Post-Acute Compliance: Key Issues for Hospice and Home Health Industries

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Key Hospice Regulatory and Compliance Issues

- CMS Final Rule on Hospice Wage Index and Payment Rate Update for FY 2015
  - Published August 22, 2014
  - Effective October 1, 2014
  - Commentary suggesting that
    - payment reforms are aimed at program integrity, beneficiary protection and quality concerns;
    - hospices will see continued auditing and enforcement activity around certification of eligibility.

Key Hospice Regulatory and Compliance Issues

- New Reporting Requirements (effective Oct. 1, 2014)
  - **Notice of Election** ("NOE") must be submitted to MAC no later than the 5 calendar days after effective date of election; If in paper form, must be received no later than 5 calendar days after effective date of election.
  - If NOE not filed within 5 days, hospice may not receive per diem payments from effective date through (but not including) submission date.
  - NOE must identify attending physician and include an acknowledgement by the patient/representative that physician was his/her choice.
  - For changes in attending physicians, hospice must obtain a statement that (1) identifies the new physician, (2) includes patient's/representative's dated signature, (3) specifies effective date of change (not earlier than the signature), and (4) includes an acknowledgment that the physician was patient's/representative's choice.
  - Notice of Termination or Revocation ("NOTR") must be submitted to the MAC no later than 5 calendar days after the date of discharge or revocation (unless hospice already submitted final claim).

Key Hospice Regulatory and Compliance Issues

- Self-Determined Aggregate Cap Liability
  - Hospices required to self-determine cap liability on or after January 31.
  - Calculation may be based on data from Provider Statistical and Reimbursement System or hospice's own data.
  - If hospice's own data, hospice must maintain supporting documentation.
  - Self-determined cap liability must be refunded no later than March 31.

Key Hospice Regulatory and Compliance Issues

- Guidance on Eligibility Determinations
  - BIPA amendment clarifying that certification "shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness" does not negate the fact that there must be a clinical basis for a certification.
  - A hospice is required to make certain that the physician's clinical judgment can be supported by clinical information and other documentation (included in medical record) that provide a basis for the certification.
  - Hospices should (1) look to clinical and functional assessment tools and information on MAC Web sites; and (2) use their expert clinical judgment in determining eligibility for hospice services.

Key Hospice Regulatory and Compliance Issues

- Intersection of Hospice and Part D
  - July 18, 2014 CMS Guidance to Part D Sponsors and Medicare Hospices (modified March 10, 2014 Guidance)
    - http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2014-PartD-Hospice-Guidance-Revised-Memo.pdf
  - CMS FAQs Regarding Part D and Hospice issued August 6, 2014.
    - http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Hospice-FAQs-v08062014.pdf

Key Hospice Regulatory and Compliance Issues

- Who pays for a hospice patient's prescription medications?
  - Hospice pays for all medications reasonable and necessary for palliation and management of terminal illness and/or related conditions.
  - Part D sponsor pays for reasonable and necessary medications unrelated to terminal illness and/or related conditions.
  - Beneficiary pays for medications related to terminal illness and/or related conditions that hospice determines are not reasonable and necessary for the palliation of pain and symptom management.

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Key Hospice Regulatory and Compliance Issues

- Part D Compliance Risk Area
  - Hospice's determination that a related drug is not reasonable and necessary
    - Decision must be clinically based not financially based.
    - Hospice must maintain documentation of clinical decision making.
    - Hospice must "fully inform" patient and document document agreement to assume financial liability.
      - If hospice does not provide the drug, no ABN required.
      - If hospice provides the drug, must issue ABN to charge beneficiary for drug.

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Key Hospice Regulatory and Compliance Issues

- Part D Compliance Risk Areas (cont.)
  - Hospice's determination drugs are unrelated.
    - Four categories of routinely related medications:
      - Analgesics
      - Anti-nauseants
      - Anti-anxiety drugs
      - Laxatives
    - Hospice may assert that drugs are unrelated (1) proactively, (2) at time of claim rejection or (3) in response to query from sponsor responding to coverage determination request.
    - Physicians (both affiliated with hospice and unaffiliated) may also designate drugs unrelated.
    - Hospice must maintain a record of the basis for the statement that the drug is unrelated and provide it upon request.

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Hospice Enforcement Activity

- 2012
  - **Odyssey Healthcare**, continuous care, $25M FCA settlement and CIA.
- 2013
  - Hospice of Arizona, false CTIs, level of care, $12 M FCA settlement and CIA.
  - Hospice of the Comforter, false CTIs, nurses without hospice training, limited physician's role in assessment terminal illness, delayed discharge, $3M FCA settlement and CIA

Hospice Enforcement Activity

- 2014
  - Oliver Herndon, Horizons Hospital Medical Director, false CTIs, guilty plea.
  - Home Care Hospice Inc., false CTIs, false claims for crisis care, DOJ intervention in whistleblower-initiated FCA case.
  - Evercare Hospice and Palliative Care (now Optum/UHC), false CTI, management pressure to admit and retain ineligible patients, disregarded physician decisions to discharge, DOJ intervention in whistleblower-initiated FCA case.

