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The Non-Clinical Side of Hospice Relatedness Determinations:

The Legal Framework to Help Improve Processes & Defend Against Government Challenges

Mary Michal, JD
Reinhart Boerner Van Deuren s.c.
(608) 229-2204
mmichal@reinhartlaw.com

Kate A. Proctor, JD
Reinhart Boerner Van Deuren s.c.
(608) 229-2213
kproctor@reinhartlaw.com

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Goals

- Understand the legal framework for relatedness decisions and implications of present guidance
- Explore key issues arising in context of relatedness determinations and their implementation
- Learn methods for substantiating and defending challenges to relatedness determinations and their implementation

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Preface

- This presentation is meant to provide a general review of non-clinical issues regarding making and implementing determinations about what is related to the terminal illness
- This presentation does not constitute legal advice, and is not intended to take the place of legal advice

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What Would You Do?

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Hypothetical

- If the government called today, how would you answer these questions?
  - What is your process for determining what is related to the terminal illness and related conditions?
  - How do you support determinations that an item or service is unrelated?
  - How do you communicate relatedness determinations to contracted providers furnishing the service?
  - Are contracted providers correctly implementing your decisions?
  - How do you communicate relatedness determinations to patients and families?

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Hypothetical (con't)

- If the government called today, could you prove your answers through documentation?
  - Process
    - E.g., What are your policies and procedures? How do you demonstrate that they are followed in making relatedness determinations?
  - Clinical Support
    - E.g., What clinical evidence is documented to support a relatedness determination? Who is documenting?
  - Communication
    - E.g., How are relatedness determinations communicated to contracted providers and patients/families? How is that communication documented?
  - Implementation
    - E.g., How are you ensuring that your relatedness determinations are being correctly acted upon?

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Why Are We Talking About Relatedness Now?

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Why Are We Talking About Relatedness Now?

- Recent government activity around how relatedness determinations are made and implemented
  - OIG
    - 2007 – 2012 Work Plans: Part D "duplicate payment" for prescription drugs for hospice patients
    - 2007 Report: Reviewed 1 pharmacy's billings for 4 hospice patients living in a nursing home
    - 2012 Report: Data analysis of Part D "duplicate payment" of drugs commonly used at end-of-life for hospice patients

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Why Are We Talking About Relatedness Now? (con't)

- Medicare Part D
  - Plan sponsor audits of pharmacy claims for hospice patients
  - CMS guidance regarding potential "duplicate payments"
    - 2010 memo to Part D plan sponsors with instructions to work with long term care pharmacies to implement safeguards
    - August 2013 memo to Part D plan sponsors to delete pharmacy claims for common hospice-related medications
    - October 2013 memo to Part D plan sponsors to recover payment from hospices for all analgesics billed by pharmacies
    - December 2013 memo to Part D plan sponsors and hospices with proposed CMS guidance on determining payment responsibility for drugs
    - March 2014 final guidance to Part D plan sponsors and hospices on determining payment responsibility for drugs

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Why Are We Talking About Relatedness Now? (con't)

- Relatedness decisions and enforcement are not limited to pharmacy
  - For example:
    - Hospital services and inpatient stays
    - Physician billing
    - DME

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Why Are We Talking About Relatedness Now? (con't)

- Medicare Hospice
  - 2014 Wage Index
    - Requires more specific diagnosis coding
      - Claims with debility, adult failure to thrive, etc. will be returned
    - Requires hospices to include the specific terminal illness, as well as related conditions, on claims
    - Requires hospices to include each fill of prescription drugs they provide on claim
      - CMS Change Request 8358

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Why Are We Talking About Relatedness Now? (con't)

- Medicaid
  - Audit hospices for payments Medicaid made to pharmacies
- RAC Audits
  - Auditing contracted provider claims that may be related to hospice patients' terminal illnesses
    - DME
    - Inpatient and outpatient services
    - Physician Part B claims

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What Issues Are Being Raised?

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Key Issues Raised

1. Covered services: "Virtually all" does not equal all
2. Process for determining coverage: Physician driven, individualized, supported and documented
3. Implementation of coverage determinations: Processes and issues after the relatedness determination is made

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Covered Hospice Services: Standard

- Coverage of "related" services codified in statute and regulations
- To be covered by the hospice, services must be (42 C.F.R. 418.200):
  - Reasonable and medically necessary
  - For the palliation and management
  - Of (i.e., related to) the "terminal illness" and "related conditions"
- Hospices should only be required to cover items and services that meet these three elements
  - Waiver of Medicare coverage is limited to those items and services related to the terminal illness

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Covered Services: "Virtually All"

- Consider covered services in light of guidance to include additional diagnoses related to the terminal illness on claim form
- 1983 CMS commentary indicates an expectation that "virtually all" services would be covered by hospices as related to the terminal illness and related conditions
  - Note patient population in 1983 included mostly cancer patients
  - Now more non-cancer patients, patients with chronic conditions

