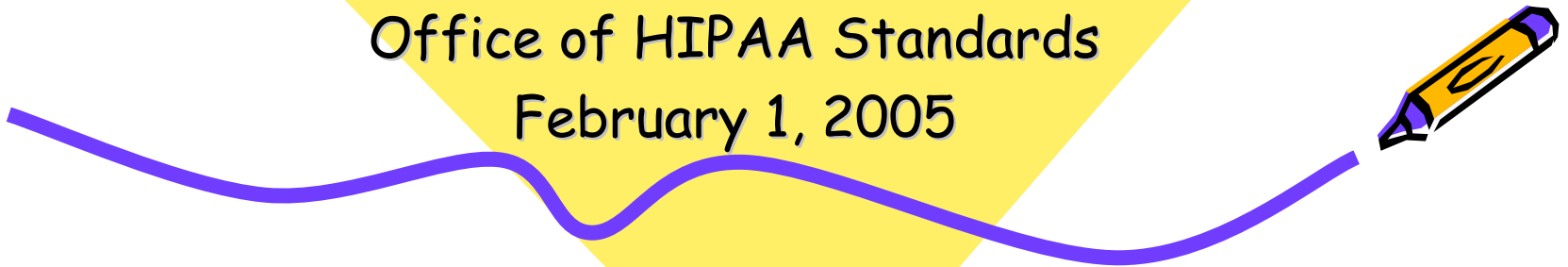




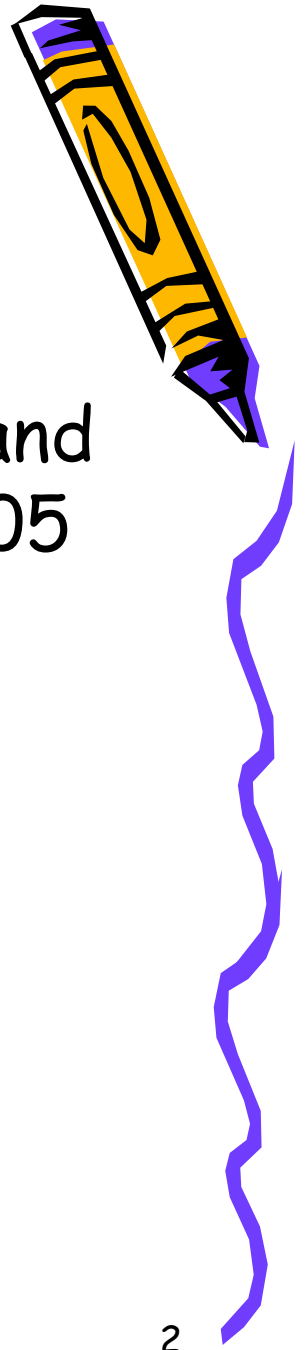
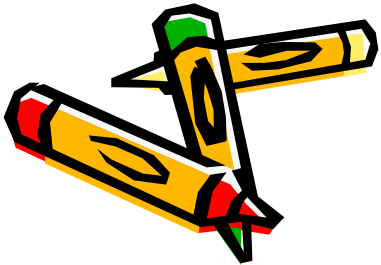
E-Prescribing and the Prescription Drug Program - Proposed Rule

