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July 1, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1609-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1609-P – Medicare Program; FY 2015 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements and Process and Appeals for Part D Payment for Drugs for Beneficiaries Enrolled in Hospice
79 Fed. Reg. 26538 (May 8, 2014)

Dear Administrator Tavenner:

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN appreciates the opportunity to comment on the fiscal year (FY) 2015 hospice wage index and other policies. Overall, ACS CAN supports CMS' proposed policies, which are discussed in greater detail below, and we offer some recommendations for further enhancing the policies.

A. Hospice Payment Reform: Research and Analysis

In the preamble, CMS expressed concern that some Medicare beneficiaries are not provided with hospice care and support at the very end of life. According to CMS data, approximately 6.2 percent of beneficiaries received no skilled visits during the last four days of life. CMS noted that more than a fifth of hospices do not provide any general inpatient care, which may be an indication that these hospice beneficiaries do not have access to an appropriate level of care for acute or chronic system management (e.g., pain control that may not be able to be achieved in other non-inpatient settings). CMS notes that it will continue to monitor hospice benefit use and utilization patterns.

ACS CAN shares CMS' concern that some Medicare beneficiaries who elect hospice may not receive all of the care they need. We are particularly concerned with reports demonstrating that a statistically significant number of beneficiaries fail to receive any care within the last four days of life. We appreciate CMS' attention to this vitally important matter and urge the agency to continue vigilant

monitoring, and where necessary, work with particular hospice organizations to determine that proper care is being provided to beneficiaries who elect hospice.

E. Proposed Timeframes for Filing the notice of Election and Notice of Termination/Revocation

The proposed rule notes CMS' intent to safeguard beneficiaries from inappropriate financial liability for care that should be provided by a hospice. CMS proposes that a hospice must file a beneficiary's Notice of Election (NOE) to the Medicare Administrative Contractor (MAC) within three calendar days after the beneficiary elects to enter the hospice program. CMS further clarifies that if a hospice fails to timely file the NOE, the hospice would bear the financial responsibility for the delay in timely notification to CMS. The proposed rule makes clear that such financial responsibility would fall to the hospice and the beneficiary could not be billed for the cost of care during for these days. Similarly, CMS proposes to require hospices to file a notice of termination or revocation (NOTR) within three calendar days after a beneficiary's discharge from a hospice to help ensure the beneficiary can access non-hospice care.

ACS CAN supports CMS' proposal and appreciates the agency's intention to protect Medicare beneficiaries from inappropriate financial liability that could occur when a beneficiary's hospice election is untimely recorded. We urge CMS to work with hospice organizations to ensure that a beneficiary's NOE or NOTR is filed with CMS prior to the three calendar day requirement. CMS should make clear to hospice organizations they should not wait until the third day to file, but rather should, as a matter of practice, file a beneficiary's NOE or NOTR as soon as possible well within the three day requirement.

In addition, we urge CMS to clarify that hospices who fail to file a timely NOTR also should bear the financial responsibility for the delay in timely notification to CMS. For example, untimely filing of an NOTR could impede a beneficiary's ability to access prescription drugs through the Medicare Part D program. As CMS is already proposing to require hospices to file an NOTR within three calendar days, clarifying that a hospice would bear financial responsibility for untimely filing would simply add additional encouragement to file timely.

F. Proposed Addition of the Attending Physician to the Hospice Election Form

The statute defines a Medicare hospice beneficiary's attending physician as a physician or nurse practitioner as "having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care." Section 1861(dd)(3)(b) of the Social Security Act. Citing reports of hospices changing the beneficiary's attending physician when the patient moves to an inpatient setting for inpatient care, the proposed rule reiterates that the beneficiary (or her representative) – and not the hospice – chooses the beneficiary's attending physician. In addition, CMS notes that some hospices fail to obtain the signature of the attending physician on the initial certification. CMS proposes to require the hospice election statement to include the beneficiary's choice of attending physician, including an acknowledgement by the beneficiary (or her representative) that the attending physician was chosen by the beneficiary (or her representative). Beneficiaries who wish to change attending physicians would have to follow a procedure similar to that for changing the designated hospice (e.g., the beneficiary (or her representative) would be required to file a signed statement acknowledging the change is the beneficiary's choice).

ACS CAN appreciates CMS' clarification. Medicare beneficiaries trust the advice and counsel provided by the physician they choose. We are concerned that if a hospice were permitted to change the attending physician designation – particularly in instances when a patient moves to an inpatient setting for inpatient care – this not only discounts the beneficiary's wishes but could also result in care that is not properly coordinated between the hospice and the beneficiary's choice of attending physician.

