

# ePrescribing Final Rules

## *A Detailed Summary for NCPDP's Workgroup 11 – ePrescribing & Related Transactions*

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# MMA & ePrescribing



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# Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)

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- ➔ Creates the Part D benefit
- ➔ Establishes a real-time ePrescribing program to be used by prescribers, plans, pharmacies & pharmacists who serve Medicare patients
  - ➔ No mandate, but if used, **standards must be followed**
  - ➔ Standards via National Committee on Vital and Health Stats
- ➔ NCVHS tasked with identifying foundation standards required for January 2006 implementations.
- ➔ Directs HHS to conduct a voluntary eRx pilot project in 2006, for areas where industry experience is insufficient

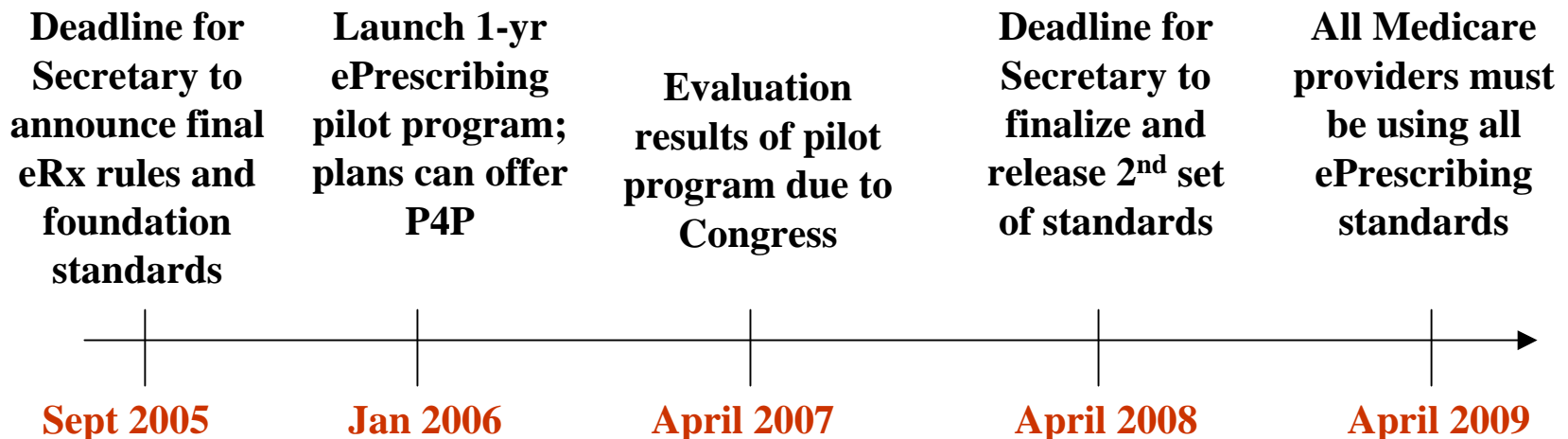


# Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)

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## ➤ Other components:

- Discretionary grants to be made available to prescribers
- Plans, hospitals, groups may purchase hardware for MDs
- Plans may pay additional fees for reduced medication errors, improved formulary compliance & fewer adverse drug events



# Final Rule



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# CMS eRx Final Rules

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- ➔ Released Nov. 2; pub. in *Federal Register* Nov. 7
- ➔ Must be used for ePrescribing as of Jan. 1, 2006
  - ➔ Question as to how firm: "Plans may take more time to work with pharmacies in their network" (*FR 67582*)
- ➔ Who must comply? (*FR 67568*)
  - ➔ Stand-alone Prescription Drug Plans (PDPs)
  - ➔ Medicare Advantage –Prescription Drug plans (MA-PDs)
  - ➔ Providers who prescribe or dispense Part D drugs



# Foundation Standards

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- “We refer to them as ‘foundation standards’ because they are a foundation for ePrescribing implementation.” *(FR 67568)*
- NCPDP SCRIPT *(FR 67573)*
  - new Rx, renewals
  - Change, cancel
  - admin functions (get msg, status, error, verification, password chng)
- X12N 270/271 (eligibility between the physician & payer)
- NCPDP Telecom (eligibility between dispenser & payer)



