



CENTER FOR MEDICARE

TO: All Part D Plan Sponsors and Medicare Hospice Providers

FROM: Amy K. Larrick, Acting Director
Medicare Drug Benefit and C & D Data Group

Laurence Wilson, Director
Chronic Care Policy Group

SUBJECT: Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice

DATE: July 18, 2014

On June 25, 2014, CMS met with a number of stakeholder groups to discuss the implementation of the final 2014 guidance on Part D payment for beneficiaries enrolled in the Medicare hospice benefit (memorandum dated March 10, 2014). Beneficiary advocates, hospice providers, Part D sponsors/pharmacy benefit managers, and pharmacies discussed their perspectives of the impact of the policy on beneficiaries as well as the operational challenges it has posed. We thank all participants of the meeting for taking an initial step to mutually work toward a solution to protect beneficiaries' access to prescription medications and the Medicare program.

Our goal for the policy we set forth in March was to ensure that the hospice and Part D programs correctly pay for prescription drugs covered under each respective Medicare benefit while ensuring timely access to needed prescription medications. While this remains CMS' objective, we recognize that the operational challenges associated with prior authorizing all drugs for beneficiaries who have elected hospice to determine whether the drug is coverable under Part D have created difficulties for Part D sponsors and hospice providers, and in some cases, barriers to access for beneficiaries. Therefore, the purpose of this memorandum is to address both the beneficiary access issues and the operational concerns encountered by the industry. This guidance supersedes portions of the March 10, 2014 guidance; those portions that remain in effect are restated in the addendum to this memorandum. In the FY 2015 Hospice Wage Index proposed rule (79 FR 26538, May 8, 2014), we solicited comments on the definition of "terminal illness" and "related conditions". We received a significant number of comments representing diverse stakeholder groups and the impact the definitions may have on those stakeholder groups. We will consider these comments for future rulemaking.

Meanwhile, the DHHS Office of the Inspector General (OIG) released a report in June 2012 identifying situations where Medicare may be paying twice for prescription drugs for hospice beneficiaries, who in turn could also be paying unnecessary co-payments for prescription drugs¹.

¹ Office of the Inspector General, Department of Health and Human Services. Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice. June, 2012. A-06-10-00059.

As described in this report, “Hospice beneficiaries generally experience common symptoms during the end of life, regardless of their terminal diagnosis. These symptoms include pain, nausea, constipation, and anxiety.” We would like to highlight that the OIG worked with CMS and the National Hospice and Palliative Care Organization (NHPCO) to identify 4 common categories of prescription drugs that are typically used to treat these symptoms: analgesics, anti-nauseants, laxatives, and anti-anxiety drugs.

Revised Guidance for Part D Sponsors

Drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. However, given the aforementioned access and operational issues, in lieu of placing a beneficiary-level prior authorization (PA) on all drugs for beneficiaries who have elected hospice, **we strongly encourage sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs identified by the DHHS Office of Inspector General (OIG) discussed above: analgesics, anti-nauseants (antiemetics), laxatives, and anti-anxiety drugs (anxiolytics).** CMS expects Part D sponsors to identify the national drug codes for drugs included within these four categories by utilizing standard industry classifications that are available through drug listing services or otherwise. Part D sponsors are not expected to place hospice PA requirements on other categories of drugs or take special measures beyond their normal compliance and utilization review activities to retrospectively review paid claims for purposes of determining whether drugs in the other categories were unrelated to the hospice beneficiary’s terminal illness and related conditions or payment recovery.

We expect that Medicare hospice providers will continue to provide all of the medications that are reasonable and necessary for the palliation and management of a beneficiary’s terminal illness and related conditions. We expect that this will routinely include the drugs in the four categories highlighted by the OIG, as discussed above. Therefore, we anticipate these drugs are the least likely to be subject to disputes concerning payment responsibility and any barriers to beneficiary access to prescription drugs will be minimized.

In addition, hospice providers should note that there are drugs that are statutorily excluded from the Part D benefit, including drugs for the symptomatic relief of cough and cold, most prescription vitamins, and nonprescription (i.e., OTC) drugs. In order to lessen beneficiary confusion, hospices should avoid referring beneficiaries to their Part D plan/pharmacy for coverage for these medications. Drugs prescribed for beneficiaries who have elected the hospice benefit that are unrelated to the terminal illness and related conditions continue to be subject to standard Part D formulary management practices, including quantity limitations, step therapy, and prior authorization, that have been approved by CMS. Nothing in this guidance should be taken as a change in the definition of a Medicare Part D covered drug or Part D payment rules or drug utilization review requirements.

