1. Hospice

a. Background

Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual, and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Medicare regulations define “palliative care” as patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice (42 CFR 418.3). The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. The hospice interdisciplinary group works with the patient, family, caregivers, and the patient’s attending physician (if any) to develop a coordinated, comprehensive care plan; reduce unnecessary diagnostics or ineffective therapies; and maintain ongoing communication with individuals and

their families and caregivers about changes in their condition. The care plan will shift over time to meet the changing needs of the patient, family, and caregiver(s) as the patient approaches the end of life.

The regulations for Medicare and Medicaid participating hospices are set forth at 42 CFR part 418. Section 418.3 defines the term "attending physician" as being a doctor of medicine or osteopathy, an NP, or a PA in accordance with the statutory definition of an attending physician at section 1861(dd)(3)(B) of the Act. Section 51006 of the Bipartisan Budget Act of 2018 revised the statute to add PAs to the statutory definition of the hospice attending physician for services furnished on or after January 1, 2019. As a result, PAs were added to the definition of a hospice attending physician as part of the "Medicare Program; FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements" final rule which was published in the August 6, 2018 **Federal Register** (83 FR 38622, 38634) (hereinafter referred to as the "FY 2019 Hospice final rule".)

The role of the patient's attending physician, if the patient has one, is to provide a longitudinal perspective on the patient's course of illness, care preferences, psychosocial dynamics, and generally assist in assuring continuity of care as the patient moves from the traditional curative care model to hospice's palliative care model. The attending physician is not meant to be a person offered by, selected by, or appointed by the hospice when the patient elects to receive hospice care. Section 418.64(a) of the hospice regulations requires the hospice to provide physician services to meet the patient's hospice-related needs and all other care needs to the extent that those needs are not met by the patient's attending physician. Thus, if a patient does not have an attending physician relationship prior to electing hospice care, or if the patient's attending physician chooses to not participate in the patient's care after the patient elects to

receive hospice care, then the hospice is already well-suited to provide physician care to meet all of the patient's needs as part of the Medicare hospice benefit. If the patient has an attending physician relationship prior to electing hospice care and that attending physician chooses to continue to be involved in the patient's care during the period of time when hospice care is provided, the role of the attending physician is to consult with the hospice interdisciplinary group (also known as the interdisciplinary team) as described in § 418.56, and to furnish care for conditions determined by the hospice interdisciplinary group to be unrelated to the terminal prognosis. The hospice interdisciplinary group must include the following members of the hospice's staff: a physician; a nurse; a social worker; and a counselor. The interdisciplinary group may also include other members based on the specific services that the patient receives, such as hospice aides and speech language pathologists. The hospice interdisciplinary group, as a whole, in consultation with the patient's attending physician (if any), the patient, and the patient's family and caregivers, are responsible for determining the course of the patient's hospice care and establishing the individualized plan of care for the patient that is used to guide the delivery of holistic hospice services and interventions, both medical and non-medical in nature.

b. Provisions

In the role of a consultant to the hospice interdisciplinary group, the hospice patient's chosen attending physician may, at times, write orders for services and medications as they relate to treating conditions determined to be unrelated to the patient's terminal prognosis. The law allows for circumstances in which services needed by a hospice beneficiary would be completely unrelated to the terminal prognosis, but we believe that this situation would be the rare exception rather than the norm. Section 418.56(e) requires hospices to coordinate care with other providers

who are also furnishing care to the hospice patient, including the patient's attending physician who is providing care for conditions determined by the hospice interdisciplinary group to be unrelated to the patient's terminal prognosis. As part of this coordination of care, it is possible that hospices may receive orders from the attending physician for drugs that are unrelated to the patient's terminal prognosis.

The FY 2019 Hospice final rule amended the regulatory definition of "attending physician," as required by the statute, to include "physician assistant." Following publication of the FY 2019 Hospice final rule, stakeholders raised concerns regarding the requirements of § 418.106(b). As currently written, hospices may not accept orders for drugs from attending physicians who are PAs because § 418.106(b) specifies that hospices may accept drug orders from physicians and NPs only. This regulatory requirement may impede proper care coordination between hospices and attending physicians who are PAs, and we believe that it should be revised.

Therefore, we proposed to revise § 418.106(b)(1) to permit a hospice to accept drug orders from a physician, NP, or PA. We proposed that the PA must be an individual acting within his or her state scope of practice requirements and hospice policy. We also proposed that the PA must be the patient's attending physician, and that he or she may not have an employment or contractual arrangement with the hospice. The role of physicians and NPs as hospice employees and contractors is clearly defined in the hospice CoPs; however, the CoPs do not address the role of PAs because the statute does not include PA services as being part of the Medicare hospice benefit. Therefore, we believe that it is necessary to limit the hospice CoPs to accepting only those orders from PAs that are generated outside of the hospice's operations.

