E-Prescribing Pilot Testing Under the MMA

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What the MMA requires

- Required to pilot test standards for which there is not adequate industry experience
- Voluntary participation via agreements with the Secretary
- Conducted during Calendar Year 2006
- Pilot testing results will be used to develop final e-prescribing standards to be adopted in 2008
- Pilot testing and Part D implementation begin on same date

What the MMA requires

- Pilot evaluation
- Results to form basis of Report to Congress by April 2007
- Because of timing issues, we will be running the pilot evaluation concurrently with pilot
- Evaluation contract has not yet been awarded

How are we going to test the standards?

- Projects to be competitively awarded
- Cooperative agreements
- CMS collaborating with AHRQ
- Pilot RFA announced on 9/15/05
- Copies available thru NIH web site
- http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-06-001.html

How are we going to test the standards?

- Proposals will be evaluated by peer review group convened by AHRQ
- $6 million available
- Anticipated awards: $500,000 and $2 million in total costs (direct and indirect).
- Decisions on who gets how much will depend on how many applications received, the scope of the proposal, types of participants
  - LTC facilities, small/rural entities

Key Dates

- Technical Assistance Conference Call: September 29, 2005
- Letters of Intent Receipt Date(s): October 7, 2005
- Application Receipt Dates(s): October 25, 2005
- Peer Review Date(s): December 2005
- Awards: December 2005
- Earliest Anticipated Start Date: December 2005

Bidders' Conference Call

- We encourage submission of questions before the call
- Call is open to any individuals or organizations intending to apply
- To register and send questions, eprescribingRFA@ahrq.gov by 9/28
- Call will be on 9/29 at 1 pm Eastern for approximately 2.5 hours

What Will We Pilot Test?

- Formulary and benefit information - NCPDP is developing a standard using RxHub protocol, and pilots should determine if it should be adopted as a standard
- Exchange of medication history – Pilots should determine readiness of the NCPDP's standard medication history message
- NCPDP SCRIPT (fill status notification function) – Pilots need to assess the business value and clinical utility
- NCPDP SCRIPT (cancellation and change functions)
- Structured and Codified Sig – Pilots should test structured and codified SIGs (patient instructions) developed through standards development organization efforts
- Clinical drug terminology – Pilots should determine whether RxNorm terminology translates to NDC for new prescriptions, renewals and changes

What will we pilot test?

- Prior authorization messages – Pilots should determine functionality of new versions of the ASC X12N 278; evaluate economic impact of automation and impact on quality of care; Support standards development organizations development of work flow scenarios
- NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004
- NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Implementation Guide, Version 1, Release 1 (Version 1.1) for the NCPDP Data Record in the Detail Data Record
- ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1

An important note on foundation standards and pilot testing

- We have conditionally included the proposed foundation standards among the initial standards to be tested
- Because HHS has not published a final rule identifying the foundation standards, we cannot specify definitively which of the proposed foundation standards will be adopted as foundation standards.
- Any proposed foundation standard that is not subsequently adopted as a foundation standard will be included in this pilot as an initial standard.
- The pilot project seeks to test the interoperability of all initial standards with the foundation standards that are adopted.

Questions to be addressed

- Are the right data being sent?
- Are the data usable and accurate?
- Are the data well-understood at all points of the transaction?
- Are all of the above listed initial e-prescribing data communications standards included in the pilot working?
- Examples: Can they effectively and unequivocally communicate the necessary information from sender to receiver to support the electronic prescribing functions? Are the data for the patient and the prescription transmitted accurately among all participants in the transaction, such as the pharmacy, pharmacy benefits manager (PBM), router, plan and prescriber?

Questions to be addressed (cont'd)

- Do the initial standards work well together and with the foundation standards? If not, why not and what workarounds were used?
- How can the initial standards be improved to address workarounds?
- How long does it take to conduct each transaction using the initial standards?
- Can all appropriate drugs and other therapies be ordered via electronic prescribing?