Accepting information from Medicare hospice providers

Under this revised guidance, hospice providers are encouraged to report a beneficiary’s Medicare hospice election to the Part D sponsor and identify any drugs in the four categories determined to

be coverable under Part D because the drugs are unrelated to the terminal illness and/or related conditions **prior** to the submission of a claim. This communication, however, is not a coverage determination or PA request. Rather the information provided by the hospice can be used by the sponsor to override the beneficiary-level hospice PA at point-of-sale (POS).

Federal regulations require that Medicare hospice providers conduct and document a patient-specific comprehensive assessment in writing, which identifies the patient's need for hospice care and services, as well as any need for physical, psychosocial, emotional, and spiritual care and be able to produce it upon request. The written assessment of the patient includes all areas of hospice care related to the palliation and management of the terminal illness and related conditions. The comprehensive assessment must also include a drug profile with all of the patient's prescription and over-the-counter (OTC) drugs, herbal remedies, and other alternative treatments that could affect drug therapy. The hospice plan of care is based on the needs identified in the initial, comprehensive, and updated plan of care assessments. Therefore, the requirement is that hospices will have appropriate medication documentation for each hospice beneficiary upon completion of these assessments. Medication information obtained through the assessments, including whether the medications are related or unrelated to the terminal illness and related conditions, should be provided to the Part D sponsor proactively—meaning before a hospice beneficiary presents a prescription for fill—or, failing proactive provision of the information by the hospice, should be provided to the Part D sponsor, after the Part D sponsor contacts the hospice provider during the PA process.

Prior authorization for drugs in the usually related 4 categories

If a claim has been rejected by a sponsor due to the beneficiary-level hospice PA, the pharmacy or beneficiary may contact the hospice provider for a statement that the drug is unrelated to the terminal illness and related conditions. The hospice provider should contact the Part D sponsor to provide an oral or written statement or provide a written statement to the pharmacy or the beneficiary to transmit to the Part D sponsor. The sponsor should accept this information to override the POS reject without requiring that the beneficiary, or others on their behalf, request a coverage determination. When the beneficiary, the beneficiary's appointed representative or the prescriber requests a coverage determination, the sponsor should contact either the prescriber or the hospice provider and accept and use the statement that the drug is unrelated to the terminal illness and/or related conditions provided by either the prescriber or hospice. A hospice provider cannot request a coverage determination on behalf of the beneficiary.

In documenting Part D coverage of the drugs in the four categories, a statement indicating the drug is unrelated to the terminal illness and related conditions is sufficient. The statement may be as simple as a "U" or "unrelated". Hospices are expected to maintain a record of the clinical basis for the statement that the drug is unrelated and provide it upon request. Consistent with the guidance set forth above, Part D sponsors should accept the prescriber's or hospice provider's statement and retain the documentation.

We strongly encourage hospice providers to provide a compassionate first fill for any medication needed by a beneficiary who is experiencing difficulty in accessing the drug at POS. If the drug

provided is unrelated to the terminal illness and related conditions, the hospice provider should contact the Part D sponsor to negotiate recovery of the hospice's payment to the pharmacy.

Standardized prior authorization form

Representatives from the prescription drug and hospice industries participating in the National Council for Prescription Drug Program's Work Group 9 Hospice Task Group have collaborated on the development of a draft two-page form that may be used either by the hospice or prescriber to provide the information necessary to satisfy the beneficiary-level prior authorization edit, for the sponsor to make a coverage determination, or by the hospice to prospectively communicate information to the Part D sponsor. The first page of the form captures the information necessary for the prior authorization of drugs in the four categories; the second page captures information on drugs related to the terminal illness and/or related conditions and specifies whether each of these drugs is the responsibility of the hospice or beneficiary. Although not required for either a prior authorization or a coverage determination, the second page provides information to support the Part D sponsor's coordination of care efforts, such as safety edits for drug-drug interaction.

