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Seema Verma Administrator Centers for Medicare and Medicaid Services US Department of Health and Human Services 200 Independence Avenue, SW Washington, D.C. 20101

RE: Medicare Program; FY 2021 Hospice Wage Index and Payment Rate Update (CMS-1733-P)

Dear Administrator Verma:

The National Hospice and Palliative Care Organization (NHPCO) is pleased to submit comments on the FY2021 Hospice Wage Index and Payment Rate Update Proposed Rule (CMS-1733-P).

NHPCO is the nation's largest membership organization for hospice providers and professionals who care for people affected by serious and life-limiting illness. Its broad community of members includes local hospice and palliative care providers, networks serving large regions of the United States, and individual professionals. NHPCO's members provide care in more than 4,000 hospice and palliative care locations and care for over two thirds of the Medicare beneficiaries served by hospice. In addition, hospice and palliative care members employ nearly 60,000 professionals and hundreds of thousands of volunteers. We offer the following comments on the proposals and forms that will impact the hospice and palliative care community.

A. <u>Proposed Routine FY 2021 Hospice Wage Index and Rate Update</u> Proposed FY 2021 Hospice Payment Update Percentage: NHPCO supports the proposed 2.6% market basket increase for FY 2021.

B. Proposed Wage Index Changes

Proposed Transition Period: NHPCO supports the adoption of the OMB recommendations for the newly identified geographic areas and the proposed one-year transition period to ease the impact of wage index value changes which will, for some providers, lower their FY2021 rates. NHPCO supports limiting the impact in FY2021 to 5 percent for those counties that will experience a decrease in their wage index, with full implementation to occur no earlier than in FY 2022.

C. <u>Implementation of the Election Statement Content Modifications and Addendum to</u> <u>Provide Greater Coverage Transparency and Safeguard Patient Rights</u>

NHPCO strongly urges CMS to delay the implementation of the changes to the election statement and the addition of the election statement addendum, currently proposed for implementation on October 1, 2020. In discussions with hundreds of hospice providers, NHPCO has heard concerns about the impact of COVID-19 on election statement and addendum preparation, the readiness of electronic medical record (EMR) vendors, the readiness of MACs and BFCC-QIOs, and the readiness of hospices who must develop policies and procedures and train staff on the new processes and form, while caring for patients during COVID-19. Feedback from the hospice provider community follows the NHPCO recommendation.

NHPCO Recommendation: NHPCO requests that CMS delay the implementation of the election statement content modifications and addendum for at least one full year beyond the end date of the COVID-19 PHE. We note that on May 8, 2020, CMS delayed the implementation of OASIS-E in home health beyond the applicable PHE period as it announced: "The release of the updated version of the OASIS will be delayed until January 1st of the year that is at least 1 full calendar year after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September 20, 2020, HHAs will be required to begin collecting data using the updated versions of the item sets beginning with patients discharged on January 1, 2022." We request that CMS provide the same consideration for hospice during the COVID-19 PHE so that providers, EMR vendors, Medicare Administrative Contractors, and BFCC-QIOs are fully prepared.

Reasons for the Need for Delay of Implementation of Election Statement Content Modifications and Addendum

1. Impact of COVID-19

Normal business operations have been at a standstill since stay at home orders went into effect across the nation. The attention of hospice clinical, IT and administrative teams who have been working on the implementation of the Hospice Election Statement changes and the addition of the addendum has been fully diverted to caring for patients in the midst of the COVID-19 pandemic. Providers report that their time has been spent on:

- Updating infection control policies and procedures and daily surveillance for staff, patients and families on possible exposure and infection;
- Providing IT support for virtual visits, including options and hardware for video visits;
- Offering IT support for virtual meetings of hospice staff, including Zoom capabilities for team meetings and meetings with patients and families;

- Acquiring adequate supplies of PPE for staff;
- Negotiating with nursing facilities on approaches to serving nursing home residents receiving hospice care;
- Offering alternatives to home visits for patients and caregivers who are anxious about hospice staff entering the home; and
- Addressing other location-specific COVID-19 issues.

When not directly caring for patients, hospices are spending much of their time developing and implementing COVID-19 specific operational and clinical processes. Providers are focused on learning as much as possible about the COVID-19 virus, educating their staff, patients, and families about safety measures, securing unmet needs for personal protective equipment (PPE), comforting patients and families and staff who are frightened and scared, and providing care to people who are dying.

Clearly when the proposed rule was under development, the Administration had not yet declared a PHE. Implementation in the midst of a PHE would give providers little time to develop forms tailored to each hospice, work with legal counsel to review and produce compliant forms for beneficiary use, work with electronic medical record (EMR) vendors to include the forms in the EMR system, or get forms printed. The businesses offering printing services for producing paper election statement and addendum forms for hospice provider use were not considered "essential" by state governments and are only beginning to open under limited operating hours in certain states. Upon finalization of the forms, hospice staff will also need to be trained in the use of the forms and must then properly explain the intent and use to patients/representatives. We estimate the production and training time alone would add up to thousands of hours that providers are currently dedicating to the response to the PHE.

2. <u>Electronic Medical Record (EMR) Software Readiness</u>

In an April 2020 New York survey of eight hospice EMR vendors, the majority of hospice EMR vendors in the country, some vendors report that they may be ready but not one vendor has delivered a finished product to their hospice clients. Vendors report that they have not been able to deliver a finished product until they receive more guidance from CMS on the details of the form specifications. Hospices are awaiting delivery of the software modifications so that they can test the software, develop processes and prepare for implementation. Providers are dependent on EMR integration of the election statement changes and the addendum to ensure accurate and compliant implementation in advance of the effective date.

