National Hospice and Palliative Care Organization

Revised Part D Guidance: NHPCO Regulatory Alert

July 24, 2014

Summary

On Friday, July 18, 2014 CMS issued revised guidance (PDF) to **replace the March 10, 2014 guidance** to hospices and Part D plan sponsors regarding payments for medications. NHPCO is very pleased with the changes in the revised guidance, and that we accomplished our primary of goal of removing hospice patients and their families from the confusion surrounding the previous policy. As frontline caregivers, the hospice community led the effort to educate Congress, CMS and the White House, in addition to engaging with relevant stakeholders. Our monumental efforts were a success and our voices were heard!

The revised guidance changes the prior authorization (PA) requirement to **ONLY** the four classes of drugs referenced in the OIG 2012 Report – analgesics, anti-emetics, laxatives, and anti-anxiety medications. In the revised guidance, CMS cites these four categories of drugs as being most often used to treat symptoms of patients at the end of life.

THIS GUIDANCE DOES NOT CHANGE THE RESPONSIBILITY OF THE HOSPICE TO PAY FOR ALL MEDICATIONS RELATED TO THE TERMINAL ILLNESS AND RELATED CONDITIONS, WHETHER OR NOT THEY ARE INCLUDED IN THE FOUR CLASSES IDENTIFIED ABOVE. THAT RESPONSIBILITY REMAINS.

WHAT DOES THIS MEAN FOR HOSPICE PROVIDERS?

Q: *Does this mean that hospices will only cover meds 'related to terminal diagnosis' going forward?*

A: Your hospice's coverage of drugs **DOES NOT CHANGE**. Your hospice will be responsible for drugs related to the terminal diagnosis **AND related conditions.**

Q: *Is CMS going back to the "old way of doing things" so that the hospice can just pay for drugs on formulary and in the four classes and Part D will pick up the rest?*

A: NO! Your hospice is expected to provide for **ALL drugs related to the terminal illness and related conditions**. If a drug prescribed for a hospice patient is not on formulary, your hospice has the responsibility to see whether a clinically equivalent drug on formulary will work. IF NOT, the hospice is responsible for the payment for any drug off formulary that will provide symptom management for the patient.

Q: *Does this mean that patients can have whatever drug they want and Part D will pay if hospice doesn't want to pay?*

A: NO! Part D will only process payments for drugs that are **unrelated** to the terminal illness and related conditions.

Q: *Because there is only a PA on four classes of drugs, does it mean that CMS is no longer watching to see what drugs are paid for under Part D?*

A: NO! CMS will be watching hospice behavior very closely to see whether this change in the PA process will increase the Part D expenditures for hospice patients. This is an interim policy. If there is an increase in the expenditures for hospice patients, the next phase of this policy will have much more serious consequences for hospice providers.

This Regulatory Alert below provides detailed analysis of the revised guidance and is designed to be an easy reference to the many complexities of the work with Part D sponsors.

Prior Authorization Process Limited

- **Prior authorization explained:** The language "Prior Authorization" (PA) refers to the process the Part D sponsor must conduct AFTER a claim has been submitted and rejected by the Part D sponsor or pharmacy. A hospice can avoid the PA process by proactively communicating with the Part D sponsor on admission. The hospice also should communicate with the Part D sponsor regarding revocation and/or discharge of a hospice patient. See the sections below for more details.
- **Effective date:** Effective immediately, and no later than October 1, 2014, Part D sponsors will require a prior authorization (PA) **ONLY** for the four classes of drugs referenced in the HHS Office of Inspector General (OIG) June 2012 Report – analgesics, anti-emetics, laxatives, and anti-anxiety medications. The guidance states:

  > ""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, antinauseants, laxatives, and antianxiety drugs."

- **Drugs in one of 4 classes unrelated to terminal prognosis:** If a hospice patient is receiving a drug in one of the four classes that is **CLEARLY AND UNEQUIVOCALLY UNRELATED** to the patient's terminal prognosis, a PA will be required by the Part D sponsor for the drug to be processed by Part D.
- **Clinical rationale for unrelated:** In the section of the standardized form entitled "Rationale to Support the Medication is Unrelated to Terminal Illness," no rationale is needed on the form but the statement in this section may be a "U" or "unrelated". However, documentation of the clinical basis for the determination that the drug is unrelated must be in the medical record and available upon request.
- **Part D accepts the provider's statement:** The guidance states that Part D sponsors should "accept the prescriber's or hospice provider's statement and retain the documentation."
- **No PA needed outside these four classes:** **NO** PA is needed for any other drug outside these four classes. **However, if the drug is related to the patient's terminal prognosis, the hospice is responsible for paying for it, and must begin to pay for drugs that are related to the patient's terminal prognosis even if Part D was paying for the drug prior to the patient's hospice election**. If it is **deemed unrelated by the hospice medical director**, no action is needed. Part D will continue to process for payment according to ongoing Part D regulations.