Given the broad industry support for the form, we are using it to replace the list of data elements we identified in Attachment 2 of the March 10, 2014 memorandum for inclusion in a Part D hospice PA form. We have made minor edits to the draft form (a copy of the edited version is attached) and we strongly recommend sponsors use the first page of the form as edited until a standard Part D hospice PA form is approved. Because only drugs that are unrelated to the terminal illness and related conditions would be reported on this page of the form, listing the drug here in effect constitutes a statement by the hospice provider or the prescriber that the drug is unrelated. The form provides space for a rationale to support the drug is unrelated; however, no clinical justification for that determination is necessary.

While hospice providers are not required to complete the second page of the form, should they choose to complete it, the information will assist sponsors in care coordination activities. Although we encourage Part D sponsors and hospice providers to use this two-page form, sponsors should not require its use. As long as the necessary statement that the drug is unrelated is provided, the sponsors should accept it in any format.

Note: the first page of the form could also be used by the hospice provider to report only a beneficiary's hospice election or termination. In these cases, the hospice could use the patient information section to report the appropriate date and check the box to indicate the form is being used solely to update a hospice election (admission) or termination (discharge).

Retrospective review and recovery of Part D payment for drugs in the four categories

As noted above, we do not expect Part D sponsors to retrospectively review paid claims for drugs outside of the four categories specifically for the purpose of determining whether the drugs were unrelated to the hospice beneficiary's terminal illness and related conditions. However, all Part D retrospective review requirements continue to apply to these claims.

If the Part D sponsor has paid claims for drugs in the four categories for hospice beneficiaries prior to receiving notification of the beneficiary's hospice election, the sponsor should perform a subsequent review of claims paid within the hospice election period for drugs in the four categories and should also conduct outreach to the hospice provider or prescriber to retrospectively determine payment responsibility for the drugs. In order to determine whether the drug is for treatment of a condition unrelated to the terminal illness or related conditions, CMS expects the prescriber or hospice provider to coordinate with the plan sponsor regarding these claims and provide the necessary written or verbal statement that the drug is either (1) unrelated to the terminal illness or related conditions or (2) is a beneficiary liability.

In those scenarios in which the drug is determined to be a hospice liability, the sponsors and hospices should negotiate repayment. In the scenarios in which the beneficiary is liable, such as when the member has requested a non-formulary drug from the hospice and refused to try a formulary equivalent, or the drug was determined by the hospice provider to be unreasonable or unnecessary, but the beneficiary agreed to assume financial responsibility for it, the sponsor should send a recovery notice to the beneficiary.

Sponsors should implement processes to handle payment resolution directly with hospice providers and beneficiaries without requiring the pharmacy reverse and rebill the original claim in the retail setting. However, whenever the network pharmacy involved is also the hospice pharmacy, as is often the case with long-term care pharmacies, reverse and rebill may be the most appropriate approach.

Medicare beneficiary hospice status

CMS conducted a review of all medication-related hospice beneficiary complaints submitted during the month of May 2014. We found that the vast majority (70%) of these complaints related to issues regarding the beneficiary's Medicare hospice election/termination. The majority of these complaints pertained to beneficiaries who claimed their Medicare hospice benefit had terminated, but were still reflected as being in a Medicare hospice benefit period in CMS' systems and therefore were subject to a beneficiary-level prior authorization edit.

Currently, hospice providers are required to file the hospice notice of election (NOE) as soon as possible after a patient elects the hospice benefit. Compliance with the obligation to file NOEs as soon as possible following the beneficiary's election minimizes the period between the beneficiary's hospice election and a Part D sponsor obtaining notice of the election. Timely filings of NOEs by hospices are essential for facilitating prompt notifications of a beneficiary's election to sponsors and reducing the number of Part D claims made for drugs related to the beneficiary's terminal illness and related conditions. Prompt notifications of a beneficiary's election will also ease the burden on sponsors to perform the retrospective review necessary to determine potential repayment obligations for any Part D claims paid in the period between the beneficiary's election and the sponsor's receipt of notification.

Similarly, if a beneficiary revokes their election of the hospice benefit, a final claim indicating the revocation of the hospice benefit should be submitted as soon as possible. Upon discharge or revocation, a beneficiary resumes the Medicare coverage that had previously been waived by

the hospice election. Therefore, the discharge or revocation should be submitted to the claims processing system in a timely manner and in accordance with the Medicare Claims Processing Manual (100-04) and 42 CFR 418.26 and 418.28. In addition, CMS encourages hospice providers to use the first page of the previously mentioned standardized prior authorization form, which can be completed and provided to Part D sponsors immediately upon hospice discharge or revocation.

