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- Q1: May a sponsor accept notification of the termination of the hospice benefit from the hospice, the beneficiary, or the prescriber? What notification is provided to the beneficiary and what is the lag in reporting the information to the Part D sponsor?
- A1: Yes, if the termination of the hospice benefit is not yet reflected in the CMS systems, a sponsor may accept documentation of the termination whether due to the beneficiary's revocation of his or her election or a hospice discharge or other termination. Documentation may be accepted from the hospice, the beneficiary, or a prescriber.

Acceptable documentation is dependent upon the reason for the termination. If the beneficiary revokes, he or she provides a written statement to the hospice that indicates the date the revocation is to be effective. If the hospice initiates a discharge, it provides a Notice of Medicare NonCoverage (NOMNC) to the beneficiary if the discharge is because the beneficiary is no longer considered "terminally ill." A NOMNC is not provided if the beneficiary is discharged for cause, or because of moving out of the service area. The hospice is expected to discharge the patient to a facility or back to his/her primary physician. As such, the hospice is required to provide the discharge summary to that follow-up provider.

CMS systems are updated to reflect the beneficiary is no longer in hospice when the hospice files either the final claim or a notice of termination or revocation. There are currently no timeframes for the filing of a notice of revocation or termination, and providers are allowed 12 months from the date of service to file the final claim. Once the final claim or notice of termination/revocation is filed by the hospice with the Medicare Administrative Contractor and the CMS Common Working File is updated, within 2-3 days the daily transaction reply report (DTRR) will report the termination to the Part D sponsor.

Given the potential length of the reporting lag, sponsors should use the highlighted documentation (i.e., written statement of revocation, NOMNC, or copy or the hospice discharge summary) presented by the hospice, beneficiary or prescriber to update their systems pending the receipt of the DTRR reporting the termination or the end of the current benefit period, if earlier. Unless a new benefit period start date is reported, sponsors may use the documentation to remove the beneficiary-level hospice PA edit.

- Q2: If a sponsor disagrees with the explanation of the unrelatedness of the drug to the terminal illness and/or related conditions, must the sponsor accept the explanation?
- A2: A sponsor might question the explanation of the unrelatedness of the drug, but if the hospice or the prescriber, even when unaffiliated with the hospice, provides a coherent clinical reason for the drug being unrelated, for this year, we expect the sponsor will document the explanation and process the claim. Since there is no dispute resolution process, the prior authorization documentation will support coverage of the drug under Part D.
- **Q3:** Is there a definition of "related condition"?

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A3: In the FY 2014 hospice final rule, CMS clarified that all of a patient's coexisting or additional diagnoses related to the terminal illness and related conditions should be reported on the hospice claim. We also stated that when an individual is terminally ill, many health problems are brought on by underlying conditions, as bodily systems are interdependent, meaning that there are multiple conditions, and hence diagnoses, contributing to the terminal prognosis (78 FR 48247). Our expectation is that hospices will follow ICD-9-CM coding guidelines for listing all diagnoses for the terminal illness and related conditions on the hospice claim.

# Q4: Can a hospice request an E1 eligibility query? How would a hospice pharmacy access E1 capability, if the pharmacy does not have this capability currently?

A4: No, a hospice cannot request an E1 eligibility query. The E1 query is only a pharmacy transaction. If a hospice pharmacy does not current have E1 capability, instructions for getting set up are available on the CMS Part D Transaction Facilitator Web site at <a href="http://medifacd.relayhealth.com/e1/getting-setup">http://medifacd.relayhealth.com/e1/getting-setup</a>.

## Q5: To whom should hospices communicate information about an enrollee's unrelated drugs?

A5: Hospices should communicate information about an enrollee's unrelated prescription drugs to the enrollee's Part D plan sponsor. This communication may be initiated prior to the submission of a claim to Part D at the time of the hospice election or may occur following the sponsor's reject of a claim when the Part D sponsor contacts the hospice in response to a beneficiary coverage determination request. Contact information for the Part D sponsors' customer service representatives is available on the CMS website at <a href="http://www.cms.gov/Medicare/Prescription-Drug-">http://www.cms.gov/Medicare/Prescription-Drug-</a>

<u>Coverage/PrescriptionDrugCovContra/PartDContacts.html</u> . The list includes the plan's marketing name, which can be used to search the list if the contract number is unknown.

# Q6: Are all the drugs in the four categories identified in the 2014 Call Letter considered related and, therefore, covered under the hospice benefit? Are all maintenance drugs considered unrelated and, therefore, covered under Part D?

A6: Any drug whether it is a maintenance drug or in the four categories of identified in the 2014 Call Letter (including analgesics, antiemetics, laxatives, or antianxiety drugs) may be unrelated to the terminal illness and/or related conditions and, therefore, coverable under Part D. As a result, coverage determinations must be made on a case-by-case basis for each drug.

#### Q7: What documentation of unrelatedness should a sponsor retain?

A7: Whether the sponsor receives the information explaining why a drug is unrelated to the terminal illness and/or related conditions in writing on a PA form or the sponsor completes

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the PA form based on the information received verbally from the hospice or the prescriber, the PA form should be retained as documentation that the drug is unrelated and is, therefore, coverable under Part D.