3. MACs and BFCC-QIO Guidance

As NHPCO understands it, the implementation of the election statement content modifications and addendum will require direct action by Medicare Administrative Contractors (MACs) and Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs). According to the MACs and BFCC-QIOs there has been no communication from CMS to the MACs related to the addendum as a condition of payment, or the BFCC-QIOs related to a patient/representative's request for an appeal of the decision of the hospice agency on items not covered because the hospice has determined that the items, services and drugs are not related to the terminal illness.

The MACs are currently preparing education for providers on the election statement changes and the addendum and expect to offer educational sessions "this summer." Despite CMS commitment in the FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule to "collaborate with the MACs to establish clear guidelines on the use of the addendum as a condition for payment," our research supports that no CMS guidance has been given to the MACs specifying their role related to this new condition of payment.

D. <u>Comments on Election Statement Content Modifications and the Requirements for the</u> <u>Election Statement Addendum in § 418.24</u>

NHPCO has studied the provisions of the FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule to consider what processes must be in place before implementation. Several issues were mentioned in the commentary language in the rule, but not included in the language in § 418.24(c).

Patient's Death and Impact on Issuance of Addendum: NHPCO notes that in the commentary, CMS stated that if the patient requested the election statement but died within five days of admission, the election statement would not be provided. However, this guidance never made it into the wording of the regulation. Adding this guidance to § 418.24(c) to clarify that the election addendum will not be provided if the patient dies within five days of the admission would be helpful.

NHPCO Recommendation: NHPCO recommends that specific language be added to § 418.24(c) to provide guidance to hospice providers if the patient dies within five days of admission.

- **2.** Conflicting language about who can request the addendum: NHPCO seeks clarification on language in § 418.24(c) about who can request an election statement addendum.
 - In § 418.24(c)(6), it clearly indicates that the individual should share the information with other health care providers.

§ 418.24(c)(6) This clinical explanation must be accompanied by a general statement that the decision as to whether or not conditions, items, services, and drugs are related is made for each patient and that the individual should share this clinical explanation with other health care providers from which they seek items, services, or drugs_unrelated to their terminal illness and related conditions.

• However, in § 418.24(c), there is language that allows non-hospice providers or Medicare contractors to request the written list.

§ 418.24(c): **Content of hospice election statement addendum.** For Hospice elections beginning on or after October 1, 2020, in the event that the hospice determines there are conditions, items, services, or drugs that are unrelated to the individual's terminal illness and related conditions, the individual (or representative), non-hospice providers furnishing such items, services, or drugs, or Medicare contractors may request a written list as an addendum to the election statement.

• While we understand this information is allowed for HIPAA purposes, the language in this section is inconsistent and we therefore request additional clarity.

NHPCO Recommendation: NHPCO recommends an adjustment in the language in § 418.24(c) that provides additional clarity regarding the sharing of information on the addendum which non-hospice providers and Medicare contractors.

3. Lack of Clarity About Patient Refusal to Sign the Addendum: As written, CMS's election statement addendum regulations at 42 C.F.R. § 418.24(c)(9) require that the addendum contain the "[n]ame and signature of the individual (or representative) and date signed, along with a statement that signing this addendum (or its updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily the individual's (or representative's) agreement with the hospice's determinations." However, CMS has not provided guidance to hospices on the scenario where the patient or representative requests an addendum but then refuses to sign. Patient or representatives may refuse to sign the addendum because they may be concerned about what they are signing, may disagree with the hospice's list of what will not be covered, or may be concerned that signing the addendum will be detrimental to the patient's care and not in the patient's best interest. We note that in the context of Notices of Medicare Non-Coverage, CMS has stated that "[i]f the beneficiary refuses to sign the NOMNC the provider should annotate the notice to that effect and indicate the date of refusal on the notice." See Medicare Claims Processing Manual, Ch. 30, § 260.3.5.

NHPCO Recommendation: NHPCO recommends that CMS address the issue of a patient or representative refusing to sign the addendum. Such guidance from CMS could be similar to the guidance provided by CMS in the context of the Notices of

Medicare Non-Coverage: the hospice should document the patient's or representative's refusal to sign the addendum.

E. <u>Comments on Election Statement Example and Hospice Election Statement Addendum</u> (Patient Notification of Hospice Non-Covered Items, Services, and Drugs) Example Forms

As part of the review of this year's proposed rule, NHPCO has also reviewed the Election Statement Example and the Patient Notification of Hospice Non-Covered Items, Services and Drugs Example forms. Our detailed comments follow. A table with the NHPCO recommendations for changes in language and their rationale is included in Appendix A.

1. <u>Comments on Election Statement Form Sample</u>

NHPCO appreciates CMS publication of model election statement and addendum forms. A workgroup of NHPCO providers met and analyzed the forms, their content and the process for implementation and suggested modifications to form content.

Questions for Clarification on the Election Statement

- Non-covered items added to addendum after the initial admission does that impact the election statement?
- The notation to the hospice on the addendum (The parenthesized statement after the check box where the patient chooses to receive a Patient Notification of Hospice Non-Covered Items) states it has to be provided with the Election Statement, yet a copy of the Election Statement is frequently left with the patient after signing the form and the hospice has up to 5 more days to provide the Patient Notification of Hospice Non-Covered Items. We believe that these two documents, while presented initially together, should not be linked related to delivery. The addendum requires discussion by the IDG and final determination by the hospice physician.
- If the patient requests the Patient Notification of Hospice Non-Covered Items later in their stay, is there a different form to sign?