CMS recently proposed upper limit timeframes for hospices to file the NOE and to file a Notice of Termination or Revocation (NOTR) (if a final claim had not already been filed) in the May 8, 2014 FY 2015 Hospice Wage Index and Rate Update proposed rule (79 FR 26538, available at <http://www.gpo.gov/fdsys/pkg/FR-2014-05-08/pdf/2014-10505.pdf>). A final rule will be issued that will describe the final specified timeframes for filing the NOE and NOTR.

In the Hospice FAQs (v.5/8/14, Q1, available at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Hospice-FAQs050814.pdf>), we stated that if an enrollee asserts that he or she is no longer in Medicare hospice, but the termination of the Medicare hospice benefit is not yet reflected in the CMS systems, a sponsor may accept documentation of the termination from the Medicare hospice, the beneficiary, or a prescriber. Acceptable documentation is dependent upon the reason for the termination:

- When a beneficiary revokes the Medicare hospice election, he or she provides a written statement to the hospice provider indicating the date the revocation is to be effective.
- If the hospice provider initiates a discharge because the beneficiary is no longer considered “terminally ill,” it provides a Notice of Medicare Non-Coverage (NOMNC) to the beneficiary.
- A NOMNC is not provided if the beneficiary is discharged for cause, or because of moving out of the service area. In these instances, the hospice provider is expected to discharge the patient to a facility or back to his/her primary physician and is required to provide the discharge summary to that follow-up provider.

Thus, Part D sponsors should accept any of the following as evidence of the termination of Medicare hospice status: the beneficiary’s written statement of revocation of the election, proof of submission of a final claim indicating the revocation of the hospice benefit, the NOMNC, the hospice provider’s discharge summary, or page 1 of the standardized prior authorization form. This evidence should be accepted from the beneficiary, the hospice provider, or the prescriber. Sponsors should accept a mailed hard copy or faxed copy of the documentation and use it to remove the beneficiary-level hospice PA edit to ensure the beneficiary has timely access to drugs under Part D.

CMS systems are updated to reflect the beneficiary is no longer in Medicare hospice when the hospice provider files either the final claim or a notice of termination or revocation. Once the final claim or notice of termination/revocation is filed by the hospice provider 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 documentation presented by the hospice provider, beneficiary, or prescriber, similar to the manner in which best available evidence (BAE) is used to establish low-income subsidy status, 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 on the four categories of drugs.

Note: if a beneficiary asserts that he or she never elected to receive Medicare hospice, but hospice election information has been reported on the TRR and is reflected in MARx, the sponsor should contact the hospice provider reported in MARx and confirm the beneficiary is not enrolled in Medicare hospice. Part D sponsors should accept verbal confirmation under these circumstances and the sponsor should document the confirmation and retain this as evidence to support Part D payment without a hospice PA.

Effective date of Medicare hospice termination

Beginning with the date of termination of the Medicare hospice benefit, whether due to revocation, or discharge, coverage of all Part D drugs including those related to the terminal illness and related conditions resumes under the member's Part D benefit. This is different from the effective date of the resumption of benefits under Part C. For beneficiaries in a Medicare Advantage (MA) plan, all services continue to process through fee-for-service Medicare through the end of the month in which the Medicare hospice benefit terminated and MA coverage resumes at the beginning of the following month.

Accepting beneficiary information from the pharmacy

Beneficiaries or their family members may have documentation at POS, including evidence of a Medicare hospice benefit termination or a PA form or other documentation from the prescriber or hospice that a drug is unrelated to the terminal illness or related condition, which could be faxed by the pharmacy to the sponsor in order to provide the beneficiary immediate access to a prescribed drug. Sponsors should communicate with their network pharmacies to encourage the pharmacies to assist plan members by faxing the documentation to the sponsor and note that the sponsor will accept this information so the beneficiary-level hospice PA edit can be overridden at POS. CMS will prepare a similar communication to be issued via the pharmacy listserv. Sponsors should also encourage their network pharmacies to explain to the beneficiary or family member why a claim has rejected at POS based on the beneficiary's hospice election and direct them to either contact their plan sponsor to request a coverage determination or the hospice provider for the information necessary for the sponsor to override the hospice edit.

