

Medicare HIT Policies: Medicare and Part D ePrescribing Issues

Toward a Seamless System for Better Outcomes



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Strategies for the digital future of healthcare information



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e-Prescribing Standards: Toward a Seamless System for Better Outcomes



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Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, P.L. 108-173

ELECTRONIC PRESCRIPTION PROGRAM Subsection(e)

- Major Dates
 - ◆ **By September 2005**, HHS Secretary will announce initial e-prescribing standards (based on NCVHS recommendations)
 - ◆ **January-December 2006**, pilot test of initial standards
 - ◆ **By April 2007**, HHS provides evaluation to Congress
 - ◆ **By April 2008**, HHS announce final e-prescribing standards
- Types of e-prescribing standards:
 - ◆ Message format standards for:
 - Eligibility and benefits (formulary and pre-authorizations)
 - Prescription messages with decision support (including medication and medical history for drug interactions) and lower cost alternatives
 - ◆ Terminologies for clinical drugs (including ingredients) and packaged drugs
 - ◆ Identifiers for prescribers, dispensers, and PBMs

Guiding Principles for Selecting Standards

- Improve quality of care
 - Improve patient safety
 - Improve efficiency (including cost savings)
 - Not present undue administrative burden on prescribers. dispensers
 - Be compatible with other standards
 - Permit electronic exchange of drug labeling and drug listing information maintained by FDA and NLM
 - Include quality assurance measures
 - Permit patient designation of dispensing pharmacy
 - Comply with HIPAA Privacy
 - Support interactive and real-time transactions
- **NCVHS added guiding principles for selecting e-prescribing standards:**
 - ◆ **Vendor neutral**
 - ◆ **Technology independent**
 - ◆ **Developed by ANSI-accredited SDO's preferred**
 - ◆ **Market acceptance desirable**



- **First set of Recommendations on E-Prescribing Foundational Standards, 09/02/04, on:**
 - ◆ General
 - ◆ Message format standards
 - ◆ Terminologies
 - ◆ Identifiers
 - ◆ Important related issues
- **NPRM (42 CFR 423), issued 01/27/05**
- **Second set of Recommendations on Security and Authentication, 03/04/05**

Letters to Secretary Thompson: www.ncvhs.hhs.gov

NCVHS September 2004

General Recommendations

- **Compatibility with other standards, e.g.,**
 - 1.1 Prescribing standards used within enterprises (institutions)**
 - 1.2 HIPAA and CHI standards and other NCVHS' recommendations**
- **Standards versioning**
 - 2.1 Allow new versions of standards as long as they are backward compatible**

NCVHS September 2004

Message Format Standards

- Prescription message standards
 - 3.1 NCPDP script is recommended as foundational standard
 - 3.2 Include fill status notification in pilot test
- Coordination of prescription message standards
 - 4.1 HHS should support coordination activities between NCPDP and HL7 for e-prescribing messages
 - 4.2 Pharmacy order entry within the same enterprise (HL7 messages) should be considered out of scope
 - 4.3 All e-prescribing messages to retail pharmacies should be in NCPDP format
- Formulary Messages
 - 5.1 Standard messages for formulary and benefits should be developed by NCPDP based on current RxHub format
 - 5.2 NCVHS will monitor progress
- Eligibility and benefits messages
 - 6.1 ASC X12N 270/271 healthcare eligibility and response recommended as foundational standards

NCVHS September 2004

Message Format Standard, Con't.

- Eligibility and benefits messages, con't.
 - 6.2 Pharmacy ID card information should be mapped to ASC X12N 270/271
 - 6.3 Verify that HIPAA situational data in ASC X12N will be appropriate for e-prescribing in pilot tests
 - 6.4 Any new ASC X12N functions/versions for e-Rx should be kept in sync with HIPAA and tested
- Prior authorization messages
 - 7.1 ASC X12N should ensure 278 can support requests for prior authorizations between prescribers, payers
 - 7.2 Prior authorization work flow scenarios should be created to help design pilot tests
 - 7.3 Pilot tests should include benefits analysis of real-time prior authorization
 - 7.4 Synchronization between HIPAA and e-prescribing
- Medication history messages from payer/PBM to prescriber
 - 8.1 Standard messages for medication history sent from payers/PBM's to prescribers should be developed by NCPDP based on current RxHub format
 - 8.2 NCVHS will monitor progress