Karen Trudel
Office of HIPAA Standards
February 1, 2005



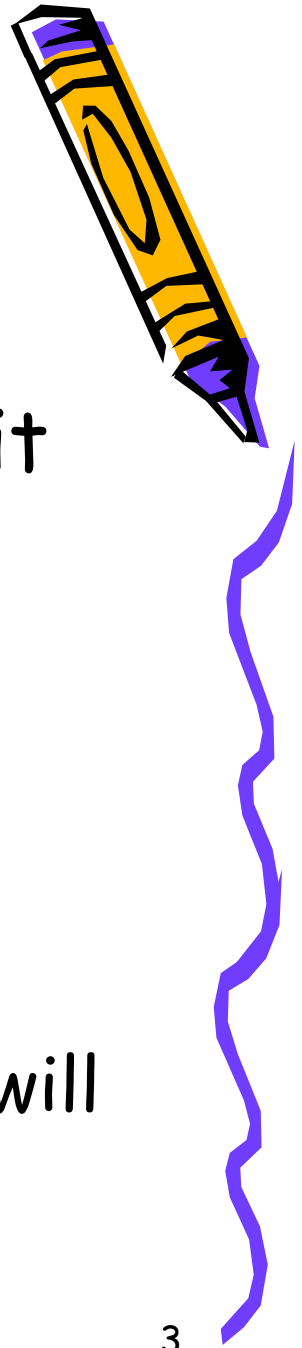
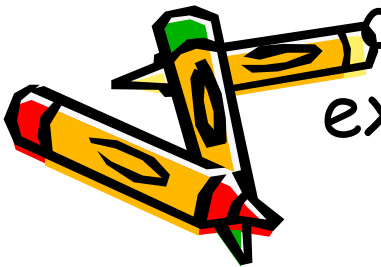
Important Dates

- Proposed Rule announced by President and displayed at Federal Register on 1/27/05
- To be published in Federal Register on 2/4/05
- 60 day comment period ends 4/5/05



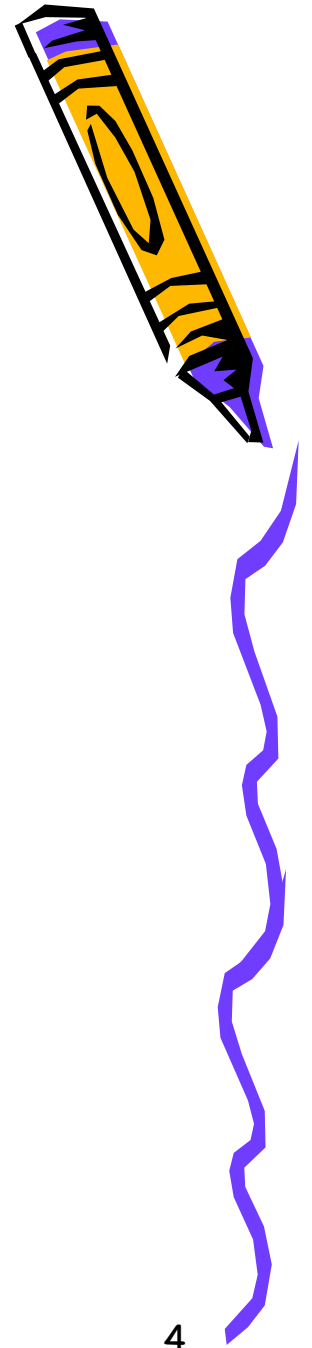
Other Part D Regulations

- Medicare Prescription Drug Benefit Final Rule published on 1/28/05
 - Requires drug plans to support and comply with e-prescribing standards
- Stark exception for e-prescribing
 - Separate proposed rule, in process, will clarify how physician self-referral exception will work



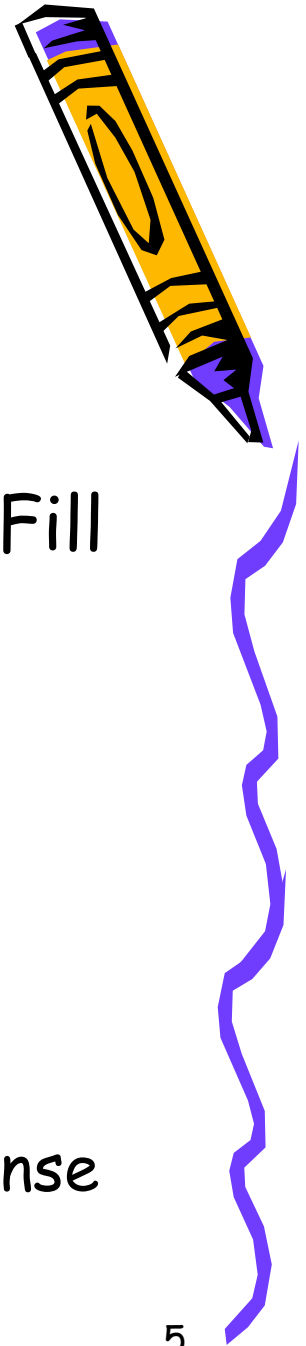
What's in the Proposed Rule?