Treatment of beneficiary complaints as coverage determination requests

Part D sponsors are receiving complaints from beneficiaries concerning the members' inability to access specific drugs through Part D due to their hospice election and the associated claims edit. Currently, some sponsors are closing these complaints because they are not processing them as a coverage determination request. Instead, sponsors must process the complaint that the enrollee has not been able to get a drug in the four categories as a coverage determination request and

contact the prescriber or hospice provider to obtain the information necessary to make a coverage determination.

Effective date of the revised guidance

This guidance will be effective as of the date of issuance. However, we recognize sponsors will require some time to implement the changes to effectuate the guidance. Therefore, although we strongly encourage sponsors to implement the guidance as soon as possible, our expectation is that all sponsors will have implemented it by October 1, 2014. Additionally, we recognize that coverage determinations will be pending for some previously rejected claims for drugs other than those in the four categories. Since these claims should no longer be subject to hospice PA reject edits, the drugs should be considered covered under the Part D benefit without the sponsor obtaining documentation regarding the relatedness of the drug.

In closing, we will coordinate with stakeholders to provide any additional clarification necessary. Questions should continue to be sent to the CMS Part D policy mailbox at PARTDPOLICY@cms.hhs.gov.

**Addendum: Applicable Portions of the March 10, 2014 Guidance
(Edited as necessary to incorporate updated guidance issued July 18, 2014)**

Drugs in the Four Categories That Are a Beneficiary Liability

There may be some drugs that were for the treatment of the terminal illness and/or related conditions prior to the hospice election that will be discontinued upon hospice election, as it has been determined by the hospice interdisciplinary group, after discussions with the hospice patient and family, that those medications may no longer be effective in the intended treatment, and/or may be causing additional negative symptoms in the individual. These medications would not be covered under the Medicare hospice benefit, as they would not be reasonable and necessary for the palliation of pain and/or symptom management. If a beneficiary still chooses to have these medications filled through his or her pharmacy, the costs of these medications would then become a beneficiary liability for payment and not covered by Part D. These medications would not be covered by Part D because their further coverage is prohibited under Medicare.

Similarly, if a beneficiary requests a drug for his or her terminal illness or related conditions that is not on the hospice formulary and the beneficiary refuses to try a formulary equivalent first; or the drug is determined by the hospice provider to be unreasonable or unnecessary for the palliation of pain and/or symptom management, the beneficiary may opt to assume financial responsibility for the drug. However, no payment for the drug will be available under Part D.

When a drug is determined by the hospice provider to be the beneficiary's responsibility, Part D has no payment responsibility and payment coordination is not an issue. In those situations involving retrospective payment recovery, as discussed in the section above on the retrospective review and recovery of Part D payment for drugs in the four categories, the sponsor should issue a recovery notice to the beneficiary.

Hospice Provider Identification of the Part D Sponsor

Hospice providers can proactively identify a beneficiary's Part D plan through the hospice pharmacy. Hospice pharmacies can identify a beneficiary's Part D plan by submitting a standard electronic eligibility (E1) query to the CMS Transaction Facilitator. The query response identifies the plan sponsor and provides the sponsor's online billing information, as well as the pharmacy help desk telephone number. The hospice provider can initiate communication or fulfill a PA through the sponsor's 24-hour pharmacy help desk.

Prior Authorization Process for Drugs in the Four Categories

Sponsors should use the existing standard PA process which begins when a Part D sponsor receives a pharmacy claim for a beneficiary who has elected hospice and rejects the claim with the following National Council for Prescription Drug Programs (NCPDP)-approved reject coding:

Code	Description
A3	This Product May Be Covered Under Hospice – Medicare A
75	Prior Authorization Required
569	Provide Notice: Medicare Prescription

Drug Coverage and Your

In addition to the reject coding, sponsors, at a minimum, should use point-of-sale messaging stating: Hospice Provider- Request Prior Authorization for Part D Drug Unrelated to the Terminal Illness or Related Conditions, and including the 24-hour pharmacy help desk phone number to call with questions.

The standardized pharmacy notice instructs the enrollee on how to contact his or her plan and explains an enrollee's right to request a coverage determination and receive a detailed written decision from the Part D plan sponsor regarding his or her Part D prescription drug benefits. Plan sponsors must arrange with their network pharmacies (including mail-order and specialty pharmacies) to distribute the notice. The pharmacy notice must be provided to the enrollee if the pharmacy receives a transaction response indicating the claim is not covered by Part D and the designated NCPDP response code is returned. The form and the form's instructions can be accessed on the CMS Website at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html>.