NCVHS September 2004

Terminologies

- Clinical drug terminology
 - 9.1 HHS should test prescriber- entered RxNorm codes and their ability to be translated to NDC codes used by dispensers
 - 9.2 HHS should accelerate promulgation of FDA's Drug Listing Rule to expedite correlation between RxNorm and NDC codes (e.g., facilitate daily updates and inclusion of FDA's SPL in NLM's DailyMed)
 - 9.3 HHS should map Medicare Part D model guidelines for drug categories and classes to NDF-RT
- Structured and codified SIG
 - 10.1 Inclusion of structured and codified SIG's in e-prescribing messages should be encouraged, but use of free text needs to be preserved
 - 10.2 Structured and codified SIG's should be included in pilot tests

NCVHS September 2004

Identifiers

- Dispenser identifier

- 11.1 NPI should be primary dispenser identifier when it becomes available
- 11.2 HHS should accelerate enumeration of dispensers to support transition to NPI
- 11.3 NCPDP Provider Identifier should be used for dispensers until NPI is available from HHS
- 11.4 HHS should evaluate use of NCPDP Provider Identifier database to expedite enumeration of dispensers in NPI
- 11.5 HHS should protect linkage between NPI and NCPDP Provider Identifier database to support claims processing

- Prescriber identifier

- 12.1 NPI should be primary prescriber identifier (at individual level) when it becomes available
- 12.2 HHS should accelerate enumeration of prescribers to support transition to NPI
- 12.3 NCPDP HCIda should be used as prescriber identifier if NPI is not available in time for Medicare Part D
- 12.4 HHS should support identification of prescriber location issues and include potential solutions in pilots
- 12.5 HHS should evaluate use of HCIda to expedite enumeration of prescribers
- 12.6 HHS should protect linkage between NPI and HCIda to support routing

NCVHS September 2004

Important Related Issues

- Pilot test objectives
 - 13.1 Enhancement of foundation standards prior to pilot tests
 - 13.2 Enhanced foundation standards in pilot tests
 - 13.3 E-Rx vendors to ensure readiness for pilot tests
 - 13.4 Goals, objectives, timelines, and metrics for pilot tests
 - 13.5 Disseminate benefits, implementation strategies, guidance for HIPAA privacy compliance, and information to promote physician and patient acceptance
- Support for standards collaboration
 - 14.1 E-prescribing standards coordination across all healthcare domains
 - 14.2 Change management process to facilitate version interoperability
- Policies to remove barriers
 - 15.1 Regulations establish safe harbors, protect provider/patient choice, and require e-prescribing messages be free of commercial bias
- Conformance testing and certification
 - 16.1 Conformance tests and implementation guides by SDOs
 - 16.2 E-prescribing vendors validate conformance
 - 16.3 ONCHIT investigate best way to certify compliance