Key Home Care Regulatory and Compliance Issues

- Medical Claims Review Update
  - ZPIC
  - RAC
  - MAC
  - Medicaid
  - Other

Key Home Care Regulatory and Compliance Issues

- OIG Oversight Activity in Home Health
  - Home Health Services
    - Home health prospective payment system requirements
    - Employment of individuals with criminal convictions

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse Concerns
  - Anti-kickback Statute
  - Physician Self-referral Laws
  - Civil Monetary Penalty Laws
  - State Laws
  - False Claims Act

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Anti-Kickback Statute (AKS)
    - 42 U.S.C. § 1320a-7b(b)
    - 42 C.F.R. § 1001.952

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Anti-kickback Statute
  - A violation requires three elements:
    - "Remuneration," which means **anything** of value, in cash or in kind
    - The remuneration must be made "knowingly and willfully"
    - The remuneration must be made with **intent to induce referrals** or business; according to certain federal courts (and the prosecutors), a violation may be found if only **one purpose** of the remuneration is to induce referrals, even if there are also legitimate reasons for the payment

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Anti-kickback Statute
  - Examples of AKS safe harbors:
    - Space rental
    - Equipment rental
    - Personal services and management contracts
    - Employee
    - (And there are several other safe harbors)

Key Home Care Regulatory and Compliance Issues

Fraud & Abuse

Your Key Questions for AKS Risk Assessment

1. Does the arrangement or practice have a **potential to interfere with, or skew, clinical decision-making**?
2. Does the arrangement or practice have a **potential to increase costs** to Federal health care programs, beneficiaries, or enrollees?
3. Does the arrangement or practice have a **potential to increase the risk of overutilization or inappropriate utilization**?
4. Does the arrangement or practice raise **patient safety or quality of care concerns**?

See OIG Supp. Compliance Guidance; 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (emphasis added).

Home Care Enforcement Activity

- National chains
- Smaller home care providers

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Physician Self-Referral Law (Stark)
    - 42 U.S.C. § 1395nn
    - 42 C.F.R. § 411.350 et seq.

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Basic prohibition:
    - Absent an exception, a physician may not refer a **Medicare*** patient for DHS to an entity with which the physician or an immediate family member has a "financial relationship"
    - An entity may not present a claim for payment for such services

*Note: Government interest in Medicaid (discussed later)

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - A financial relationship means (i) an ownership or investment interest, or (ii) a "compensation arrangement" between the referring physician and the provider
    - A compensation arrangement means any arrangement involving any remuneration, direct or indirect, between the referring physician and the provider
    - An ownership or investment interest includes any kind of equity or debt arrangement

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Key Home Care Regulatory and Compliance Issues

Fraud & Abuse

Designated Health Services (DHS)

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services (also nuclear medicine)
- Radiation therapy services and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services
- Durable medical equipment and supplies

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Key Home Care Regulatory and Compliance Issues

Fraud & Abuse

Your Key Questions for Stark Analysis

1. Is there a referral from a physician for a DHS?
2. If yes, does the physician (or an immediate family member) have a financial relationship with the entity furnishing the DHS?
3. If yes, does the financial relationship satisfy an exception?

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Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Examples of common financial relationships:
    - Medical Director Agreements,
    - Professional Services Agreements,
    - Equipment Leases,
    - Medical Office Space Leases,
    - Recruitment Agreements,
    - Medical Staff Appreciation Events,
    - Dinners/lunches/golf outings with MDs…

***All** need to comply with Stark*

Key Home Care Regulatory and Compliance Issues

- Fraud & Abuse
  - Examples of Stark exceptions:
    - In-office ancillary services
    - Rental of office space
    - Rental of equipment
    - Personal service arrangements
    - Non-monetary compensation
    - Fair market value compensation

(And there are several other exceptions)

Home Care Enforcement Activity

- National chains
- Smaller home care providers

Key Home Care Regulatory and Compliance Issues

Fraud & Abuse

Civil Monetary Penalties Law

- Any person who, among other things:
  - Offers to or transfers remuneration to any individual eligible for benefits under title XVII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVII, or a State health care program (as so defined);
  - Knows of an overpayment (as defined in paragraph (4) of section 1128J(d)) and does not report and return the overpayment in accordance with such section is subject to civil monetary penalties.

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Key Home Care Regulatory and Compliance Issues

Fraud & Abuse

State Fraud & Abuse Laws

- State specific provisions
- State provisions specific to home health agencies

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Homecare Enforcement Activity

- False Claims Act
  - Federal
  - State

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Key Home Care Regulatory and Compliance Issues

- Regulatory Issues and HHA-Facility Affiliations
  - Fraud & Abuse
  - Patient Choice/Patient Steering
  - Patient Confidentiality & Privacy
  - Licensure
  - Credentials
  - Physician Involvement

Key Home Care Regulatory and Compliance Issues

- HHA Survey and Sanctions Rule
  - Overview
  - IDR process
  - CMP

Post-Acute Trends and Takeaways

- Effective Compliance Program
- Continue to track and address risk areas for particular organization and industry
- Develop and revise policies and procedures as necessary
- Qualified person responsible for tracking and analyzing key changes in industry
- Distribution of information to all needed
- Training is critical-right topics and people
- Robust audit and monitoring program
- Qualified person responsible for tracking audits and appeals
- Clinical expertise is important
- Employee exit process

Questions?

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