If the beneficiary, the beneficiary's appointed representative, or the prescriber contacts the Part D sponsor to request a coverage determination for a drug in the four categories, a number of scenarios may occur:

- The sponsor contacts the prescriber to complete the PA. The prescriber may provide a verbal explanation to the sponsor regarding why the drug is unrelated to the terminal illness or related conditions or complete the PA form and submit it to the sponsor via fax or mail.
- In some cases, such as when the prescriber is unaffiliated with the hospice provider and unable or unwilling to coordinate with the hospice provider to provide a statement that the drug is unrelated, the sponsor may contact the hospice for the statement that the drug is unrelated to the terminal illness or related conditions. In these instances, the hospice provider can provide a verbal statement to the sponsor that the drug is unrelated to the terminal illness or related conditions or complete the PA form. We believe that these instances are most likely to occur when the prescriber is unaffiliated with the hospice provider and may require that the hospice provider contact either the prescriber or the Part D sponsor in order to provide the statement that the drug is unrelated to the terminal illness or related conditions.
 - To ensure care coordination, we believe prescribers who are unaffiliated with the hospice provider, in addition to providing a statement that the drug is unrelated to the terminal illness or related conditions, should also attest that they have coordinated with the hospice provider and the hospice provider confirmed the unrelatedness of the drug.
- The sponsor contacts the hospice provider to provide the statement of unrelatedness for the PA and is informed that, although the drug is related to the terminal illness or related conditions, it has been determined to be a beneficiary liability.

Upon receiving and accepting the verbal statement or the completed PA form, the sponsor instructs the pharmacy on how to override the edit and notifies the beneficiary. If the prescriber initiated the PA, the prescriber also receives notice from the sponsor. If the sponsor has determined that the prescriber is not affiliated with the hospice provider, the sponsor may also fax an informational copy of the PA to the hospice provider.

As previously noted, Part D coverage of a drug depends on whether the drug is covered under the hospice benefit. As a result, if the hospice provider or the prescriber does not respond or refuses to

provide the required statement that a drug in the four categories is unrelated to the terminal illness or related conditions, Part A coverage cannot be ruled out and the PA is unfulfilled; therefore, the sponsor must inform the beneficiary that the drug is not covered under Part D.

In addition to the beneficiary-level hospice PA for determining whether the drug in the four categories is coverable under Part D, a plan sponsor may have a utilization management (UM) edit on the drug that must also be satisfied. Although the beneficiary-level hospice PA is the threshold issue that must be considered when a coverage determination has been requested, we expect Part D plan sponsors to concurrently obtain and review the information necessary to promptly determine whether any applicable drug-specific UM requirement has been satisfied (or, alternatively, whether an exception to that UM requirement has been requested).

For purposes of the coordination of benefits processes outlined in this memo for drug in the four categories, 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 statement that the drug is unrelated 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.

Hospice Election, Certification, and Benefit Periods

To receive hospice care, an individual (or an authorized representative) must elect the hospice benefit and must be certified by a physician as terminally ill. A hospice election continues until the beneficiary revokes the election, is discharged, or passes away. As noted previously, a NOE is completed by the hospice and filed with the Medicare contractor, to transmit the data to CMS' Common Working File (CWF) in electronic format. The data are reported by the CWF to other CMS systems (see Attachment 3 for a chart of the data flow). An election is comprised of one or more benefit periods. The initial certification and benefit period is for 90 days. After the initial period, subsequent periods consist of another 90-day period and an unlimited number of 60-day periods.

Hospice Information Reported on the TRR

Hospice election information is sent to sponsors on the DTRR. As specified in the Plan Communications User Guide, the DTRR includes a hospice indicator, a hospice start date and a hospice termination date). Hospice data are reported on the DTRR at the time of the beneficiary's enrollment in a Part D plan, or hospice election if that election is made later. Updated data are reported when the hospice start dates change to reflect a new benefit period or a termination date is added due to death, discharge, or revocation of the election by the beneficiary.