H. Proposed Updates to the Hospice Quality Reporting Program

6. Proposed Adoption of the CAHPS® Hospice Survey for the FY 2017 Payment Determination

In its FY 2014 Hospice Wage Index final rule, CMS noted that it would impose a national implementation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey beginning January 1, 2015. Initially the survey will be available in English and Spanish, though CMS notes it will provide additional translations of the survey over time. CMS identified a number of groups of individuals ineligible to participate in the survey, including: primary caregivers of patients who died within 48 hours of admission to hospice care and patients or caregivers of patients who requested they not be contacted (e.g., sign a "no publicity" requests while under the care of the hospice or otherwise directly request not to be contacted).

ASC CAN supports CMS' proposal to include a beneficiary survey as part of the quality reporting measures for FY 2017. Patient experience can be one of the most valuable measures to determine the quality of care provided by the hospice. However, we are concerned that CMS proposes to exclude primary caregivers of patients who die within 48 hours of admission to hospice care. More than 10 percent of cancer patients are admitted to hospice during the last three days of their life.[1] Obtaining information from the beneficiary's personal representative can be informative with respect to the overall quality of care provided at an individual hospice.

I. Solicitation of Comments on Coordination of Benefits Process and Appeals for Part D Payment for Drugs While Beneficiaries Are Under a Hospice Election

Citing an HHS Office of Inspector General (OIG) analysis[2] indicating that the Medicare hospice program sometimes pays for drugs covered under the Part D benefit, in March 2014, CMS released final guidance requiring that Part D plans place prior authorization (PA) requirements on all drugs for beneficiaries who have elected hospice to determine whether the drug is covered under Part D.[3] While we appreciate CMS' desire to provide additional clarity with respect to whether a drug should be covered under the hospice or Part D program, we are concerned the current guidance creates the potential for an undue burden on beneficiaries' access to necessary medications. We urge CMS to rescind the current guidance

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[1] Goodman, D. C., Morden, N. E., Chang, C. H., Fisher, E. S., & Wennberg, J. E. (2013). Trends in cancer care near the end of life. *A Dartmouth Atlas of Health Care Brief*.

[2] Department of Health and Human Services, Office of the Inspector General, "Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice" (A-06-10-00059) June 28, 2012, available at https://oig.hhs.gov/oas/reports/region6/61000059.pdf.

[3] CMS, Center for Medicare, Memorandum to All Part D Sponsors and Medicare Hospice Providers, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Final 2014 Guidance" (Mar. 10, 2014), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Part-D-Payment-Hospice-Final-2014-Guidance.pdf.

and work with all stakeholders – including hospice organizations, Part D plans, providers, pharmacists, and beneficiary groups – to develop a workable solution to ensure that beneficiaries receive access to necessary medications, while at the same time ensuring the drug is properly covered under the Part D or hospice program.

1. Part D Sponsor Coordination of Payment with Hospice Providers

In the proposed rule, CMS solicits comments on a process it is considering to enhance coordination between Part D Plans (PDPs) and hospices.

Part D Plan and Hospice Coordination: CMS is considering requiring Part D sponsors to coordinate with hospices to determine coverage for drugs whenever a coverage determination process is initiated or the hospice provides information regarding the beneficiary's election to hospice and/or drug profile. Under this scenario, the hospice would notify the Part D plan of the beneficiary's hospice election.

ASC CAN supports this requirement. As beneficiaries are admitted to hospice they should provide the hospice organization with information regarding their Medicare coverage options (including any Part D coverage). As discussed above, CMS is proposing to require hospices to file an NOE or NOTR with CMS within three calendar days. Thus, this proposed policy is neither administratively complex nor overly burdensome for the beneficiary or her personal representative.

Early Communication with Part D Plan: Alternatively, CMS is considering permitting hospices to initiate communication with a beneficiary's Part D plan prior to a claim submission, such as hospice election. CMS – and hospice organizations – claim this policy would address the time lag between hospices' filing of election information and Part D plan's ability to access that information.

ASC CAN supports this proposal. This proposed policy is similar to the policy discussed above, except that it allows hospices and Part D plans to communicate well before a claim has been submitted. This notice should help to give Part D plans and hospices amply opportunity in which to coordinate prescription drug coverage for the hospice beneficiary.

Point-of-Sale: CMS also is considering requiring that Part D plans determine Part A versus Part D coverage at the point-of-sale for any drugs for beneficiaries who have elected hospice. Part D sponsors would be permitted to use point-of-sale messaging and reject coding to indicate the beneficiary has elected hospice and that an explanation is needed if the drug is unrelated to the terminal illness. In order for the beneficiary (or her representative) to obtain Medicare coverage of the drug, the beneficiary, her elected representative, or the prescriber would then be required to initiate a coverage determination request with the Part D plan, who would then contact the hospice to determine whether the drug is related to the terminal illness and related condition.