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Covered Services: "Virtually All" Is Not All

- Recent CMS guidance to Part D plans and hospices issued December 6, 2013 reiterated expectation that hospices cover "virtually all" care
  - Except items and services unrelated to the terminal illness and related conditions
  - "The regulations do not enumerate the specific services that . . . might [be] related or equivalent to hospice care because it was recognized that there are many illnesses which may occur when an individual is terminally ill, which are brought on by the underlying condition(s) of the patient."
  - "[B]eneficiaries should only very rarely be taking drugs that are not covered under the hospice per diem."
- Services that are related to the terminal illness and related conditions, but not medically necessary, are covered by the beneficiary
- In March 10, 2014 final guidance, CMS reiterated they "expect drugs covered under Part D for hospice beneficiaries will be unusual and exceptional circumstances."

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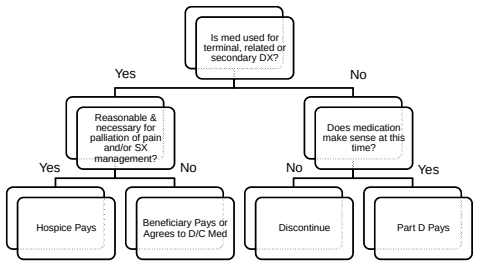
Hospice Fundamentals Decision Tree



Process: Determining Coverage

- Process for determining relatedness generally includes 4 considerations:
  - There is a determination that needs to be made
    - Default is that items and services are related to the terminal illness
  - Who makes the determination
  - What is the standard for relatedness
  - The determination is documented and supported

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Process: Physician-Driven

- CMS commentary indicates physicians should make related determination
  - Acknowledge relatedness decisions require "clinical expertise and judgment" of the hospice physician (Commentary to Final FY 2014 Wage Index)
  - Prescriber contacts Part D plan sponsor to complete PA process (March 10, 2014 CMS memo)
  - But, expect documentation to support that the service is "completely unrelated" to the terminal illness and related conditions (Commentary to 1983 proposed rule on Medicare Hospice Benefit; December 6, 2013 memo to Part D plans and hospices)

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Process: Standard

- An item or service needs to be "completely unrelated" to the terminal illness and related conditions (CMS commentary to the 1983 proposed rule on the Medicare Hospice Benefit)
  - Decision should be made on a "case-by-case basis" (CMS commentary to the 1983 final rule on the Medicare Hospice Benefit)
  - Based on "the unique physical condition of each terminally ill individual" (CMS commentary to the 1983 final rule on the Medicare Hospice Benefit)
  -

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Process: Documentation and Support

- CMS indicates physicians should document if they determine an item or service is not related
  - "Clear evidence" needed to show that a service is unrelated (CMS commentary to Final FY 2014 Wage Index)
  - Little guidance as to what "clear evidence" would consist of

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Implementation: Covering Related Services

- If a service is determined related and otherwise covered, hospice needs to cover by providing directly or arranging for another provider
- Hospices finding correct decision was made, but incorrectly implemented by contracted provider (e.g., DME, pharmacy)
  - How did this happen?
  - What do you do about it?

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What Can You Do Now?

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Hypothetical

- If the government called tomorrow, how could you improve your answers to the following questions?
  - What is your process for determining what is related to the terminal illness and related conditions?
  - How do you support determinations that an item or service is unrelated?
  - How do you communicate relatedness determinations to contracted providers furnishing the service?
  - Are contracted providers correctly implementing your decisions?
  - How do you communicate relatedness determinations to patients and families?

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Process: Considerations

- Real-time decision making
- Affirmative determinations for both related and unrelated items and services
- Consistent process regardless of cost
- Consider which physician will be primary decision-maker regarding relatedness
- Physician consultation with IDT and others (e.g., pharmacist)

Note: There will be prior authorization and other requirements for Part D

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Process: Considerations (con't)

- Consider additional processes
  - May want higher level of review for expensive, unique or recently scrutinized services (e.g., analgesics, laxatives, antinauseants, antianxiety)
    - Medical director (if IDT physician makes original determination)
    - Quality review committee
    - Others, with physician
  - Re-evaluate relatedness decisions periodically

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Clinical Support: Considerations

- Review standards to consider:
  - "Clear evidence"
  - "Substantial evidence" – Reasonable person would accept evidence as supporting the determination
  - Reasonable degree of clinical certainty
- Documentation takes into account the patient's particular terminal illness and "related conditions"
- Consider whether coverage determinations are consistent with diagnoses listed on claim
- Having a formulary is not enough

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Clinical Support: Considerations (con't)

- Who is documenting decision?
  - Proof that physician is making determination
- How is decision documented?
  - Conclusory statement vs. narrative explanation
  - Standardized form may help probe reasoning and encourage thorough documentation
- Is there additional clinical support?
  - Assessments, labs, diagnostics
    - Obtaining clinical support vs. patient palliative care goals
  - Journal articles, reference texts