Recommendations for Election Statement Changes by Section

In the recommendations that follow, the underlined text is a NHPCO recommendation for a wording change. This information can also be found in Appendix A.

A. Top of Form

• Name of Hospice

CFR § 418.24(b)(1) requires the "Identification of the particular hospice and of the attending physician that will provide care to the individual." There should be a space for the name of the hospice at the top of the form. If a hospice uses this

example, they will no longer be compliant with this Medicare requirement and their form could be judged out of compliance.

• Name of Patient

The patient's name should also be at the top of the form for identification.

NHPCO Recommendation: Both the name of the hospice and the name of the patient should be included in the Hospice Election Statement Example posted on the CMS website for providers to use.

B. Effects of a Medicare Hospice Election

• A bulleted list will make this section more readable and understandable.

NHPCO Recommendation: NHPCO recommends the following changes to this section, as shown in Appendix A:

- Add bullets to the various acknowledgements for additional clarity.
- Change the verb tense of some statements so that the same tense is used with all five bullets.

C. <u>Hospice Coverage and Right to Request "Patient Notification of Hospice Non-</u> <u>Covered Items, Services and Drugs", also known as the "addendum"</u>

• List of provisions

NHPCO Recommendation: NHPCO believes that a bulleted list, similar to the list in the previous section, will make this section more readable and understandable to the patient and their representative.

• **Copayments:** Most hospices do not use the copayments for drugs and inpatient respite care, as it is optional. Providers should share their policy and whether there is any financial responsibility to the patient.

NHPCO Recommendation: NHPCO recommends that the words "the option for charges for" be added at the beginning of the sentence and the words "and my financial responsibility, if applicable" be added to the end of the sentence so that it reads:

"I acknowledge that I have been provided with information about <u>the</u> <u>option for charges for</u> certain hospice services (drug copayment and inpatient respite care), <u>and my financial responsibility, if applicable</u>."

• Elect/Decline Checkboxes with Initials and Dates: The patient or their representative has received information about the addendum in the bullets above. There is no requirement for initials and a date and inclusion could be confusing and easily overlooked by the patient and their representative during a very stressful time.

NHPCO Recommendation: NHPCO recommends the deletion of these checkboxes, initials and dates on the sample form.

• **Timeframes for hospice:** No timeframe is indicated on the form so that the patient or representative understands when the hospice must provide the "Patient Notification of Hospice Non-Covered Items" form. We suggest adding the time frame to the Election Form to increase clarity.

NHPCO Recommendation: In the guidance for the hospice under the "I elect to receive the "Patient Notification of Hospice Non-Covered Items, Services and Drugs" box, NHPCO recommends the following change in language, as underlined:

"(**Hospice:** Please provide the beneficiary/<u>representative</u> with the addendum <u>within 5 days if requested when the election statement is</u> signed. **Hospice:** Please provide the addendum within 72 hours if requested at any time during the course of care.)

• Unlink election statement and addendum timeframes: Decisions about relatedness are completed by the physician after receiving and reviewing clinical information from the registered nurse's assessment of the patient. The hospice will not be able to provide both the signed election statement and the addendum at the same time, and we believe that there will be confusion about the requirement that they be provided together.

NHPCO Recommendation: NHPCO recommends that the sentence "Must be signed and dated accompanying the election statement" be deleted from this section.

D. Right to choose an attending physician

• Identifying the attending physician: During the admission process, the patient can choose any physician to serve as the attending physician, but unless that doctor is available and agrees to be the attending physician, then the hospice may not act on that choice. In § 418.52(c)(4), the patient has the right to choose his or her attending physician. The Interpretive Guidelines (L-515) make that more

specific: "Patients have the right to choose their attending physician and to have this person involved in their medical care in all hospice settings as long as the attending physician, in turn, undertakes to provide care for the patient."

NHPCO Recommendation: NHPCO recommends that a phrase be added to the second sentence in this section to clarify that the attending physician must be available and agree to serve in this role. We recommend that the section now read:

"I understand that I have a right to choose my attending physician to oversee my care. If s/he is available and agrees to serve in this role, my attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions.

____ I do not wish to choose an attending physician <u>and understand the</u> <u>hospice's physicians will manage my medical care related to my</u> <u>terminal illness and related conditions.</u>

_____I choose _______ as my attending physician. If my chosen attending physician declines to serve in that role, I understand that the hospice's physicians will manage my medical care related to my terminal illness and related conditions unless I choose a different attending physician.

• **Physician identifier:** Hospice providers report wide variance in how much information the patient or their representative may have about the physician they are naming to be their attending physician. A request to provide any information that would be unique to the attending physician being named would be helpful guidance to patients and representatives.

NHPCO Recommendation: After the check box that acknowledges the choice of an attending physician, NHPCO recommends that additional guidance on identifying physician information be added. We recommend that the check box now read:

□ I acknowledge that my choice for an attending physician is (<u>Please</u> provide any information that will uniquely identify your attending physician choice):

E. Acknowledgement

• NHPCO believes that some hospices who admit patients from the hospital or other settings with an uncertain discharge date may overlook going back to the form and filling in the effective date of election. The addition of the specification of a future date could reduce the potential for election date confusion and denials.

NHPCO Recommendation: NHPCO recommends a change in the acknowledgement language to read as follows:

I acknowledge and understand the above, and authorize Medicare hospice coverage to be provided by the hospice agency identified above to begin on the date I sign this election statement, or if specified, a future date of _____.

