HIPAA and Medicare Part D

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Medicare Part D

Overview

- Part D effective January 1, 2006
- Voluntary Outpatient Prescription Drug Program
- Provided by private entities
  - Prescription Drug Plans (PDPs)
  - Medicare Advantage Plans (MA-PDs)
- Provides drug coverage for Medicare beneficiaries
HIPAA and Medicare Part D

- Privacy Considerations
  - Marketing
  - State Medicaid Programs
  - Long Term Care Facilities
- Compliance Guide—Draft Issued 2/8/06
- Transactions & Code Sets
  - E-prescribing
  - Data transmission issues
- Security
- HIPAA Enforcement Rule issued 2/16/06
PRIVACY

- Privacy Considerations
  - Marketing
  - State Medicaid Programs
  - Retiree Drug Subsidy
  - Enrollment issues
  - Long Term Care Facilities
Marketing

- MMA directs:
  - CMS to broadly disseminate information on prescription drug plans
  - PDP and MA-PDP to market their plans to potential enrollees
Secretary has authority to disclose identifiable information to PDPs to facilitate marketing and enrollment under 1861D-1(b)(4)

- Benefit: To facilitate outreach to beneficiaries to ensure participation in program
- Risks: Inappropriate use; selective marketing (‘cherry-picking’); historically vulnerable population
CMS issued marketing guidelines August 15

Available at
http://www.cms.hhs.gov/pdps/PrtDPlnMrktngGdlns.asp

Marketing began October 1, 2005
Plans and Providers must comply with HIPAA Privacy Rules

- If plans use brokers or agents, must comply with state licensing laws

- Tele-marketing materials require advance review and approval by CMS

- Non-compliant plans can be subject to closure of new enrollment; referral to OIG; imposition of CMPs; other law enforcement sanctions
  - Sanctions for practices that may deny or discourage enrollment where medical condition or history indicates a need for substantial future medical services
Marketing

- Disclosures to Prescription Drug Plans
  - PDPs are covered entities under HIPAA
  - Can ONLY use PHI for marketing and enrollment
  - No individual beneficiary authorization required
  - Restrictions on use of claims & enrollment data
Physicians, pharmacists, and other health care professionals can provide information on plans, benefits, cost-sharing, formularies, etc.

Providers can display plan marketing materials and information regarding the provider’s relationship with the plan.

But a provider can’t steer a beneficiary to a plan based on the provider’s financial interest.
State Medicaid Programs

- Coordination of Benefits (COB)
  - Information sharing is allowed between Part D Plans and State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage
  - Enables the payment of premiums, coverage and Supplemental benefits under Part D
  - Prevents duplication of payment; determines MSP
  - Calculation of TrOOP (true-out-of-pocket expenses)
State Medicaid Programs

- Dual Eligible identification
  - Permitted payment (includes determination of eligibility or coverage) disclosure
  - Minimum necessary requirement where applicable (45 CFR §164.502(b) and 45 CFR §164.514(d))
    - Standard Transaction (i.e. X12N 270/271)= no minimum necessary
    - Outside a standard transaction= minimum necessary applies
Retiree Drug Subsidy

- Requires electronic submission and updating of enrollment information
  - Security rule applies- if employer’s group health plan is a covered entity.
- Group health plan or health insurance issuer may disclose PHI (i.e. enrollment information) without obtaining individual authorization for the retiree drug subsidy
  - Only if the conditions in 45 CFR §164.504(f) are met
  - Still subject to minimum necessary
Retiree Drug Subsidy

- 2 main types of disclosures
  - Disclosures by Group health plans to obtain the subsidy payment:
    - Categorized as a permitted disclosure (plan administration disclosure)
  - Disclosures by group health plans to sponsors of qualified retiree prescription drug plans
    - Falls under regulatory authority of Subpart R of MMA
Enrollment Issues

- Call Center Privacy protections
  - Applicable to Contractors, SHIP employees and volunteers, state Medicaid agencies, providers/physicians,
Long Term Care Facilities

- Concerns for residents in long-term care
  - Significant health needs
  - Eligible for Part D; many are dually-eligible for Medicare and Medicaid
  - Need access to required medications
  - Typically utilize particular pharmacy
  - Need assistance in making informed choices about Part D Prescription Drug Plans
Long Term Care Facilities

Who makes decisions regarding plan enrollment?

- Patient (consider dementia, alzheimers, complexity of options, computer availability)
- Facility staff
- Family
- Agency on Aging, Volunteers
Compliance Guidance

- Part D Program to Control Fraud, Waste and Abuse (chapter 9, Prescription Drug Benefit Manual)—Draft issued 2-8-06
  - Sponsors are required to implement a comprehensive program to prevent and detect fraud, waste and abuse in the prescription drug program.
  - HIPAA Requirements:
    - Policies and Procedures
    - Compliant Marketing Practices
    - Electronic data interchange
Section 101 of MMA requires that electronic prescriptions for covered Part D drugs comply with uniform standards:

- Standards to be used by all physicians, pharmacies, and pharmacists who serve Medicare beneficiaries with Part D benefits
- Voluntary, does not require providers to write electronic prescriptions
E-Prescribing

- CMS published proposed rule on February 4, 2005
- Initial e-Prescribing standards released - September 2005
- Pilot began - January 2006
- Report to Congress on Pilot - April 2007
- Additional Standards Final Rule - April 2008
E-Prescribing

- Final standards must be compatible with HIPAA
- Exemptions
  - Computer-generated faxes
  - LTC facilities
  - Internal messaging for staff model HMOs and other closed systems
- Eventual use of the NPI under Part D
- Incentives to providers to implement
  - Proposed Anti-Kickback safe harbor and Stark exception published on October 11, 2005
  - Comment period ended on December 12, 2005
Data Transmission

- Coordination of Benefits electronic transaction expansion
  - Prescription drug coverage information
    - Existing: MSP VSDAs and COBAs
    - New: SPAPs and PBMs
  - TrOOP information
    - Payers will need to send data concerning payments back for proper TrOOP administration
    - TrOOP Contractor Æ Part D Plans Æ Payer primacy and TrOOP calculations
  - Enrollee eligibility
    - Health plan to health plan Æ X12N 270/271 transaction