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Communication: Considerations

- Communicating relatedness/coverage decision to whom:
  - Patient and family
  - Facilities (e.g., nursing home, assisted living)
  - Contracted providers (e.g., PBM, pharmacy)
  - Part D plan sponsors – PA process
- Consider how to document communication
  - Initial determinations of coverage
  - Changes to prior determinations
  - Determinations of coverage for new services

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Communication: Considerations (con't)

- Consider how to distinguish between "not related" vs. "not medically necessary" in communication
- Written policy/procedure
- Educate staff and retain copies of training materials

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Implementation: Considerations

- Responsibilities for ensuring coverage decisions regarding "related" and "unrelated" are correctly implemented
- Types of errors:
  - Contracted provider bills patient or third party payor for "related" item or services
  - Contracted provider bills hospice for "unrelated" items or services

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Implementation: Considerations (con't)

- Beyond communication of coverage decision, consider implementation safeguards at each level:
  - The patient/family
    - Verbal communication (e.g., explain "related" coverage at admission)
    - Written communication (e.g., explain patient's role in admission materials)
    - Specific written information (e.g., care plan with coverage determination at home)

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Implementation: Considerations (con't)

- The facility
  - Written notice of relatedness decisions (e.g., care plan)
  - Reminders (e.g., medical record stickers)
  - Contract obligations (e.g., confirm with hospice item or service "unrelated" before arranging, providing or billing)

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Implementation: Considerations (con't)

- Contracted providers
  - Document communication of:
    - Hospice status
    - Coverage determinations
  - Contract obligations (e.g., confirm with hospice item or service "unrelated" before providing or billing)
  - Education

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Implementation: Considerations (con't)

- Consider ways to audit and monitor implementation
  - Look for anomalies in cost or number of services
  - Spot check billing
    - New patients
    - Change in plan of care

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Implementation: Considerations (con't)

- Work with payment processors (e.g., PBM) on monthly activity reports
- Work with contracted providers (e.g., pharmacies, hospitals, DME providers) to return duplicate payments
  - Error if billed "related" item or service to third party payor
  - Payment for "related" item or service governed by contract

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Implementation: Considerations (con't)

- Appeals Process
  - Redetermination, Reconsideration, ALJ
  - Expect independent reviewers for Part D
- Coordinate appeals of challenges to hospice's "unrelatedness" determinations
  - If contracted provider billed as "unrelated," recoupment may be sought from contracted provider

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What Is On Your To Do List?

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Your To Do List

1. Understand inherent challenges
   - Many parties involved
2. Evaluate process from relatedness determination to implementation
   - No one size fits all
   - Include all parties involved in providing, ordering or billing item or service
   - Determine what has worked and what could be improved

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Your To Do List (con't)

3. Set priorities for improving process, documentation and implementation
   - Have multi-layer process addressing each party involved
   - Create redundancies as safeguards
   - Institute spot check audits going forward
4. Educate
   - Physicians and staff
   - Facilities
   - Contracted providers

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Questions?

Thanks!

Mary Michal, JD
Reinhart Boerner Van Deuren s.c.
(608) 229-2204
mmichal@reinhartlaw.com

Kate A. Proctor, JD
Reinhart Boerner Van Deuren s.c.
(608) 229-2213
kproctor@reinhartlaw.com

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Selected Resources

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Selected Resources

- Office of the Inspector General, Work Plans 2007 – 2012.
- Office of the Inspector General, "Medicare Could Be Paying Twice for Prescription Drugs for Beneficiaries in Hospice," A-06-10-00059, June 28, 2012.
- "Office of Inspector General's Partnership Plan – Oklahoma Health Care Authority's Report on Hospice Covered Drugs for Dually Eligible Beneficiaries," 06-06-00102, Feb. 23, 2007.

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Selected Resources

- CMS Memorandum to Plan D Sponsors and Hospices, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Final 2014 Guidance," March 10, 2014.
- CMS Memorandum to Plan D Sponsors and Hospices, "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice – Request for Comments," Dec. 6, 2013.
- CMS Memorandum to Plan D Sponsors, "Clarification of Recovery of Part D Payment for Pain Medications for Beneficiaries Enrolled in Hospice," Oct. 30, 2013.
- CMS Memorandum to Plan D Sponsors, "Preventing Part D Payment for Hospice Drugs," Oct. 22, 2010.
- CMS, Change Request 8358, "Additional Data Reporting Requirements for Hospice Claims," Reissued January 31, 2013.

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Selected Resources

- CMS, Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform (Proposed Rule), 78 Fed. Reg. 27823 (May 10, 2013).
- CMS, Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform (Final Rule), 78 Fed. Reg. 48234 (Aug. 7, 2013).

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