- Q8: When does Part D coverage for related drugs begin following the termination of the hospice benefit? The MA manual indicates Part C coverage starts the first of the month following termination of the hospice benefit and until then, services are paid by the Medicare Administrative Contractor under fee-for-service.
- A8: Unlike the Medicare Advantage program, there is no alternative access to Part D drugs under Medicare fee-for-service. Thus, effective with the date of termination of the hospice benefit due to revocation, discharge or other termination, all Part D drugs, including those related to the terminal illness and related conditions, are coverable under the member's Part D benefit.
- Q9: Per Chapter 18 of the Medicare Prescription Drug Benefit Manual, tolling is not allowed for PA requests. Is tolling allowed for these beneficiary-level hospice PAs?
- A9: For purposes of the 2014 coordination of benefits processes outlined in this memo, we believe it is appropriate to apply the processing timeframes applicable to exception requests as described in section 30.2 of Chapter 18 of the *Medicare Prescription Drug Benefit Manual* to coverage determination requests that involve the beneficiary-level hospice PA. In other words, the applicable adjudication timeframe of 24 hours (for expedited requests) or 72 hours (for standard requests) begins when the clinical explanation of unrelatedness to the terminal illness or related conditions is received from the hospice provider or prescriber.

In accordance with existing guidance on processing timeframes for exception requests, a plan sponsor must not keep the request open indefinitely; while the adjudication timeframe may be tolled pending receipt of the necessary information, the start of the adjudication timeframe can only be tolled for a reasonable period of time based on the facts and circumstances of the case. Further, for coverage determination requests that also involve an exception to a drug-specific UM requirement, the adjudication timeframe can only be tolled once consistent with the above-stated expectation that the beneficiary-level hospice PA and the drug-specific UM requirement be considered concurrently.

- Q10. Must a sponsor verify that a prescriber is affiliated with the hospice? If the prescriber is unaffiliated, may the sponsor accept a verbal attestation that the prescriber has conferred with the hospice?
- **A10:** No, a sponsor need not verify that a prescriber is affiliated with the hospice. If during the PA process, the sponsor determines that the prescriber is unaffiliated with the hospice, the sponsor should secure confirmation that the prescriber has conferred with the hospice and the hospice agrees to the unrelatedness of the drug. This attestation may be verbal or written and should be documented on the PA form and retained to support the sponsor's coverage of the drug under Part D.

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- Q11: When a claim is retrospectively determined to be a hospice or beneficiary liability, should the PDE be deleted or adjusted to zero dollars?
- A11: When payment is retrospectively determined to be the responsibility of the hospice or the beneficiary, the sponsor must delete the PDE for the claim because the drug does not meet the definition of a covered Part D drug. The sponsor must also remove the costs from the member's TrOOP and gross covered drug costs.
- Q12: If a claim is retrospectively determined to be a member liability and the sponsor collects from the beneficiary, must the sponsor request the pharmacy reverse the claim and/or delete the PDE?
- A12: Beneficiaries will be responsible for drugs related to the terminal illness and/or related conditions, but waived through the beneficiary's hospice election or unavailable through the hospice due, for example, to the imposition of the hospice's formulary requirements or the hospice's determination that the drug is not medically necessary. Since the drugs are related, they are not coverable under Part D and the PDE must be deleted. However, once the Part D sponsor has recovered the erroneous payment from the beneficiary, there is no need to request the pharmacy reverse the claim.
- Q13: The guidance states no independent review entity (IRE) will be available in 2014. Does this mean beneficiaries are unable to appeal?
- A13: Although no IRE will be available to resolve payer vs. payer disputes when the Part D sponsor disagrees with the hospice or prescriber explanation of the unrelatedness of the drug, this absence does not affect the beneficiary's appeal rights under either Part A or Part D. Beneficiaries retain the right to appeal Part A coverage decisions through the Medicare fee-for-service process and Part D coverage decisions through the Part D appeals process.
- Q14: Although CMS encourages sponsors to employ a single-use PA form for the beneficiary-level hospice PAs, is it acceptable for sponsors to use a general PA form when other utilization management PAs are required?
- A14: Although we recognize there will be instances when other utilization management requirements must be satisfied in addition to the beneficiary-specific hospice PA edit, we do not believe this will occur at a frequency sufficient to warrant general use of a single multi-purpose PA form. Thus, for simplicity we continue to encourage sponsors to use only the suggested hospice-related data elements on a form that would be used exclusively for hospice PAs.
- Q15: Does the guidance apply to Medicare Advantage-Prescription Drug (MA-PD) plans as well as stand-alone Prescription Drug Plans (PDPs)?
- A15: The Part D hospice guidance issued March 10, 2014 and titled, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice," applies to all sponsors of Medicare Part D benefit

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plans. This would include plans such as MA-PDs, PDPs, and Medicare-Medicaid plans (MMPs).

#### Q16: Do the beneficiary-level hospice PA edits apply to Medicare/Medicaid dual eligible?

A16: The beneficiary-specific hospice PA edits apply to all Medicare Part D enrollees who are in a hospice election period as of the date the prescription is submitted for filling. These PA edits are necessary to determine whether or not the prescribed drug is related to the beneficiary's terminal illness and/or related conditions and, therefore, covered under the Part A hospice benefit. A beneficiary's dual Medicare and Medicaid eligibility is irrelevant to the determination of whether a drug is covered under the Part A hospice benefit or may be covered under Part D.

## Q17: Why are Part D sponsors imposing the requirements prior to the May 1, 2014 effective date?

A17: Prior to May 1, 2014, sponsors should at a minimum comply with the guidance specified in the 2014 Call Letter issued in April 2013 and effective January 1, 2014. This guidance strongly encourages sponsors to place beneficiary-level PA requirements on 4 categories of drugs (analgesics, antiemetics, laxatives and antianxiety drugs). However, since sponsors have always been required to ensure appropriate coverage under the Part D benefit for any drug where Part D coverage is in question, sponsors may place PA edits on all drugs for hospice beneficiaries, even prior to the May 1, 2014 effective date of the new guidance.