• NHPCO also believes an adjustment to the language in the acknowledgement section will make this section clearer to the patient and their representative. NHPCO recommends that the language "start of care date" be added before the "effective date of the election" to make the timeframe of the form more understandable to the patient or representative.

NHPCO Recommendation: "The <u>start of care date, also known as the</u> effective date of the election, may be the first day of hospice care or a later date but may be no earlier than the date of the election statement <u>as indicated</u> <u>above</u>. An individual may not designate an effective date that is retroactive."

F. Relationship of Representative to Patient

It is important to document that only an individual that has legal authority may sign. This follows the definition of "representative" in § 418.3.

NHPCO Recommendation: NHPCO recommends that a space be made available under the signature of the "representative" that states: "<u>Representative's Legal Authority (e.g. health care power of attorney or guardian"</u>

G. <u>Witness</u>

There is no legal requirement which requires that the form be witnessed.

NHPCO Recommendation: NHPCO recommends that the requirement for a witness be deleted.

2. <u>Comments on Patient Notification of Hospice Non-Covered Items, Services, and Drugs</u> (Addendum)

The following are detailed recommendations on changes to the Patient Notification of Hospice-Non-Covered Items, Services, and Drugs. The changes can also be found in a table in Appendix A.

General Comments regarding Addendum

In the FY 2020 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements final rule, CMS noted reasons for the Notice of Election Addendum, one of which is to reduce the number of improper payments provided by nonhospice providers for supplies, services and specifically pharmaceuticals which CMS has stated should be covered under the Hospice benefit. The addendum provides a record of the hospice provider's decision on diagnoses, supplies, items, services and drugs unrelated to the hospice diagnosis, however, this information is only shared upon request. It is unclear how CMS intends to use information for program oversight when it is voluntary, not issued for every patient and not shared unless a record is pulled.

NHPCO has worked with the National Council for Prescription Drug Plans (NCPDP) since 2013 to consider options for the timely notification of the Part D plan when an enrollee elects hospice. A new process, using a transaction facilitator, has been proposed to Part D which could drastically reduce the number of days for Part D notification of the hospice election. NHPCO believes that this new process is an important first step in reducing the number of drugs paid by Part D in error when the hospice is responsible, but the Part D plan is unaware of the hospice election. This new process joins the Notice of Election and the new addendum as methods for alerting other Medicare providers of the patient's hospice election.

NHPCO Recommendation: We request additional details regarding CMS' intent to use the addendum to reduce inappropriate spending when the document is not available unless it is requested.

A. <u>Date of Request/Hospice Agency/Patient Name/Medical Record Number</u>

• **Date of request** is not required.

NHPCO Recommendation: NHPCO recommends removal from the model form.

• **Hospice agency:** The description under **Hospice Agency** gives the timeframe requirements for furnishing the form. The descriptive language says "at the time of election" but the term used in § 418.24(b)(4) is "effective date of the

election." The date someone signs an election could be different than the effective date. The effective date is going to trigger the assessment timelines, so the words "election effective date" should be used, as underlined.

NHPCO Recommendation: The description should read as follows:

(Hospice must furnish this addendum within 5 days <u>of the election effective</u> <u>date</u> if requested at the time of hospice election and within 72 hours if requested during the course of care.)

B. Diagnoses related to Terminal Illness and Related Conditions

The instructions in parentheses is not a requirement and should be deleted.

Current language reads: Diagnoses Related to Terminal Illness and Related Conditions (hospice is responsible to cover all items, services and drugs):

NHPCO Recommendation:

NHPCO recommends that some of the language above be deleted as follows: Diagnoses Related to Terminal Illness and Related Conditions (hospice is responsible to cover all items, services and drugs) be removed.

C. <u>Noncovered Items, services and drugs determined by hospice as not related to my</u> <u>terminal illness and related conditions</u>

• In this section, the hospice will be completing the list of items/services/drugs that are determined by the hospice to not be related to the patient's terminal illness or related conditions and the reasons for non-coverage. NHPCO recommends clarifying language to make in consistent with the language "unrelated" in this section.

Current language reads: Non-covered items, services, and drugs determined by hospice as not related to my terminal illness and related conditions:

NHPCO Recommendation: NHPCO recommends that the current language above be amended as follows:

Non-covered items, services, and drugs determined by the hospice <u>to be</u> <u>unrelated</u> as not related to my terminal illness and related conditions:

• NHPCO believes that the "Note" section under the table could be more explanatory for patients, representatives and families reading this addendum.

Current language reads: Note: The hospice makes the decision as to whether or not conditions, items, services, and drugs are related for each beneficiary. This addendum should be shared with other healthcare providers from which you seek

items, services, or drugs, unrelated to your terminal illness and related conditions to assist in making treatment decisions.

NHPCO Recommendation: NHPCO recommends that the "Note" section be amended as follows:

Note: The hospice makes the decision as to whether or not conditions, items, services and drugs are related for each beneficiary patient. This addendum should be shared with As the patient or representative, you should share this clinical explanation with other healthcare providers from which you seek items, services or drugs unrelated to your terminal illness and related conditions to assist in making treatment decisions.

D. <u>Right to Immediate Advocacy</u>

- NHPCO recognizes CMS's rationale for the availability of immediate advocacy through the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) if the beneficiary (or representative) disagrees with the hospice's determination. The regulation does not use the word "appeal" and NHPCO is unclear about what this advocacy process will entail and whether it is legally correct to characterize it as an appeal.
- NHPCO also requests the BFCC-QIO advocacy process be spelled out in advance of the election addendum implementation for hospice providers and beneficiaries/representatives. We also request that education about hospice care be provided to the BFCC-QIOs in advance of the election addendum implementation to ensure competency to related to decision making.
- NHPCO believes that edits to the language in this section will make the section more understandable to the patient and/or their representative.

