E-Prescribing and the Prescription Drug Program – Proposed Rule

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Important Dates

- Proposed Rule announced by President and displayed at Federal Register on 1/27/05

- Published in Federal Register on 2/4/05

- 60 day comment period ends 4/5/05

What's in the Proposed Rule?

- Describes NCVHS process and summarizes recommendations
- Proposes foundation standards
- Explains incremental strategy
- Discusses State preemption

Proposed Foundation Standards

- NCPDP SCRIPT standard, Version 5, Release 0 (except for the Prescription Fill Status Notification Transaction) - for transactions between prescribers and dispensers for:
  - New prescriptions
  - Prescription refill requests and response
  - Prescription change request and response
  - Prescription cancellation request and response
  - Ancillary messaging and administrative transactions

Proposed Foundation Standards (cont)

- ASC X12N 270/271, Version 4010 and Addenda – for eligibility and benefits inquiries and responses between prescribers and Part D sponsors

Proposed Foundation Standards (cont)

- NCPDP Telecommunications Standard, Version 5.1 (and the equivalent Batch Standard, Version 1.1) – for eligibility and benefits inquiries and responses between dispensers and Part D sponsors

Proposed Foundation Standards (cont)

Formulary and benefit and medication history standards will be adopted in Final Rule only if certain characteristics are met, including:

- Accreditation by an ANSI-accredited SDO,
- Standards permit interface with multi product, router and point-of-care (POC) vendors

Proposed Foundation Standards (cont)

- **Formulary and benefits:**
  - Standards provide a uniform means for pharmacy benefit payers to communicate a range of formulary and benefit information to prescribers via POC systems
  - The standards cover a range of formulary and benefit data
- **Medication history:**
  - Standards provide an uniform means for a prescriber, dispenser, or payer to request a listing of drugs that have been prescribed or claimed for a patient within a certain time frame.
  - Standards provide a uniform means for a Part D plan, dispenser, or prescriber to request information to describe the patients medication history
- **Solicit comment on what specific standards (including RxHub) meet these criteria**

Other Standards

- First set of standards does not represent full set of standards necessary for e-prescribing
- Additional standards will be identified, pilot tested, and proposed through separate rulemaking to build on foundation standards
- Request comments on this incremental approach

State Preemption

- Options for scope of preemption
    - **Only applies to transactions and entities that are part of an Electronic Prescription Drug Program under Part D; or**
    - **Applies to a broader set of transactions and entities**
- Proposed rule takes narrow interpretation, public comments invited

Use of NPI

- Public comments invited on
  - Possible use of NPI for Medicare Part D e-prescribing transactions;
  - Earliest time when NPI should be required for use in e-prescribing program;
  - Effect on industry of accelerating use of NPI in e-prescribing ahead of HIPAA compliance dates;
  - Alternatives to NPI, particularly short term;
    and
  - Options for phasing in use of NPI in e-prescribing.

Use of Standards within an Enterprise

- NCVHS Recommendation:
  - Exempt transactions within an entity (e.g., staff model HMO with pharmacy) from using standards
  - Exception: entity would be required to use standards to communicate with external partners
- NPRM:
  - Communicates NCVHS recommendation
  - Notes that this treatment is not consistent with HIPAA administrative simplification, which requires standards to be used as long as transaction meets definition of HIPAA transaction
  - Solicits comments

Pilot Testing

- MMA requires pilot testing in CY 2006 of e-prescribing standards not in widespread use
- CMS will soon solicit applications from physicians, hospitals, prescriptions drug plan sponsors, Medicare Advantage organizations, pharmacies and others to voluntarily participate in pilots to test new or emerging standards.

Pilot Testing (cont)

- Announce initial standards for pilot tests by Sep 2005
- Pilots operational in 2006
- Structure of Pilots
  - NCVHS recommendations
  - Results of analysis of existing e-prescribing programs
  - Secretary reports to Congress by April 2007
  - Secretary promulgates final uniform standards not later than April 2008

Subsequent Milestones

- Report to Congress – April 2007

- Proposed and Final Rule – no later than April 2008