To more fully understand the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs, we requested public comment on the following questions:

- What is the role of a NPP in delivering safe and effective hospice care to patients? What duties should they perform? What is their role within the hospice interdisciplinary group and how is it distinct from the role of the physician, nurse, social work, and counseling members of the group?

- Nursing services are a required core service within the Hospice benefit, as provided in section 1861(dd)(B)(i) of the Act, which resulted in the defined role for NPs in the Hospice COPs. Should other NPPs also be considered core services on par with NP services? If not, how should other NPP services be classified?

- In light of diverse existing state supervision requirements, how should NPP services be supervised? Should this responsibility be part of the role of the hospice medical director or other physicians employed by or under contract with the hospice? What constitutes adequate supervision, particularly when the NPP and supervising physician are located in different offices, such as hospice multiple locations?

- What requirements and timeframes currently exist at the state level for physician co-signatures of NPP orders? Are these existing requirements appropriate for the hospice clinical record? If not, what requirements are appropriate for the hospice clinical record?

- What are the essential personnel requirements for PAs and other NPPs?

We received public comments on the proposed regulatory change to allow hospices to accept medication orders from PAs who are attending physicians as chosen by the patient that do not have an employment or contractual relationship with the hospice. We also received information in response to our solicitation for public comments regarding the current and future role of NPPs, including PAs, in hospice care and the hospice CoPs. The following is a summary

of the comments we received and our responses.

Comment: All comments regarding the proposed regulatory change to allow hospices to accept medication orders from PAs who are attending physicians as chosen by the patient that do not have an employment or contractual relationship with the hospice noted support for allowing hospice to accept drug orders from such PAs. Some commenters suggested that hospices should be allowed to accept orders from PAs employed by or under arrangement with the hospice.

Response: We agree with the commenters that this proposed change is appropriate to assure care coordination between attending physicians who are PAs and hospices, and we are finalizing the proposal without change. We do not agree that PAs employed by or under arrangement with the hospice should be included in this rule, as such piecemeal inclusion without complimentary regulations to establish the scope of PA services in hospices may create patient safety and program vulnerabilities. It is clear from the comments that a notable portion of the physician assistant and hospice communities view the role of the physician assistant as an acceptable substitute for hospice physicians, which is not in accordance with current statutory provisions. We believe that this disconnect between public perception of the role of the PA and the requirements of the statute necessitates rulemaking to clearly set forth what is and is not permissible. We will consider this suggestion for future rulemaking.

Comment: A few commenters disagreed with the idea that attending physicians who are physician assistants should be limited to prescribing only those medications or therapies that are not related to the terminal prognosis.

Response: We did not propose, nor are we finalizing, any such limitations. Attending physicians, regardless of their qualifications, are consultants to the hospice interdisciplinary group. It is the hospice interdisciplinary group, comprised of, at minimum, a physician, nurse,

social worker, and counselor in accordance with the requirements set forth in section 1861(dd)(2)(B)(i) of the Act, that is responsible for determining the content of the patient's hospice plan of care and issuing all necessary orders to implement that plan of care. Given that: (1) Each interdisciplinary group contains, at minimum, a physician member employed by or under arrangement with the hospice actively involved in the patient's care at all times, (2) hospice physician services must be available at all times, and (3) the physician member has the authority to write all orders necessary to implement the plan of care, the need for an attending physician outside of the hospice to write orders related to implementing the hospice plan of care should be rare.

Comment: The majority of the commenters submitted information regarding the current and future role of NPPs, including PAs and advanced practice registered nurses (APRNs), in hospice care and the hospice CoPs.

Response: We thank the commenters for sharing this information, and will take it into consideration when developing all future hospice CoPs related to the role of NPPs.

Comment: One commenter posed the following question: There are a number of PAs in palliative care that are employed or under contract with the parent company that also operates the hospice. Would CMS consider these PAs to be an employee of the hospice if everyone operates under the same tax identification number?

Response: Section 418.3, Definitions, of the hospice CoPs defines an employee as a person who: (1) Works for the hospice and for whom the hospice is required to issue a W-2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice. If a PA is assigned by the "parent company" to the hospice,

then the PA is considered to be an “employee” of the hospice.

Comment: Some commenters made suggestions related to hospice payment requirements, CMS manuals, and statutory requirements that are not within the scope of our proposal to revise the hospice CoPs or within our regulatory authority.

Response: We have shared these out of scope comments with the appropriate CMS stakeholders.

In accordance with public comments, we are finalizing the change at § 418.106(b)(1) as proposed.