Current language: As a Medicare beneficiary you have the right to appeal the decision of the hospice agency on items not be covered because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. You have the right to contact the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) for immediate assistance.

NHPCO recommendation: NHPCO recommends that the language in the "Right to Immediate Advocacy" section of the addendum be clarified as follows, as underlined below:

As a Medicare beneficiary, You have the right to <u>immediate advocacy</u> through the Medicare Beneficiary and Family Centered Care – Quality Improvement Organization (BFCC-QIO) if you or your representative disagree with the hospice's determination that an item, service, or drug is <u>unrelated to your</u> appeal the decision of the hospice agency on items not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. You have the right to contact the Medicare Beneficiary and Family Centered Care Quality Improvement Organization (BFCC-QIO) for immediate assistance.

E. <u>Acknowledgement of non-covered items, services and drugs not related to my</u> <u>terminal illness and related conditions</u>

• Bulleted list:

NHPCO Recommendation: NHPCO believes that a bulleted list, similar to the lists in the election statement, will make this section more readable and understandable.

• **Signature requirement:** NHPCO has heard from providers about the signature requirement for the addendum, particularly a concern that the patient or representative will believe that by signing the addendum, it will signal that they agree with its details. In addition, what recourse does the hospice have if the patient/representative does not sign the addendum? NHPCO is recommending additional clarity on the policy and in the wording for this requirement.

NHPCO Recommendations:

- 1. The first bullet is not required and NHPCO recommends its deletion.
- 2. NHPCO recommends additional clarity in the language for the signature requirements to read as follows:
 - Signing this addendum (or its updates) is only <u>an</u> acknowledgement of receipt of the addendum (or its updates).
 - <u>Signing this addendum does not necessarily indicate</u> and not necessarily agreement with the hospice's determinations.

F. Signature of Beneficiary/Representative

It is important to document that only an individual that has legal authority may sign. This follows the definition of "representative" in § 418.3.

NHPCO Recommendation: Add a line under "representative" for the legal authority of the representative to the patient.

G. <u>Witness</u>

There is no legal requirement which requires that the form is witnessed.

NHPCO Recommendation: Eliminate the line and requirement for a witness.

F. Other Issues

1. Utilization of the Addendum and Advance Beneficiary Notice (ABN)

NHPCO recently asked the CMS Medicare Enrollment Appeals Group about utilization of an ABN in hospice care and the relationship between the ABN and the new election addendum statement. We received the following response:

"If the item or service is denied by the hospice physician as not medically reasonable and necessary related to the terminal illness and related conditions and will not be included in the hospice plan of care, the ABN is issued to transfer financial liability to the beneficiary/representative. Given this information, it is our understanding that the election addendum is used for an item or service that is determined by the hospice physician as unrelated to the terminal illness and related conditions and that the addendum and the ABN serve two different functions."

NHPCO Recommendation: NHPCO recommends that in the preamble or explanatory language in the final rule, CMS clearly delineate the differences between the election statement addendum and the Advance Beneficiary Notice (ABN) and provide guidance on when each document will be used.

2. <u>Electronic Format for Election Statement and Addendum</u>

Hospice providers have moved to electronic platforms for many functions. We anticipate that both the election statement and the addendum will be in electronic format, assisting the hospice with fields in the EMR and allowing standardization and electronic exchange of some data elements. NHPCO is hopeful that, if the election statement in particular is in an electronic format, the electronic exchange of same data elements from the election statement can be used to provide hospice election information to Part D plans more timely.

NHPCO Recommendation: NHPCO recommends that an electronic format for both the election statement and the addendum should be encouraged. NHPCO is also hopeful that data elements from the election statement can be used to increase timeliness in communicating hospice election information with Part D plans.

3. <u>Electronic Signatures</u>

NHPCO agrees with CMS in their recognition that electronic signatures can be used by beneficiaries to sign the election statement and election statement addendum. Further, we understand that the use of electronic signature platforms like, but not limited to, DocuSign should be recognized by the MACs and permitted for use by beneficiaries and their representatives. NHPCO has researched this issue and know that some hospices may obtain (or may want to obtain) electronic signatures from beneficiaries using a wide variety of applications and platforms, some of which may not have the same authenticating elements and security properties as DocuSign.

While there are no electronic signature regulations, in sub-regulatory guidance CMS has discussed electronic signatures in the context of medical review of *provider* signatures. In both the Medicare Program Integrity Manual (Ch. 3, § 3.3.2.4) and in the May 2018 MLN Fact Sheet "<u>Complying with Medicare Signature Requirements</u>," CMS has described several guidelines for using electronic signatures. These guidelines focus largely on *authentication* of electronic signatures and include the following excerpts from the MLN Fact Sheet:

- "Systems and software products must include protections against modification, and you should apply administrative safeguards that correspond to standards and laws."
- "The individual whose name is on the [electronic] signature method and the provider bear the responsibility for the authenticity of the attested information."

NHPCO requests guidance from CMS regarding electronic signature standards specifically for beneficiary and/or representative signatures. Such guidance would confirm the requirement for an electronic signature platform to authenticate the signature and secure the underlying patient information. With CMS guidance, the Medicare Administrative Contractors would have a standardized approach to accepting electronic signatures.