Hospice Responsibility for Medications

- **Hospice responsibility for payment:** **NOTHING** in the revised guidance will change Medicare hospice providers' responsibility to provide **ALL** of the medications that are reasonable and necessary for the patient's terminal illness and related conditions, even those which are not on formulary for the hospice but are successful in treating the patient's symptoms.

- **CMS watching:** CMS will be watching very carefully to see what medications outside the 4 classes have been requested for payment by Part D. It is up to the hospice community to maintain their responsibility to pay for all related medications. This is interim guidance. If the result is a significant increase in Part D expenditures for patients after their hospice election, the next phase of guidance and regulation for hospice providers will be impacted.
- **Documentation in medical record:** While the clinical justification that a drug is "unrelated' is no longer required on the standardized form, documentation supporting the determination that medications are not related to the terminal illness and related conditions should be maintained in the clinical record and must be available for audit by the Part D sponsor or others.
- **Documentation on relatedness part of drug profile:** Hospices should complete the drug profile during the comprehensive assessment, as the plan of care is being developed and updated. CMS expects that hospices will have appropriate medication documentation for each hospice beneficiary upon completion of these assessments, including documentation on whether the medications are related or unrelated to the terminal illness and related conditions.
- **Proactive communication to Part D:** Hospice providers should be prepared to provide information on unrelated medications to the Part D sponsor proactively, as soon as a patient is admitted – so that there is no claim rejected – or if not provided proactively before a claim is rejected, provided when the Part D sponsor contacts the hospice provider during the Prior Authorization (PA) process.

Over the Counter Medications

- **Inappropriate hospice requests for Part D coverage:** In the period after the March 10, 2014 guidance was implemented, some hospices submitted requests to Part D for payment of multi-vitamins, calcium supplements, 81 mg aspirin, cough drops and other OTC medications. These drugs are not covered by Part D.
- **Statutory requirement for noncoverage:** The revised guidance specifically states 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."**
- **Hospices should not submit requests for OTC coverage from Part D:** Please ensure that OTC medications are not submitted to Part D plans or pharmacies for coverage and that patients are not led to expect that such drugs will be covered by Part D.

Standardized Form

- **Use revised form:** CMS recognized that a standardized form was developed by the National Council of Prescription Drug Programs (NCPDP) Hospice Task Group, where NHPCO was an active participant. The form is now widely accepted by the industry. CMS offered several edits to the May 2014 form and released the revised version with the revised guidance on July 18, 2014. A fillable form is now available on the NHPCO website. **Providers should use the revised form in future communications with Part D sponsors (PDF).**
- **Form availability:** The form is available on the NHPCO website at nhpco.org/regulatory or on the CMS website (PDF). Note that the form on the NHPCO website has been designed as a fillable form (PDF). The downloaded form from the CMS website is not fillable.

- **Use page 1 of form:** CMS strongly recommended that the first page of the form be used by hospices in communication with Part D sponsors until a standardized form has been through the CMS official approval process. **Only drugs unrelated to the terminal illness and related conditions are reported on page 1.**
- **Form use confirms unrelated drug:** CMS states that "listing the drug here in effect constitutes a statement by the hospice provider or the prescriber that the drug is unrelated."
- **Marking form for unrelated:** The space for a rationale is provided on the form. However, only a "U" or "unrelated" needs to be included on the form. While a clinical rationale is not required for the form, hospices should document the basis for the determination and include the findings in the medical record.
- **Second page of form:** Hospice providers are not required to complete the second page of the form, but completing it will assist Part D sponsors in their care coordination activities.
- **Part D sponsor form acceptance:** CMS states that "as long as the necessary statement that the drug is unrelated is provided, the sponsors should accept it in any format."
- **Reporting election or termination:** The hospice can also use the first page of the form to report only a beneficiary's hospice election or termination, even if the patient is not taking any drugs requiring PA. 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 or revocation). This will ensure more timely notification of Part D sponsors that a beneficiary has elected hospice, or that they have revoked or been discharged from the benefit and should resume access to their full Part D benefit.

Communicating with the Part D Sponsor about Hospice Election

- **Report a hospice election to the Part D sponsor:** Report the beneficiary's hospice election as soon as the patient elects. The standardized form may be used for this purpose, checking the box on the first page indicating the hospice election. The form should then be faxed or mailed to the Part D sponsor, depending on the Part D sponsor's direction and guidance to the hospice provider.
- **CMS guidance to Part D sponsors:** CMS states that they "strongly recommend sponsors use the first page of the form as edited until a standard Part D hospice PA form is approved."

Communicating with the Part D Sponsor about Hospice Revocation and Discharge

- **Report a hospice revocation or discharge to the Part D sponsor:** Report the beneficiary's hospice revocation or discharge as soon as the patient revokes or is discharged. Hospice providers are "encouraged to report a beneficiary's discharge or revocation from the Medicare hospice benefit to the Part D sponsor."
- **Standardized form:** The standardized form (PDF) may be used for this purpose, checking the box on the first page indicating the hospice revocation or discharge.
- **Acceptable documentation:** CMS states that "Acceptable documentation is dependent upon the reason for the termination. In addition to the standardized form, this may include:

- **Revocation:** 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.
- **Discharged because no longer terminally ill:** 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.
- **Discharged for cause or moves out of service area:** 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."

- **Evidence of revocation or discharge:** 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 Notice of Medicare Non Coverage (NOMNC)
  - the hospice provider's discharge summary
  - page 1 of the standardized prior authorization form
- **Part D sponsor acceptance of evidence:** CMS states: "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."
- **Lag time:** Both hospices and Part D sponsors have expressed concern about the potential length of the lag time in reporting a revocation or discharge. In this guidance, CMS has encouraged plans to use the evidence above as "best available evidence" or BAE, to update systems **before** the DTRR reporting system for Part D sponsors is updated. The action the Part D sponsor would take is to remove the beneficiary-level hospice PA edit on the four categories of drugs, unless the reports show that a new benefit period has started.

Compassionate First Fill If the Beneficiary is Having Difficulty Accessing Needed Drugs

- **Medications needed by patient:** CMS strongly encourages hospice providers to "provide a compassionate first fill for any medication needed by a hospice patient who is experiencing difficulty in accessing the drug at "point-of-sale" in spite of the efforts described above.
- **Unrelated?:** 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.
- **Beneficiary responsibility**: The hospice should pay particular attention to whether the "compassionate first fill" is for a medication that is related or unrelated but no longer medically necessary, for which the beneficiary is responsible. Beneficiaries also may be responsible if the drug is unrelated to the terminal prognosis but is not covered by Part D.
- **Resources:** NHPCO will develop sample language for hospices to use when seeking reimbursement from a Part D sponsor for compassionate first fills that are **unrelated to the terminal illness and related conditions.**

Medicare Advantage/Part C

- **Resumption of Coverage under MA Plans:** For hospice patients 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.

Advanced Beneficiary Notice (ABN)

- **No ABN required:** 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).
- **ABN required when:** 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**.

Pharmacy Involvement

- **Patients and families at pharmacy counter:** There are times when a patient or their family bring documentation to the pharmacy counter (point of sale – POS) showing a hospice termination, or evidence that a particular drug is unrelated to the terminal illness or related condition. Often this documentation will provide information that allows immediate access to a prescribed drug.
- **Pharmacy help for patients and families:** CMS states: "Part D 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."
- **Pharmacy direction to hospice or Part D sponsor for more information:** Pharmacies may also explain to patients and families why a claim has been rejected because of the patient's hospice election and provide additional guidance to contact the Part D sponsor or the hospice for more detailed information.

Beneficiary Appeals

- **Hospice communication with patients about financial liability:** 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.
- **Beneficiary appeal rights:** 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.
- **Complaints to QIO:** CMS states: "**Beneficiaries may also submit quality of care complaints to a Quality Improvement Organization (QIO) 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."**

Pending Claims

- **Coverage determinations pending:** Hospices may have some claims that are awaiting a coverage determination because the claim was previously rejected under the March 10 2014 policy.
- **CMS direction to Part D sponsors:** CMS states: "Since these claims should no longer to 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."**

Retroactive Recoupment

- **Part D Payment After Hospice Election:** If a Part D sponsor has paid for drugs in the four classes after the patient elects hospice but before a hospice election is known, the Part D sponsor should review claims after the hospice election and determine retrospective payment responsibility. CMS expects the hospice provider or unaffiliated prescriber to provide necessary written or verbal statements to the Part D sponsor that "the drug is either unrelated to the terminal illness or related conditions, or is a beneficiary liability."
- **Hospice payment responsibility:** If the drug is determined to be a hospice responsibility, the Part D sponsor and the hospice should negotiate repayment.
- **Beneficiary responsibility:** If the drug is determined to be a beneficiary responsibility, the Part D sponsor should send a recovery notice to the beneficiary.
- **Part D payment process:** Part D sponsors should develop processes to handle resolution of payment directly with hospice providers without involving the pharmacy in the retail setting. If a network pharmacy is also the hospice pharmacy, as in long-term care pharmacies, reversing the claim and rebilling may be appropriate.

Updates to PECOS

- **Hospice updates:** It is more important than ever that hospices update and keep current any information about the hospice in the PECOS system. This system will be used by the Part D sponsor for communication with the hospice about Part D PA issues and beneficiary concerns.
- **Link to PECOS:** The system is accessible via the CMS Website.

NHPCO will continue to work with other stakeholders to insure a smooth transition to the new guidance and to continue discussions about issues and a longer term solution. Watch for educational opportunities, webinars and other written resources from NHPCO to assist providers in implementing these changes and adjusting admission and medication management processes for the revised guidance.

This revised guidance is likely to raise many questions about implementation about this complex issue. NHPCO has been in the forefront of work on this issue and can answer questions or raise additional concerns to CMS or to Part D plans. Please don't hesitate to write us at regulatory@nhpco.org.

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Visit the NHPCO Part D Revised Guidance page online for updated information.

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