

Marketing and Refill Reminders under the HIPAA Privacy Rule

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“Refill Reminders” & Other Sponsored Adherence/Educational Programs

- Improve patient adherence and compliance
- Three out of four Americans not adherent
- Poor adherence costs over \$290 billion/year
- CBO: 1% increase in prescriptions filled: >\$1.7 billion in savings
- Personalized protocols, personalized messages
- Health and wellness

Compliance and Persistence

Recognized by:

- CMS – Medicare Part D
- Provider Star Ratings
- AHRQ
- FDA – REMS
- HITECH Act: specific exception for refill reminders
 - Payment: “reasonable in amount”

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Role of the Pharmacist

- Professional duty
- Ethical obligation
- Counsel patient/customer
- Encourage persistence/compliance

Patient Privacy

- Importance of patient privacy
- Importance of compliance/persistence
- Both goals must be achieved

NACDS Concerns: Pre-Guidance

- Role of the business associate
 - whether allowed when there is remuneration
 - whether business associate profit is allowed
- “Reasonable in amount”
 - Wide range of direct and indirect costs
 - Fair return on investment

NACDS Concerns: Pre-Guidance

- Scope of communications should be broad
 - New formulations
 - Adjunctive therapies
 - Recently lapsed prescription
- Treatment communications should be encouraged
- Promoting a privacy interest?

Post-Guidance

- OCR Guidance
 - Clear Signal HHS supports programs
 - B/A Allowed
 - “Reasonable in Amount” defined
 - Scope of communication

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Post-Guidance

- Most: Comfortable running programs
- Some: Still evaluating and quantifying “reasonable cost”
 - Benefit/risk analyses
 - Scrutinizing costs
 - OCR punitive focus
- Face-to-face communications exempt

Looking Ahead

- OCR Field Office interpretation/activity
- State AG activity
- Ideally, guidance codified into rule
- Further broaden policy
- Re-start compliance programs in California
 - Only state not occurring

NACDS

Thank You!

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