NHPCO Recommendation: NHPCO urges CMS to consider issuing additional guidance for the hospice community and for Medicare contractors on patient/representative electronic signatures. Included in such guidance should be some requirement to be able to print an electronically signed document to provide a hard copy to a patient or their representative. While the Medicare contractors should all be able to "address patient/representative electronic signatures in their review of medical records," NHPCO believes that it does not make sense to have differing guidance from each MAC on what would be acceptable for medical record review.

4. The Hospice Addendum as a Condition of Payment

NHPCO strongly disagrees with CMS's decision to proceed with implementing the requirements related to the election statement addendum for hospice elections beginning on or after October 1, 2020. Not only is the addendum redundant to existing obligations which hospices have with regard to informing patients about the services covered under the hospice benefit, but there is no basis for the addendum to be treated as a condition of payment for hospice services. The Social Security Act only authorizes CMS's conditioning of payment on a patient's having made "an election . . . to receive hospice care". The addendum, which is provided after the patient's election, cannot and should not legally alter the patient's election or, as is suggested, make it retroactively invalid for purposes of payment. The fact that CMS has chosen to title the document an "addendum" to the election does not overcome the plain language limitations on the requirements that can be considered conditions of coverage in Sections 1814(a)(7) and 1812(d)(1) of the Social Security Act and in 42 C.F.R. § 418.200.

If CMS proceeds with its treatment of the addendum as a condition of payment, NHPCO cautions CMS that even single "errors" in the addendum or an unreturned addendum will give rise to non-payment of hospice services for what CMS implies could be the patient's entire election period. These errors are not material to the payment for services hospices provide to clinically eligible patients who have unquestionably exercised their right to elect to receive hospice care.

Thank you for your consideration of NHPCO's comments on this proposed rule and recommendations for changes to the election statement and addendum forms. We welcome continued engagement with you and your staff and the opportunity to meet to discuss our recommendations. If you have questions, please contact Judi Lund Person, Vice President, Regulatory and Compliance at jlundperson@nhpco.org.

Sincerely,

Edo Banach, JD President and CEO

Appendix A

Hospice Election Statement Model Form NHPCO Recommendations – June 9, 2020

Note: Throughout these charts, <u>underlined</u> or strikethrough words in the middle column are changes recommended by NHPCO

Existing Election Statement Model Form	NHPCO Recommendations	NHPCO Rationale
	Top of Form	
	Name of hospice and name of patient	 CFR §418.24(b)(1) requires the "Identification of the particular hospice and of the attending physician that will provide care to the individual." There should be a space for the name of the hospice at the top of the form. If a hospice uses this example, they will no longer be compliant with this Medicare requirement and their form could be judged out of compliance.
	Effects of a Medicare Hospice Election	
I understand that by electing hospice care under the Medicare Hospice Benefit, I am acknowledging that I understand the palliative rather than curative nature of hospice care, as it relates to my terminal illness and related conditions. I understand that by electing hospice care under the Medicare Hospice Benefit, I am waiving (give up) all rights to Medicare payments for services related to my terminal illness and related conditions and I understand that while this election is in force, Medicare will make payments for care related to my terminal illness and related conditions only to the designated hospice and attending physician that I have selected. I understand that services not related to my terminal illness or related conditions will continue to be eligible for coverage by Medicare; however, I also understand that services unrelated to my terminal illness and related conditions are exceptional and unusual and hospice should cover all care related to my terminal illness and related conditions needed under the hospice election.	 I understand that by electing hospice care under the Medicare Hospice Benefit: I <u>acknowledge</u> that I understand the palliative rather than curative nature of hospice care, as it relates to my terminal illness and related conditions. I understand that by electing hospice care under the Medicare Hospice Benefit: I <u>waive</u> (give up) all rights to Medicare payments for services related to my terminal illness and related conditions; I understand that while this election is in force, Medicare will make payments for care related to my terminal illness and related conditions; I understand that services not related to my terminal illness or related. I understand that services not related to my terminal illness or related. I understand that services not related to my terminal illness or related to my terminal illness orelated to my terminal illness	 A bulleted list will make this section more readable and understandable. Verb tense was changed to accommodate bullets

Existing Election Statement Model Form	NHPCO Recommendations	NHPCO Rationale
	exceptional and unusual and <u>that</u> hospice should cover all care. needed	
Hospice Coverage and Right to Req	uest "Patient Notification of Hospice Non-C	Covered Items, Services, and Drugs"
I acknowledge that I have been provided with information about my financial responsibility for certain hospice services (drug copayment and inpatient respite care). I understand that I have the right to request at any time, in writing, the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" addendum that lists the items, services, and drugs that the hospice has determined to be unrelated to my terminal illness and related conditions that would not be covered by the hospice. I acknowledge that I have been provided information regarding the provision of Immediate Advocacy through the Beneficiary and Family-Centered Care Quality Organization (BFCC-QIO) if I disagree with any of the hospice's determinations and I have been provided with the contact information for the BFCC- QIO that services my area.	 I acknowledge that I have been provided with information about the option for charges for certain hospice services (drug copayment and inpatient respite care), and my financial responsibility, if applicable. I understand that I have the right to request at any time, in writing, the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" addendum that lists the items, services, and drugs that the hospice has determined to be unrelated to my terminal illness and related conditions that would not be covered by the hospice. I acknowledge that I have been provided information regarding the provision of Immediate Advocacy through the Beneficiary and Family-Centered Care Quality Organization (BFCC-QIO) if I disagree with any of the hospice's determinations and I have been provided with the contact information for the BFCC-QIO that services my area. 	 A bulleted list, similar to the list in the previous section, will make this section more readable and understandable to the patient and their representative. Copayments: Most hospices do not use the copayments for drugs and inpatient respite care, as it is optional. Providers should share their policy and whether there is any financial responsibility to the patient.
□ I elect to receive the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" Initials Date	☐ I elect to receive the "Patient Notification of Hospice Non-Covered Itoms, Services, and Drugs" InitialsDate	• Elect/Decline Checkboxes with Initials and Dates: The patient or their representative has received information about the addendum in the bullets above. There is no requirement for initials and a date, but
□ I decline to receive the "Patient Notification of Hospice Non-Covered Items, Services, and Drugs" Initials Date	H decline to receive the "Patient Notification of Hospice Non-Covered Itoms, Services, and Drugs" InitialsDate	rather a requirement to document in the medical record. The inclusion of this requirement is overly burdensome and could be confusing to the patient and their representative during a very stressful time.
(Hospice : Please provide the beneficiary with the addendum. Must be signed and dated accompanying the election statement.)	(Hospice : Please provide the beneficiary/ <u>representative</u> with the addendum Must be signed and dated accompanying the election statement within <u>5 days if requested when the</u> election statement is signed or within 72	Timeframes for hospice: No timeframe is indicated on the form so that the patient or representative understands when the hospice must provide the "Patient Notification of Hospice Non-Covered Items" form.