Only one hospice benefit period can be reported on the DTRR. Thus, the hospice start date will be the date the current benefit period started. When the current benefit period ends, a new start date will be reported reflecting the start date of the new benefit period. Termination dates are reported on the DTRR only when the hospice benefit has terminated due to death, discharge, or revocation of the beneficiary's election. Thus, if no hospice termination date is reported on the DTRR, the new start date is the beginning of a new benefit period. Therefore, a new start date should not be viewed as an indication that the beneficiary revoked his/her hospice election and then re-elected the benefit, or was discharged and re-elected, creating an entirely new election. When a beneficiary revokes a hospice election or is discharged, the effective date of the revocation or discharge will be reported as the hospice termination date on the DTRR. If the beneficiary revoked the election, a hospice revocation indicator will be included in the MARx system. Please note that when a beneficiary revokes his/her hospice election or is discharged from hospice care, the beneficiary immediately resumes Medicare coverage of the benefits waived when hospice care was elected.

Since only a single hospice benefit period can be reported on the DTRR, sponsors will need to store the hospice data in their systems so historical data are available when needed for claims adjudication and adjustments. Sponsors can also access additional hospice data via MARx User Interface, including prior benefit period start and end dates and the hospice revocation indicator.

Hospice Information Available through the Health Plan Management System (HPMS) and on the cms.gov Website

Sponsors may use the MARx User Interface or information supplied by the pharmacy, prescriber or beneficiary to identify the hospice and, once hospice is identified, the hospice contact information will be available to sponsors through HPMS prior to the effective date of the guidance. The hospice information from the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) also will be accessible on the CMS Website on the Hospice Center Webpage located at <http://www.cms.gov/Center/Provider-Type/Hospice-Center.html> in the Spotlight section; the list will be posted as soon as possible, but no later than the effective date of the guidance.

According to Medicare Enrollment policy, providers are required to submit any changes to their enrollment information in PECOS in a timely manner. Therefore, we expect hospice providers will ensure that their information is current and complete and will review the list and submit any required changes electronically to PECOS. The system is accessible via the CMS Website at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>.

Part D Star Ratings

Several Part D sponsors requested that hospice-related complaints be excluded from the sponsors' star rating. We would expect that most complaints will be about the hospice and sponsors should report these to CMS Regional Office via the usual process and such complaints would not be attributable to the plan. However, sponsors should work to ensure that PAs are acted upon quickly once the prescriber or hospice responds.

Implications for Beneficiaries

Beneficiary Fee-for-Service Claims and Appeals

Sometimes a beneficiary requests a certain medication that a hospice can't or won't provide because it's not reasonable and necessary for the palliation and management of the terminal illness and related conditions. The cost of such a medication, which is not reasonable and necessary for the management of the terminal illness or related conditions, would be a beneficiary liability. If the hospice does not provide the medication, the hospice is not obligated to provide any notice of non-coverage (including the Advance Beneficiary Notice of Non-coverage or ABN). If the hospice provides the medication even though it is not reasonable and necessary, it must issue an ABN in order to charge the beneficiary for the medication. Regardless of whether or not the hospice furnishes the drug, if the beneficiary feels that the Medicare hospice should cover the cost of the drug, the beneficiary may submit a claim for the medication directly to Medicare on Form CMS-1490S. If the claim is denied, the beneficiary may file an appeal of that determination under the appeals process set forth in part 405, subpart I.

If the beneficiary desires to continue taking drugs that are not covered by Medicare Part A or Part D, then the hospice must fully inform the beneficiary of his or her financial liability. Beneficiaries who disagree with such determinations may continue raising these issues through the Medicare fee-for-service appeals process if the determination relates to Part A or B coverage and the Part D appeals process if the determination relates to Part D coverage. Beneficiaries may also submit quality of care complaints to a Quality Improvement Organization when the beneficiary prefers a non-formulary drug because, for example, it's believed to be more efficacious than the formulary drug prescribed by the hospice.

Part D Transition for Changes in Level of Care

Existing transition guidance in Chapter 6 of the Medicare Prescription Drug Benefit Manual §30.4.7 discusses level of care changes and transition. The guidance states that circumstances exist in which unplanned transitions for current enrollees could arise and in which prescribed drug regimens may not be on sponsor formularies. These level of care changes involve a beneficiary changing from one treatment setting to another, and include beneficiaries who revoke hospice to revert to standard Medicare benefits.

For these unplanned transitions, beneficiaries and providers must avail themselves of sponsor exceptions and appeals processes. CMS has streamlined the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, CMS makes it clear that a Part D sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires.