Let's Talk About

- The History: How We Got to Where We Are Today
- Understanding Part D
- The 2014 Final Part D Guidance
- Key Internal Processes
- Final Thoughts – Gazing into the Crystal Ball

The History: Medicare Part D & Hospice

- 1983: Hospice Medicare benefit created; includes coverage of medications related to pain control and symptom management of terminal diagnosis and related conditions
- 1983-2006: Medicaid programs were paying for many medications that actually were the responsibility of hospices; problem particularly pronounced in NF residents receiving hospice care
- 2006: Medicare Part D commenced – problem continued but now with Medicare paying
- 2006 forward: Office of the Inspector General (OIG) includes the issue in almost every annual work plan
- 2009: OIG starts visiting hospices to start to learn more about provision of medications
- 2012: OIG issues report Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice
OIG FY 2012 Work Plan

Duplicate Drug Claims for Hospice Beneficiaries

We will review the appropriateness of drug claims for individuals who are receiving hospice benefits under Medicare Part A and drug coverage under Medicare Part D. We will determine whether payments under Part D are correct, supported, and not duplicated in hospice per diem amounts. We will also determine the extent of any duplication found and identify controls to prevent duplicate drug payments. ... (OAS; W-00-10-35307; W-00-11-35307; various reviews; expected issue date: FY 2012; work in progress)

OIG Report A-06-10-00059 (June 2012)

The Catchy Title

Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice

The Project Objective

To determine whether Medicare Part D paid for prescription drugs that likely should have been covered under the per diem payments made to hospice organizations

The OIG’s Methodology

• They set out to see if they could identify specific medications that should always be covered by hospice
• Determined that hospice patients, regardless of terminal DX, routinely experience 4 symptoms
  • Pain
  • Nausea
  • Constipation
  • Anxiety
• Identified 469 medications that hospices likely should cover but recognized that there could be exceptions
• Using same methodology, identified 54 COPD drugs and 1 ALS drug
Findings

Using data from 2009 claims, the OIG determined that Medicare Part D paid for the following types of drugs that should have been (in most cases) paid for by hospices

- Analgesics
- Anti-nausea
- Laxatives
- Antianxiety drugs

Additionally, they identified some COPD and ALS medications they believed should have been covered by hospice.

<table>
<thead>
<tr>
<th>Category</th>
<th># of Medicare Part D Prescription Drug Event Records</th>
<th>Amount of Medicare Part D Payments</th>
<th>Amount of Beneficiary Copayments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Analgesic</td>
<td>428,084</td>
<td>$21,904,799</td>
<td>$2,348,515</td>
</tr>
<tr>
<td>2. Anti-nausea</td>
<td>95,137</td>
<td>$2,908,456</td>
<td>$409,606</td>
</tr>
<tr>
<td>3. Laxative</td>
<td>76,404</td>
<td>$1,888,267</td>
<td>$252,688</td>
</tr>
<tr>
<td>4. Antianxiety</td>
<td>23,884</td>
<td>$279,270</td>
<td>$81,745</td>
</tr>
<tr>
<td>TOTAL</td>
<td>623,503</td>
<td>$26,980,792</td>
<td>$3,092,554</td>
</tr>
</tbody>
</table>

DX Specific

<table>
<thead>
<tr>
<th>Category</th>
<th># of Medicare Part D Prescription Drug Event Records</th>
<th>Amount of Medicare Part D Payments</th>
<th>Amount of Beneficiary Copayments</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPD</td>
<td>52,861</td>
<td>$6,085,347</td>
<td>$693,432</td>
</tr>
<tr>
<td>ALS</td>
<td>652</td>
<td>$571,998</td>
<td>$49,561</td>
</tr>
<tr>
<td>TOTAL</td>
<td>53,513</td>
<td>$6,657,345</td>
<td>$742,993</td>
</tr>
</tbody>
</table>

* Included 14,500 RXs for chemotherapeutic agents totally ~ $7m

OIG Recommendations to CMS

1. Educate sponsors, hospice and pharmacies that it is inappropriate for Part D to pay for drugs related to terminal DX
2. Perform oversight to make sure that Part D is not paying for drugs that Medicare has already paid through via payments to hospices
3. Require sponsors to develop controls that prevent Part D from paying for drugs that are already covered under the per diem payments
Understanding Controls

- Built in stop-points in the claims processing system that cause a claim to "kick-out" without paying
- Examples for beneficiaries in a current hospice election period
  - Hospital inpatient and SNF claims – unless claim contains "07" condition code
  - Continuous care when Q code indicates beneficiary is in an acute care setting

There were no controls in place for Part D claims at that time – and CMS knew that it would be difficult to institute given Part D structure.

Common Process Problems at that Time

1. Is medication used for terminal, related or secondary DX?  
   - Yes: PROBLEM #1
   - No: Common Process Problems at that Time

2. Is it reasonable & necessary for palliation of pain or SX management?  
   - Yes: PROBLEM #2
   - No: PROBLEM #3

3. Hospice Pays  
   - Yes: PROBLEM #4
   - No: PROBLEM #5

4. Beneficiary told that it will not be covered under Hospice Medicare Benefits  
   - Part D Covers

Medicare Part D
### Medicare Options

<table>
<thead>
<tr>
<th>Traditional Products</th>
<th>Managed Care Type Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>A 80/20 Plan</td>
<td>C Medicare Managed Care</td>
</tr>
<tr>
<td>B Physicians +</td>
<td>D Prescription Drug Plans</td>
</tr>
</tbody>
</table>

### Medicare Part D Quick Look

- Part D is an optional benefit; must be enrolled in Part A or Part C to access it.
- Since 2006 share of Medicare beneficiaries enrolled in Part D Plans has risen from 53% to 72%.
- Average enrollee had a choice of 30 PDPs and 15 MA-PD plans in 2015.
- PDP premiums vary widely across plans and across regions.
- Three largest plans: United Health, Humana & CVS.
- Each sponsor can establish its own processes and policies – as long as they meet the CMS requirements.

### Inherent Structural Problems

- Due to benefit structure, usual control over payment or coverage is absent.
- Hospice issue is not the first to surface.
- Part of challenge is how to make coverage determinations in a timely manner with sometimes limited information.
- CMS goal: do not cause hardship for beneficiaries.
Some Important Definitions

Part D Plan Sponsor
Company that has applied to CMS and been approved to offer a plan

Part D Plan
Insurance product with specific formulary, coverage rules, and monthly premium

Utilization Management Tools
Set of techniques used by or on behalf of purchasers of health care benefits to manage health care costs by influencing patient care decision-making through case-by-case assessments of the appropriateness of care prior to its provision

(Institute of Medicine Committee on Utilization Management by Third Parties 1989)

Three Utilization Management Tools*

Quantity Limits
For certain drugs, we limit the amount of the drug we will cover per prescription or for a defined period of time

Step Therapy
In some cases, we require you to first try certain drugs to treat your medical condition before we will cover another drug for that condition. For example, if Drug A and Drug B both treat your medical condition, we may not cover Drug B unless you try Drug A first. If Drug A does not work for you, we will then cover Drug B

Prior Authorization Requirements
We require you to get prior authorization for certain drugs...This means that you will need to get approval before you fill your prescriptions. If you don’t get approval, Care1st may not cover the drug

*as defined in Care1st Part D subscriber Information

Back to the History

2012
OIG issues report Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice
Part D plans instructed to recoup money from hospices for 2011 & 2012 prescriptions analgesics paid for by Part D

2013
Directed Part D plan sponsors to put PA requirements in place for all prescriptions for hospice beneficiaries

March 2014
Memo to All Plan B Sponsors: Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – 2015 Guidance directed sponsors to put a PA requirement in place for all hospice medications

July 2014
Memo to All Plan B Sponsors: Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice retracted earlier direction and advised PAs on the four drug classes only

Dec 2014
Standard PA form developed and approved to facilitate coordination between Part D sponsors, hospices and prescribers.
Payment Responsibility

Assuming that the beneficiary is enrolled in Part D, once a hospice election is made, payment responsibly for any prescription medication will belong to one of three parties.

Who Pays?

Hospice  Part D  Beneficiary

The Assumptive Answer

Drugs Covered under Part D for a Beneficiary Who Has Elected Hospice

For prescription drugs to be covered under Part D when the enrollee has elected hospice, the drug must be for treatment of a condition that is completely unrelated to the terminal illness or related conditions; in other words, the drug is unrelated to the terminal prognosis of the individual. We expect drugs covered under Part D for hospice beneficiaries will be unusual and exceptional circumstances.

CMS Final 2014 Guidance

The New Question

Is medication used for TERMINAL, RELATED OR SECONDARY DX?

Is it reasonable & necessary for palliation of pain and/or symptom management?

Does medication make sense at this time?

Yes

No

Yes

No

Yes

No

Hospice Pays

Beneficiary Pays or Agrees to D/C Med

Discontinue

Part D Processes
Where We Are Today

1. Part D Plans are to fill prescriptions presented for beneficiaries under a current hospice election period unless they are for one of the 4 classes of medications.
2. In those situations the hospice must complete and submit the PA form to the plan in order to secure coverage under Part D.
3. CMS continues to push towards “related to the terminal prognosis” rather than diagnosis.
4. Hospice physicians are expected to document reasons why a specific medication for a specific patient is found to be unrelated to the prognosis.
5. Hospices are getting recoupment requests for medications in the 4 categories filled after a hospice election.
6. There are no immediate appeal rights for beneficiaries if a hospice denies coverage of a specific related medication.

New Reject Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Verbiage</th>
</tr>
</thead>
<tbody>
<tr>
<td>822</td>
<td>Drug is unrelated to the terminal illness and/or related conditions. Not covered under Hospice.</td>
</tr>
<tr>
<td>823</td>
<td>Drug is beneficiary’s liability – not covered by Hospice or Part D. Hospice non-formulary.</td>
</tr>
</tbody>
</table>

Key Internal Processes

1. Determining coverage
2. Documenting and communicating coverage
3. Documenting and communicating non-coverage
4. Assessing competencies in having the conversations with patients and families.
Determining Coverage

Who does it now & how consistent is it?
- Individual RN case managers
- Hospice physicians
- Consulting pharmacists
- The IDG

On what basis is the determination being made?
- Preferred drug list
- Observed efficacy
- Habit
- Cost

Determination Sequence

Step 1 Determine terminal diagnosis

Step 2 Categorize additional diagnoses and conditions into related, secondary and unrelated. Are they impacting prognosis?

Step 3 Make coverage determinations

Documenting & Communicating Coverage

Documenting coverage or non-coverage
- Plan of care and/or medication list
- If coverage decision involved deliberation, is that process documented?

Communicating coverage – pharmacies & other providers & Part D plan
- Based on how your hospice obtains medications, how is the communication made and by whom?
- If working with a long term care pharmacy, how is that communication made? Is it effective?
- What communication is made with nursing facility?

Communicating coverage – beneficiary and family
- By whom and how?
- If switching meds to those on preferred drug list, how does that communication go?
- If drug will not be covered, how does that communication go?
Communicating Coverage: Part D Plans

Document developed jointly by task force & made available for use in 2014

Purpose: facilitate coordination between Part D sponsors, hospice and pharmacies

Two primary uses
1. Document that a drug is unrelated to a beneficiary's terminal prognosis
2. Convey a beneficiary's change in hospice status

Can we expect expansion of use in the future?

Implications for Beneficiaries

• One positive for hospices is the clarity that this discussion has brought regarding situations in which the beneficiary may have financial liability

• Examples
  • Beneficiary wants to continue or start a medication that a hospice determines is not reasonable or necessary for the palliation and management of the terminal illness and related conditions
  • Beneficiary wants a non-formulary drug and refused to try a formulary equivalent first
  • With this clarity as well as the increase in discussions on Part D have come some challenges for hospices

Communication with Patients & Families

1. We need to increase the frequency of conversations about discontinuing medications that no longer make sense – related and unrelated
2. We need to do so without using jargon, particularly in conversations that involve telling a patient or family that something will not be covered
3. We must recognize that those conversations are about much more than medications
Areas to Evaluate

1. Initial process of establishing terminal DX, sorting out the others and sorting out the medications
2. External and internal communication of above
3. Documentation of above – needs to be consistent and easily retrievable
4. Current competencies in having conversations with patients and families
5. Knowledge level of patient’s encounters with other non-attendings
6. Communications with Part D sponsors: who, how, when, record keeping, etc.

Some Larger Considerations

Do you know what your hospice is paying for and what Part D is paying for?
The government does! Data mining is very easy and rewarding these days

1. ICD – CM 10 Coding
2. Medications – Provided by Hospice
3. Medications – Provided under Part D

What May Be Coming?

• Continued analysis of medications paid for by Part D
• No backing off from CMS on prognosis versus diagnosis expectation
• Independent review function for hospice coverage decisions for clearly related medications
Related Medications Outside the POC

The OIG report did not address situations in which the hospice IDG determined that a medication, although related, will not be covered in the hospice POC

* Is that allowable?
* How is it handled in your hospice?

§418.106 Condition of Participation:
Drugs and biologicals, medical supplies, and DME

Medical supplies and appliances, as described in §410.36 of this chapter; durable medical equipment, as described in §410.38 of this chapter; and drugs and biologicals related to the palliation and management of the terminal illness and related conditions, as identified in the hospice plan of care, must be provided by the hospice while the patient is under hospice care.

Related Medicines Outside the POC

What about situations in which
* Medications are outside of hospice formulary and hospice has provided clinical equivalent
* Medication is determined to no longer be clinically indicated but beneficiary wishes to continue
* Hospice formulary calls for step therapy but beneficiary chooses to skip step one and move straight to other medication first

ABN is not required unless the hospice
* Has determined that the medication is beneficiary's financial responsibility
* Will provide the medication and bill the beneficiary
Independent Review Function

- December 2013 memo discussed the establishment of an independent review process – would require rulemaking
- Commenters suggested that stakeholders work with CMS to
  - Establish standards and criteria for reviewer to use in making coverage determinations
  - Reviewer qualifications
  - Timeframes for each phase of the process
- CMS concurs and "will consider the process for future rulemaking"
- Expect an expedited review process in the future

Some Closing Thoughts

1. Assume that at some time in the future someone from the outside will be looking at every piece of documentation created to support your position that Part D should cover a med. Document well.
2. Surprises at the pharmacy make everyone unhappy. Do all that you can to minimize them.
3. Don’t get too comfortable with this free-pass system – consider it a short term situation and sharpen medication evaluation and management skills
4. Expect another chapter

To Contact Us

Susan Balfour
919-491-0699
Susan@HospiceFundamentals.com

Roseanne Berry
480-650-5604
Roseanne@HospiceFundamentals.com

Charlene Ross
602-746-0783
Charlene@HospiceFundamentals.com

The information enclosed was current at the time it was presented. This presentation is intended to serve as a tool to assist providers and is not intended to grant rights or impose obligations.

Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.
## Coordination of Benefits for Hospice Medicare Patients with Part D Coverage

### Significant Documents

<table>
<thead>
<tr>
<th>Year</th>
<th>Issuing Entity</th>
<th>Title</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec 2013</td>
<td>CMS</td>
<td>Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Request for Comments</td>
<td><a href="https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-PartD-Payment.pdf">https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/Hospice-PartD-Payment.pdf</a></td>
</tr>
</tbody>
</table>

January 2016