Existing Election Statement Model Form	NHPCO Recommendations	NHPCO Rationale
	hours if the addendum is requested at any time during the course of care.	We suggest adding the time frame to the Election Form to increase clarity.
		• Unlink election statement and addendum timeframes: Decisions about relatedness are completed by the physician after receiving and reviewing clinical information from the registered nurse's assessment of the patient. The hospice will not be able to provide both the signed election statement and the addendum at the same time, and we believe that there will be confusion about the requirement that they be provided together.
Righ	nt to choose an attending physician	
I understand that I have a right to choose my attending physician to oversee my care. My attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions. I do not wish to choose an attending physician I acknowledge that my choice for an attending physician is:	I understand that I have a right to choose my attending physician to oversee my care. If s/he is available and agrees to serve in this role, my attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions. I do not wish to choose an attending physician <u>and understand that the hospice's physicians will manage my medical care related to my terminal illness and related conditions.</u> I acknowledge that my choice for attending physician is choose <u></u> as my attending physician declines to serve in that role, I understand that the hospice's physicians will manage my medical care related to my terminal illness and related conditions <u>unless I choose a different attending</u> physician (Please provide any information that will uniquely identify your attending physician choice):	 Identifying the attending physician: During the admission process, the patient can choose any physician to serve as the attending physician, but unless that doctor is available and agrees to be the attending physician, then the hospice may not act on that choice. In § 418.52(c)(4), the patient has the right to choose his or her attending physician. The Interpretive Guidelines (L-515) make that more specific: "Patients have the right to choose their attending physician and to have this person involved in their medical care in all hospice settings as long as the attending physician, in turn, undertakes to provide care for the patient."
Physician Full name: NPI (if known) Office Address:	Physician Full Name: NPI (if known)	 Physician identifier: Hospice providers report wide variance in how much information the patient or their representative may have about the

Existing Election Statement Model Form	NHPCO Recommendations	NHPCO Rationale
	Office Address <u>(if known)</u> :	physician they are naming to be their attending physician. A request to provide any information that would be unique to the attending physician being named would be helpful guidance to patients and representatives.
I acknowledge and understand the above, and authorize Medicare hospice coverage to be provided by (Hospice Agency) to begin on (Effective Date of Election)	I acknowledge and understand the above and authorize Medicare hospice coverage to be provided <u>by the hospice agency</u> <u>identified above</u> to begin on <u>the date I sign</u> <u>this election statement, or if specified, a</u> <u>future date of</u> <u>(Effective Date of Election)</u>	• NHPCO believes that some hospices who admit patients from the hospital or other setting with an uncertain discharge date may overlook going back to the form and filling in the effective date of election The addition of the specification of a future date could reduce the potential for election date confusion and denials.
Note: The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement. An individual may not designate an effective date that is retroactive.	Note: The <u>start of care date</u> , <u>also known as</u> the effective date of the election, which may be the first day of hospice care or a later date but may be no earlier than the date of the election statement, <u>as indicated</u> <u>above</u> . An individual may not designate an effective date that is retroactive.	• NHPCO believes an adjustment to the language in the acknowledgement section will make this section clearer to the patient and their representative. NHPCO recommends that the language "start of care date" be added before the "effective date of the election" to make the timeframe of the form more understandable to the patient or representative.
Signature of Beneficiary/Representative (Date Signed)	Signature of Beneficiary/Representative (Date Signed)	
□ Beneficiary is unable to sign -Reason:	Representative's Legal Authority (e.g. <u>health care power of attorney or</u> guardian:	• Add a line for the representative's legal authority. It is important to document that only an individual that has legal authority may sign. This follows the definition of "representative" in § 418.3.
	■ Beneficiary is unable to sign — Reason:	• It is important to document the legal authority for the representative to sign, not the reason the beneficiary is unable to sign.
Witness signature (Date Signed)	Witness signature (Date Signed)	 <u>Witness</u> There is no legal requirement which requires that the form be witnessed.

