biennial** emergency preparedness training for all providers.

d. Annual Emergency Preparedness Testing

The final rule requires **inpatient providers, including hospice inpatient facilities,** to conduct **two** testing exercises annually**. Outpatient providers**, **including hospice home care providers,** must conduct **one** testing exercise annually.

NHPCO did not support the reduction in the testing exercises for outpatient providers, including hospices. NHPCO received feedback from hospices who experienced recent natural disasters that frequent testing has been very important. NHPCO will be updating the *Emergency Preparedness Guide for Hospices* once the full content of the changes in regulations at § 418.113 are finalized after the implementation date of November 29, 2019.

For additional questions, please contact regulatory@nhpco.org for assistance.

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