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



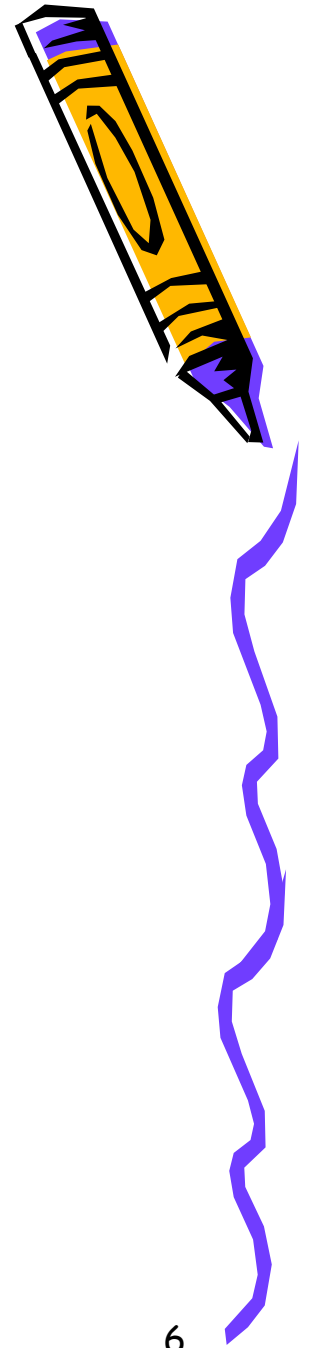
Proposed Foundation Standards

- 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 (con't)

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



Proposed Foundation Standards (con't)

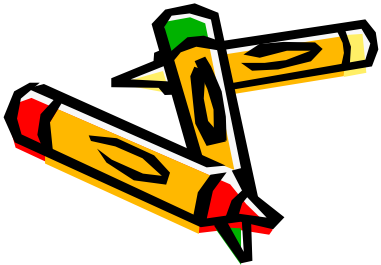
- NCPDP Telecommunications Standard, Version 5.1 (and the equivalent Batch Standard, Version 1.1) - for eligibility and benefits inquiries and responses between dispensers and Part D sponsors



Proposed Foundation Standards (con't)

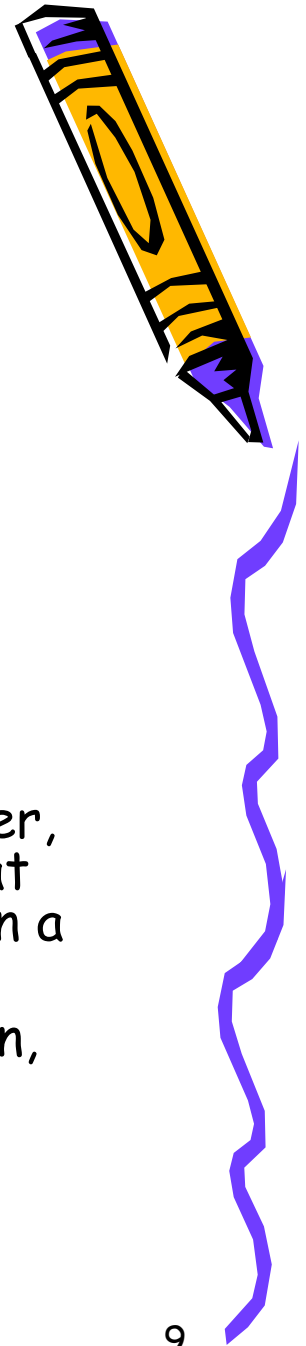
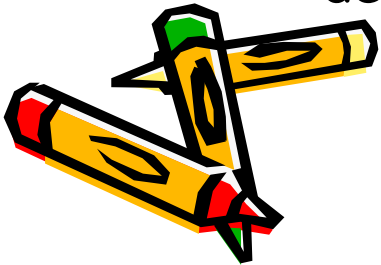
Formulary and benefit standards will be adopted in Final Rule only if certain characteristics are met, including:

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



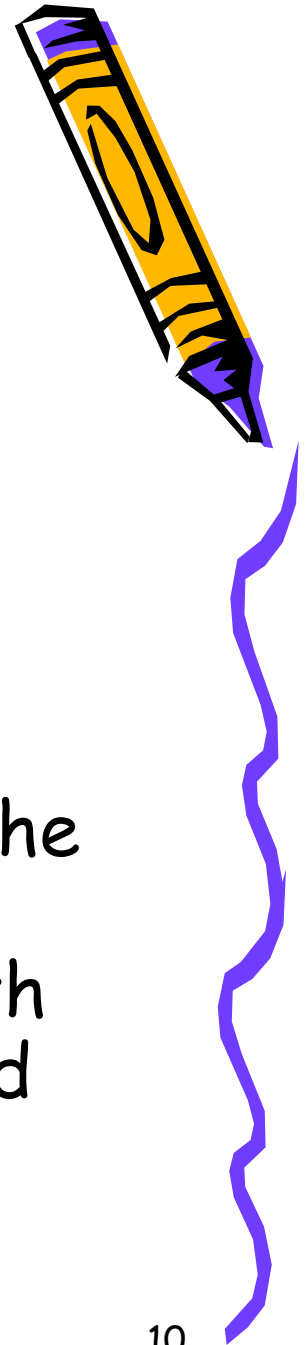
Proposed Foundation Standards (con't)

- Medication history standards will be adopted in Final Rule only if certain characteristics are met, including:
 - Accreditation by an ANSI accredited SDO,
 - The standards permit interface with multi product, router and point-of-care (POC) vendors
 - 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



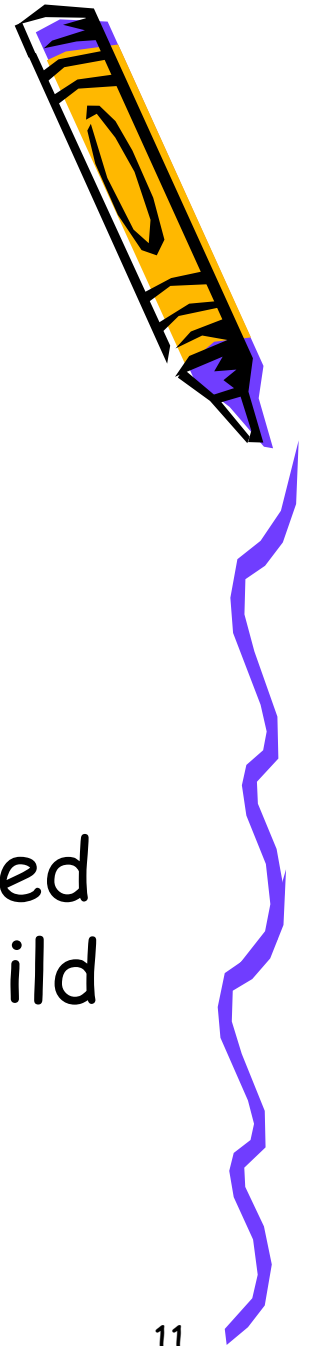
How were foundation standards selected?

- Recommended by NCVHS
- "Adequate industry experience:"
 - (1) American National Standards Institute (ANSI) accredited;
 - (2) Implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external partner; and
 - (3) Recognized by key stakeholders as industry standard.