Patient Notification of Hospice Non-Covered Items, Services, and Drugs Example

NHPCO Recommendations

June 9, 2020

Note: Throughout these charts, underlined or strikethrough words in the middle column are changes recommended by NHPCO

Patient Notification of Hospice Non-Covered Items, Services, and Drugs Example	NHPCO Recommendations	Rationale
Date of Request:	Date of request	This is not required.
Hospice Agency (Hospice must furnish this addendum within 5 days if requested at the time of hospice election and within 72 hours if requested during the course of care.	Hospice Agency (Hospice must furnish this addendum within 5 days of the election effective date if requested at the time of hospice election and within 72 hours if requested during the course of care	The addendum section says "at the time of election" but the term used in § 418.24(b)(4) is "effective date of the election". The date someone signs the election could be different than the effective date. The effective date is going to trigger the assessment timelines, so election effective date should be used.
Patient Name		No change
Medical Record Number		No change
Diagnoses Related to Terminal Illness and Related Conditions		
(hospice is responsible to cover all items, services and drugs):1.4.2.5.3.6.	(hospice is responsible to cover all items, services and drugs):-1.4.2.5.3.6.	This is not a requirement.
Diagnoses U	Inrelated to Terminal Illness and Related Cor	nditions
Diagnoses Unrelated to Terminal Illness and Related Conditions: 1. 4. 2. 5. 3. 6. Non-covered items, services, and drugs determined by hospice as not related to my terminal illness and related conditions: Items/Services/ Drugs Reason for Non- coverage	Diagnoses Unrelated to Terminal Illness and Related Conditions: 1. 4. 2. 5. 3. 6. Non-covered items, services, and drugs determined by hospice to be unrelated as not related to my terminal illness and related conditions: Items/Services/ Drugs Reason for Non-coverage	NHPCO recommends this change to make it consistent with the language "unrelated" above.

Patient Notification of Hospice Non-Covered Items, Services, and Drugs Example	NHPCO Recommendations	Rationale
Note: The hospice makes the decision as to whether or not conditions, items, services, and drugs are related for each beneficiary. This addendum should be shared with other healthcare providers from which you seek items, services, or drugs, unrelated to your terminal illness and related conditions to assist in making treatment decisions.	Note: The hospice makes the decision as to whether or not conditions, items, services, and drugs are related for each <u>patient</u> . This <u>addendum should be shared with</u> As the <u>patient or representative</u> , you should share this clinical explanation with other healthcare providers from which you seek items, services, or drugs, unrelated to your terminal illness and related conditions to assist in making treatment decisions.	• The additions to the "Note" section will provide additional clarity and will help patients and families understand this form and its purpose.
	Right to Immediate Advocacy	
Right to Immediate Advocacy As a Medicare beneficiary you have the right to appeal the decision of the hospice agency on items not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. You have the right to contact the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) for immediate assistance. Visit this website to find the BFCC-QIO for your area. https://qioprogram.org/contact- zones or call 1-800-MEDICARE (1-800- 633-4227). TTY users can call 1-877-486- 2048.	Right to Immediate Advocacy As a Medicare beneficiary, You have the right to immediate advocacy through the Medicare Beneficiary and Family Centered Care – Quality Improvement Organization (BFCC-QIO) if you or your representative disagree with the hospice's determination that an item, service, or drug is unrelated to your appeal the decision of the hospice agency on items not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. You have the right to contact the Medicare Beneficiary and Family Centered Care-Quality Improvement Organization (BFCC-QIO) for immediate assistance.	The regulation does not use the word "appeal" and NHPCO is unclear about what this advocacy process will entail and whether it is legally correct to characterize it as an appeal. NHPCO also requests the BFCC-QIO advocacy process be spelled out in advance of the election addendum implementation for hospice providers and for beneficiaries/representatives. We also request that education about hospice care be provided to the BFCC-QIOs in advance of the election addendum implementation to ensure competency related to immediate advocacy decision making.
	dgement of non-covered items, services or o	lrugs
The purpose of this addendum is to notify beneficiary (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. I acknowledge that I have been given a full explanation and have an understanding of the list of items, services and drugs not related to my	 The purpose of this addendum is to notify beneficiary (or representative), in writing, of those conditions, items, services, and drugs the hospice will not be covering because the hospice has determined they are unrelated to the individual's terminal illness and related conditions. I acknowledge that I have been given a full explanation and have an understanding of the list of items, 	 Bulleted list for patient/representative ease of understanding The first bullet "I acknowledge that I have been given a full explanation and have an understanding of the list of items, services and drugs not related to my terminal illness and related conditions not being covered by

Patient Notification of Hospice Non-Covered Items, Services, and Drugs Example	NHPCO Recommendations	Rationale
terminal illness and related conditions not being covered by hospice. Signing this addendum (or its's updates) is only acknowledgement of receipt of the addendum (or its updates) and not necessarily agreement with the hospice's determinations.	 services and drugs not related to my terminal illness and related conditions not being covered by hospice. Signing this addendum (or its updates) is only an acknowledgement of receipt of the addendum (or its updates). Signing this addendum does not necessarily indicate agreement with the hospice's determinations. 	 hospice" is not required. NHPCO recommends that it be removed. There is a concern that the patient or representative will believe that by signing the addendum, it will signal that they agree with its details. What recourse does the hospice have if the patient/representative does not sign the addendum?
Signature of Beneficiary/Representative (Date Signed)	Signature of Beneficiary/Representative (Date Signed)	No change
□ Beneficiary is unable to sign -Reason:	Representative's Legal Authority (e.g. health care power of attorney or guardian) Beneficiary is unable to sign - Reason:	• Add a signature line for the representative's legal authority. It is important to document that only an individual that has legal authority may sign. This follows the definition of "representative" in § 418.3.
 Witness signature (Date Signed)	Witness signature (Date Signed)	• Witness There is no legal requirement which requires that the form is witnessed, and NHPCO recommends this be eliminated.