Project characteristics

- The methods of testing as well as why the particular methods are being chosen
- The nature of the prescriber pool, including specialty, size of practice, and percent participation
- Testing of digital transmission of prescriptions between transactors. It is not adequate to only test processes which are fax- or handwriting-dependent.
- Number of patients and their demographic characteristics (at least 25% of the patient population must be age 65 or older or Medicare-eligible)
- A description and analysis of prescriber uptake (enrollment and disenrollment) in electronic prescribing

Project characteristics (cont'd)

- Identification of vendors, the e-prescribing hardware and software systems employed, payers (plans and PBMs), and router
- Number of pilot sites
- Site locations
- Baseline number of prescriptions per month (electronic and on paper, including FAX)
- Baseline callbacks to pharmacy (electronic and on paper) and types of personnel resources used for callbacks, including staff involved, their hourly rate and hours spent on callbacks.
- Proposed data collection and method of analysis

Outcomes to be reported

- Use of on-formulary medications and generics
- Changes in the rate of potential inappropriate prescribing (e.g. Beers criteria)
- Changes in the rate of hospital and emergency department use overall
- Medication errors
- Adverse drug events
- Rates of hospitalizations and emergency department visits associated with adverse drug events (e.g., bleeding while anticoagulated, ACE inhibitor-caused acute renal failure, anaphylaxis, rash, etc.)

Outcomes to be reported (cont'd)

- Workflow changes in prescriber offices (fewer interactions with pharmacies, freeing up support staff time for other functions, more time available for patient interaction)
- Workflow changes relating to verbal orders
- Prescriber uptake and dropout rates
- Changes in prescription renewal rates
- Changes in new prescription rates
- Changes in fill status rates
- Patient satisfaction

Additional characteristics to be considered

- Use of multiple sites.
- Geographic diversity (regional and urban vs. rural) as well as a mix of provider types and large and small entities.
- Applications from public/private partnerships whose patient base includes Medicare beneficiaries.
- Programs in which organization and patient population will yield results that are relevant to the Part D program.
- Applications with a plan for both intervention and control sites.

Additional characteristics to be considered (cont'd)

- Applications that employ partnerships beyond a single provider network.
- Applications that involve practice-based research networks.
- Partnerships that include prescription flow between ambulatory and long term care or inpatient settings.
- Use of the Food and Drug Administration/National Library of Medicine (FDA/NLM) structured product label for electronic drug information.

Additional considerations

- Applicants must offer a proposed evaluation methodology.
- Applicants should provide an estimate of what the proposed evaluation would cost.
- Applicants will need to work with the evaluation contractor (TBD) due to timing
- All proposed cooperative agreements must comply with the privacy, security and transaction and code set requirements set forth under HIPAA.

Additional considerations (cont'd)

- If pilot testing will be conducted through a collaborative arrangement, such as a public/private partnership or consortium, the application must specify the details of the arrangement.
- If this information is not included, the application will be returned without review.
- This information includes, for example,
  - Names of the participating entities,
  - Description of roles and responsibilities for each, Breakdowns of funding for each,
  - Description of nonmonetary contributions (such as training) for each.

Who can apply

- Eligible institutions include:
  - For-profit organizations
  - Non-profit organizations
  - Public or private institutions, such as universities, colleges, hospitals, and laboratories
  - Units of State government
  - Units of local government
  - Eligible agencies of the Federal government
  - Faith-based or community-based organizations

Who can apply (cont'd)

- Foreign entities and individuals cannot apply. However, they can participate as subcontractors
- As specified by MMA, CMS intends to enter into cooperative "agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacies."
- Other appropriate entities include long term care facilities and rural health clinics.

A final note

- The proposals will be evaluated using the criteria specified in the application
- Rigor is important. You must show that the project is doable, it unequivocably addresses what is asked for in the RFA, the budget makes sense, the principal investigator and other participants are qualified.
- Deadlines must be met.
- Good projects with poor applications—or those that do not do what is specified in the RFA--will not be funded. Applications must pass a rigorous review process—the kind that scientific grants undergo.
- GET HELP WITH YOUR PROPOSAL IF THIS PROCESS IS UNFAMILIAR!