# Exemptions

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- ▶ “Computer-generated faxes to transmit prescriptions to a dispenser’s fax that prints a hard (paper) copy ...” (*FR 67571*)
  - ▶ NOT EXEMPT: “prescriber is already ePrescribing but the ability to transmit (via EDI) is ‘turned off’”
  - ▶ EXEMPT: “prescriber is merely using word processing software and the computer’s fax capabilities in lieu of faxing paper”
- ▶ Entities transmitting eRxS where prescriber is required by law to issue a Rx for patient to a non-prescribing entity (eg nursing facility) that, in turn, forwards to a dispenser. (*FR 67594*)
- ▶ “Entities (enterprises) may use either HL7 or SCRIPT to transmit eRxS internally when part of the same legal entity” (*FR 67581*)
  - ▶ “If an entity sends eRxS outside the entity, it must use SCRIPT”
  - ▶ “Any pharmacy within an entity must be able to receive SCRIPT”



# State Preemption (*FR 67574-6*)

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- “Preempts State laws that are contrary to ePrescribing standards or that restricts the ability to carry” them out
- Scope: *all* Part D-eligible individuals and drugs
- Examples include state laws that:
  - expressly prohibit ePrescribing
  - prohibit the transmissions of eRx thru intermediaries
  - require certain language, such as ‘dispense as written’
  - require handwritten signatures or other handwriting

CMS “PUNTS”

- For security, CMS reverts to HIPAA
- “Variations within privacy laws will be addressed in the broader context of EHRs”
- “HHS & DEA are working on controlled substances”



# Version Control (*FR 67579,80*)

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- ➔ Bound by Administrative Procedure Act (APA)
- ➔ Will establish a review process to determine:
  - ➔ Whether a standard should be updated w/new version
  - ➔ Whether the update would necessitate notice and comment rulemaking
- ➔ Where it is determined that notice and comment rulemaking is not required, the new version will be published in the *Federal Register*
- ➔ Where required, compliance will be mandated only after notice and comment rulemaking



# Version Control (*FR 67579,80*)

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- ➔ Under the APA, only the Secretary can waive notice and comment rulemaking
- ➔ NCVHS will assess new versions of standards and provide recommendations to the Secretary
- ➔ Where there is substantive changes, anticipate comment and rulemaking
- ➔ Entities that voluntarily adopt later versions of standards that are backward compatible must still accommodate earlier version w/o modification
- ➔ Agreed to work with SDOs and NCVHS to establish a predictable timetable for evaluating standards



# Other Interesting Components

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- ➔ NPI won't be required until May 2007 (or May 2008 for small health plans) (*FR 67578*)
- ➔ Prior Authorization should be (a) pilot tested and (b) include criteria (*FR 67578*)
- ➔ CMS did not agree with commentors who tried to get them to mandate PKI (*FR 67582-3*)
- ➔ In response to concerns about commercial messaging, CMS will "monitor this as an operational issue, provide guidelines to plans at a future date and, if necessary, propose more specific standards." (*FR 67583*)
- ➔ "Not aware of any medical history standards"



# Other Interesting Components (cont.)

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- Diagnosis codes not required because “field is optional in SCRIPT and not in widespread use.” (*FR 67583*)
- Comments that were acknowledged but not acted on (*FR 67583*):
  - Plans should not be allowed to influence prescribing habits
  - CMS should provide guidance on how drug product selection criteria may be transmitted separately (presumably with RxNorm)
  - No transaction for alteration of the status of a refill
  - Need an order set for home infusion
- CMS believes adoption will increase by 10% annually over the next 5 years (*FR 67585*)



# Other Interesting Components (cont.)

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- Costs to physicians “could be offset by the grants that will be made available in 2007” (*FR 67592*)
- “Most of the costs of changing over to new ePrescribing technology should be absorbed as a usual cost of doing business, and may be offset by tax reductions” (*FR 67592*)
- Interesting numbers and statistics in the impact section.



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