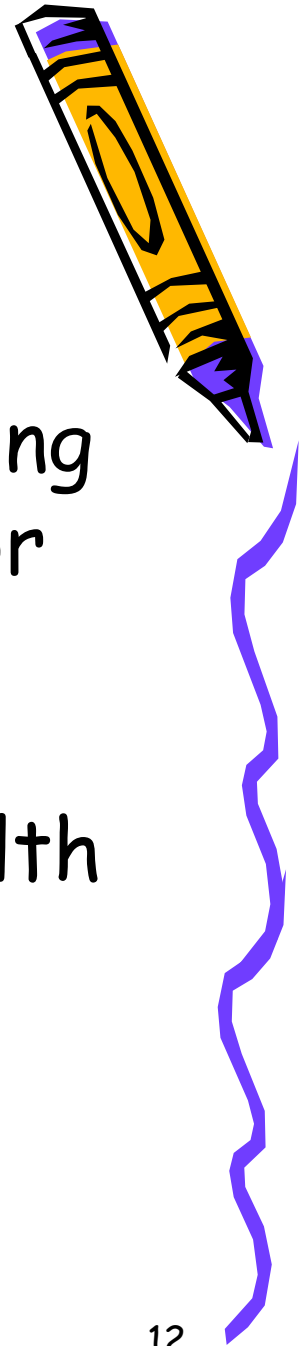
Other Standards

- 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



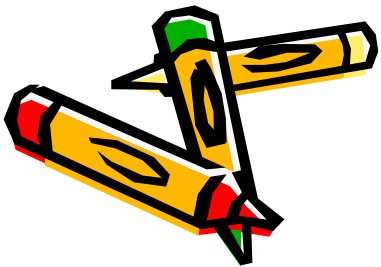
Proposed Definitions

E-Prescribing - the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network



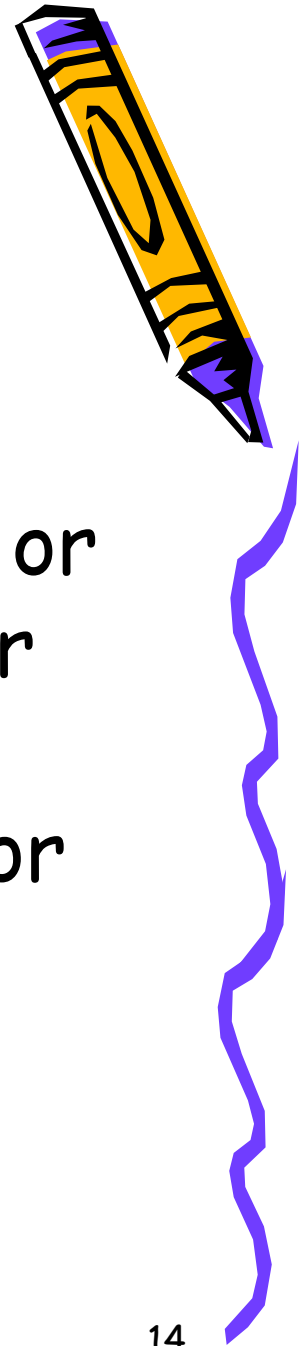
Proposed Definitions (cont)

Electronic Prescription Drug Program -
a program that provides for e-
prescribing for covered Part D drugs
prescribed for Part D eligible
individuals who are enrolled in Part D
plans



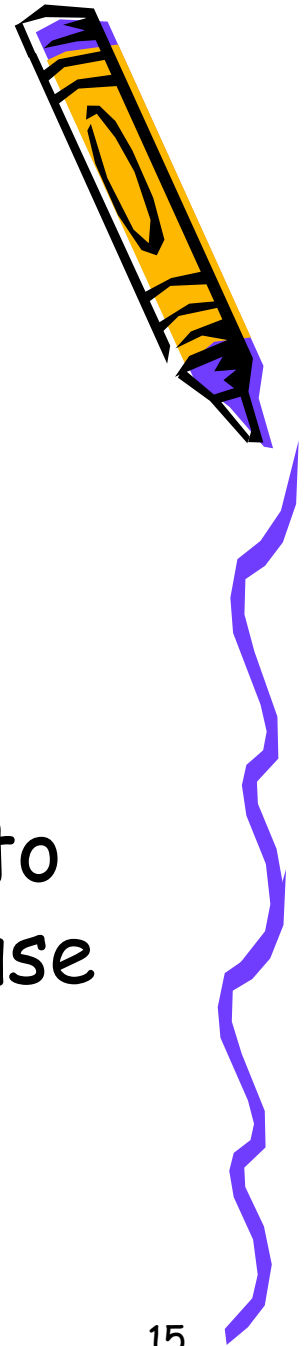
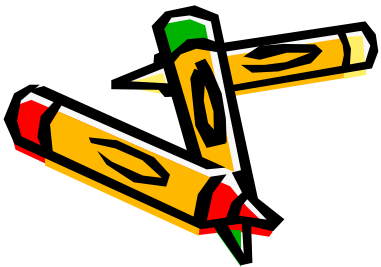
Proposed Definitions (con't)