ASC CAN is concerned this policy could hinder a beneficiary's access to necessary medication. Under this policy, a hospice beneficiary (or her caregiver) would present a prescription to be filled only to find that the Part D plan has rejected coverage of the drug on the grounds that the beneficiary is now in hospice care. The beneficiary (or her personal representative) or the pharmacist must then attempt to contact the prescriber to either determine whether an alternative drug is available or file a coverage determination request. If an alternative drug is not appropriate, the onus then falls to the beneficiary (or her personal representative) to initiate a coverage request. Unfortunately, as a practical matter, beneficiaries continue to encounter problems throughout the Medicare Part D appeals process, and in

some cases a beneficiary may choose to pay out-of-pocket for a drug that might otherwise be covered under Part D simply to forgo the appeals process. Given the undue burden this policy places on the beneficiary, we urge CMS to adopt an alternative approach, such as the proposals discussed above.

2. Hospice Coordination of Payment with Part D Sponsors and Other Payers

In the preamble, CMS notes that it has received anecdotal information from Medicare hospice beneficiaries that they are not receiving medications related to their terminal illness and related conditions because the medications are not included on the hospice's formulary. Medicare regulations require hospices to cover all drugs which are reasonable and necessary to meet the needs of the patient in order to provide palliative and symptom management of the beneficiary's terminal illness and related conditions. § 418.202(f). If the hospice's formulary does not include drugs to provide the necessary relief, then the hospice must provide alternatives even if it requires the hospice to use drugs not included on its formulary. CMS is considering how hospices can coordinate with Part D plans with respect to a standardized process (a prior authorization (PA)) in determining recovery payments when the wrong party has been paid. In addition, CMS is soliciting comments on whether hospices need to determine within a given time, a beneficiary's drug needs and communicate that information to the Part D plan, verbally or in writing, to insure there is no lapse in drugs for the beneficiary.

ACS CAN appreciates CMS' focus on ensuring that hospice beneficiaries are provided all medications related to their terminal illness and related conditions. We urge the agency to continue vigilantly monitoring any information – regardless of whether it is anecdotal – to ensure that beneficiaries are receiving the care and services to which they are entitled. As discussed above, we urge CMS to require that hospices and Part D plans establish a process for determining whether a drug is covered under Part D or hospice.

CMS should consider requiring Part D plans and hospices to report to CMS regarding the frequency with which hospices and Part D plans differ regarding coverage issues. Such information could be useful to CMS as it determines whether additional clarity may be necessary with respect to specific drugs. In addition, CMS should continue to monitor hospices' formularies to determine its adequacy with respect to the population it serves.

3. Beneficiary Rights and Appeals

CMS notes that in some cases a beneficiary may request a certain medication which the hospice fails to provide to the beneficiary on the grounds the medication is not reasonable and necessary for the palliation and management of the terminal illness or related condition. In such instances, the hospice is not obliged to provide any notice of non-coverage (including an Advance Beneficiary Notice of Non-Coverage (ABN)). However, if the hospice does provide the medication it must first issue an ABN in order to charge the beneficiary for the cost of the medication. CMS notes that beneficiaries who believe the hospice should have covered the drug and choose to purchase the drug on their own may do so, and may file a claim with CMS. Alternatively, if a beneficiary chooses a non-formulary drug because she feels it may be more efficacious than the formulary drug, the beneficiary may submit a quality of care complaint to a Quality Improvement Organization. The preamble notes that CMS plans to increase its education and outreach efforts to inform beneficiaries (and their caregivers and/or personal representatives) of their rights and provide information on the appeals process.

ACS CAN appreciates CMS' plans to provide greater education and outreach to beneficiaries (and their caregivers and/or personal representatives). As part of these efforts, we encourage CMS to reach out to beneficiary advocates to ensure that such information is provided in a consumer friendly manner. ACS CAN would welcome the opportunity to be involved in such a process.

In addition, we encourage CMS to vigilantly monitor the complaints submitted to the agency and/or the QIOs as a proxy for determining the adequacy of a hospice's formulary. Recognizing that most beneficiaries (and their personal representatives) are not aware of their appeal rights, any information provided to CMS and/or a QIO as part of this process should be reviewed carefully to determine whether the complaint represents an isolated instance or whether the hospice should consider changes to its formulary.

DEA Hydrocodone Rescheduling

And finally, as CMS works to finalize the FY 2015 hospice wage index, we also encourage the agency to work with the Drug Enforcement Agency on its proposal to reschedule hydrocodone combination products (HCPs) from Schedule III to Schedule II – a policy that would have major implications for hospice organizations and the beneficiaries they serve. Our April 28, 2014 comment letter to the FDA on its proposed rule notes that, while we acknowledge there have been serious issues with abuse of HCPs, there is no evidence to suggest that "upscheduling" these products will deter abuse. At the same time, "upscheduling" could hinder beneficiaries' access to necessary pain medications – especially hospice patients, because of the prohibition on phone or fax prescriptions, which are more common in hospice environments.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Principal, Policy Development, Access to and Quality of Care at Anna.Howard@cancer.org or 202-585-3261.

Sincerely,

Kirsten Sloan
Senior Policy Director
American Cancer Society Cancer Action Network