Prescriber - a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use



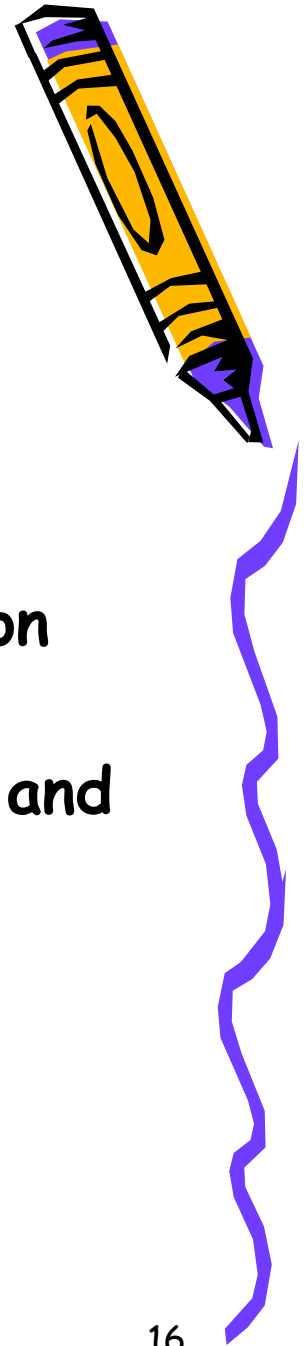
Proposed Definitions (con't)

Dispenser - a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use



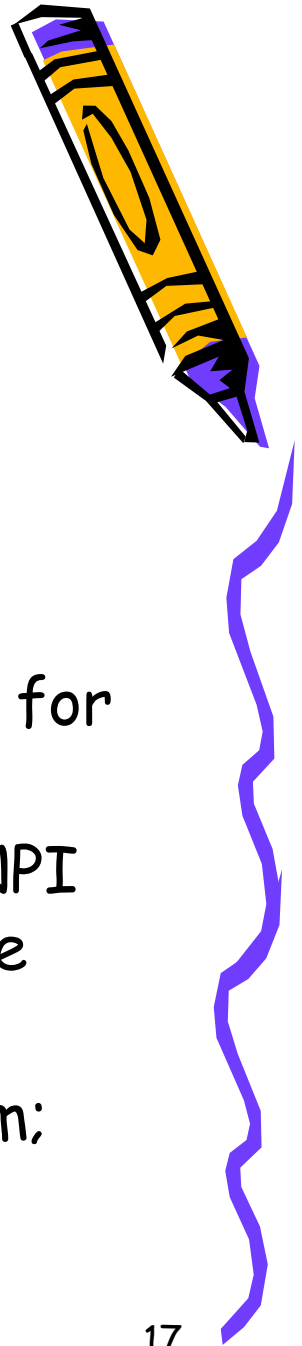
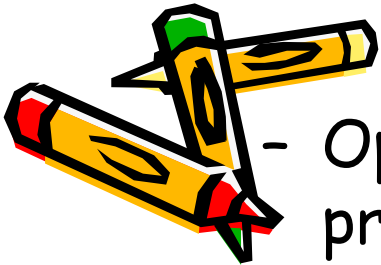
State Preemption

- 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.



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 participate in pilots to test new or emerging standards.