NCVHS September 2004

Topics Not Addressed

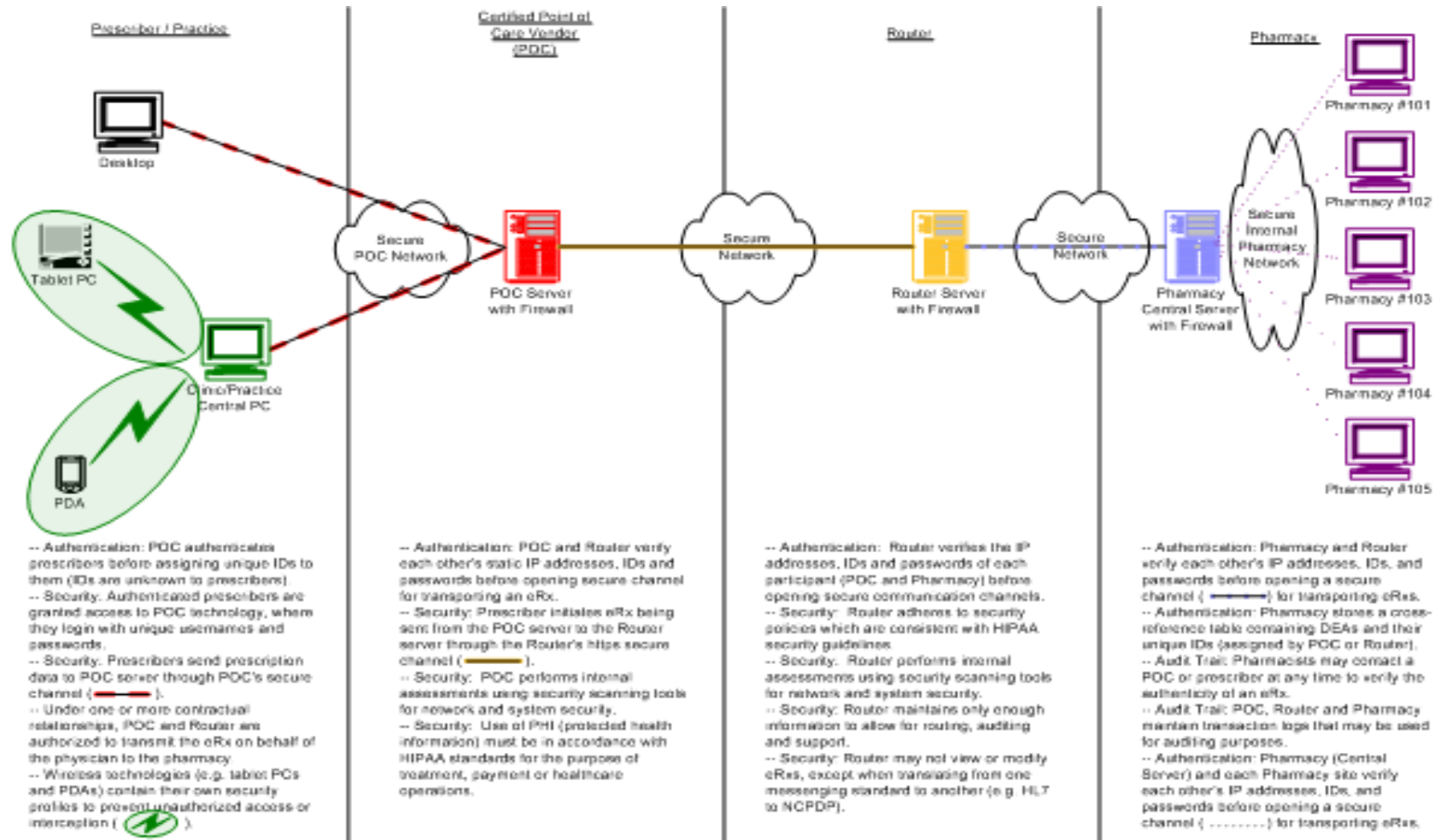
- E-Signatures
- Privacy and security
- Directory for prescribers, nursing facilities, pharmacies
- Codification of allergens, drug interactions, other adverse reactions
- Drug therapy indication codes
- Standards for units of measure
- Methods for patient identification
- Use of HIPAA health plan identifier for e-prescribing
- Formulary identifier
- Standards for medication history
- Standards for medical history
- Interoperability among e-prescribing standards
- Standard codes for orderable items such as supplies
- Standards for drug labeling and drug listings
- Clinical decision support standards

NCVHS March 2005

Recommendations: E-Signature

- 1.1 HHS, DEA, and State boards of pharmacy should recognize current e-Rx network practices that are in compliance with HIPAA security and authentication requirements as a basis for securing e-prescriptions
 - ◆ See (Appendix) for e-Rx Network
 - ◆ Differing requirements may be needed for transmission of electronic prescriptions that do not go through such networks
- 1.2 HHS and DOJ should work together to reconcile different agency mission requirements in a manner that will address DEA needs for adequate security of prescriptions for all controlled substances, without serious impairing the growth of e-prescribing in support of patient safety as mandated by MMA
- 2.1 HHS should evaluate emerging technologies such as biometrics, digital signature, and PKI for higher assurance authentication, message integrity, and non-repudiation in a research agenda for e-Rx and all other aspects of health information technology

Current Security and Authentication Practices in E-Prescribing Networks



NCVHS March 2005

- Observations and Recommendations on Progress on NCVHS Recommendations from September 2004 Letter
- Privacy of E-Prescribing
 - 10.1 HHS should identify and evaluate any privacy issues that arise during the 2006 pilots, with special attention on issues regarding individuals' rights to request restrictions on access to their prescription records
 - 10.2 HHS should use experience gains from e-Rx pilots to develop appropriate actions for handling privacy issues
- Other Standards and Important Related Issues
 - ◆ *Enumeration of other issues*

e-Prescribing Standards: Toward a Seamless System for Better Outcomes



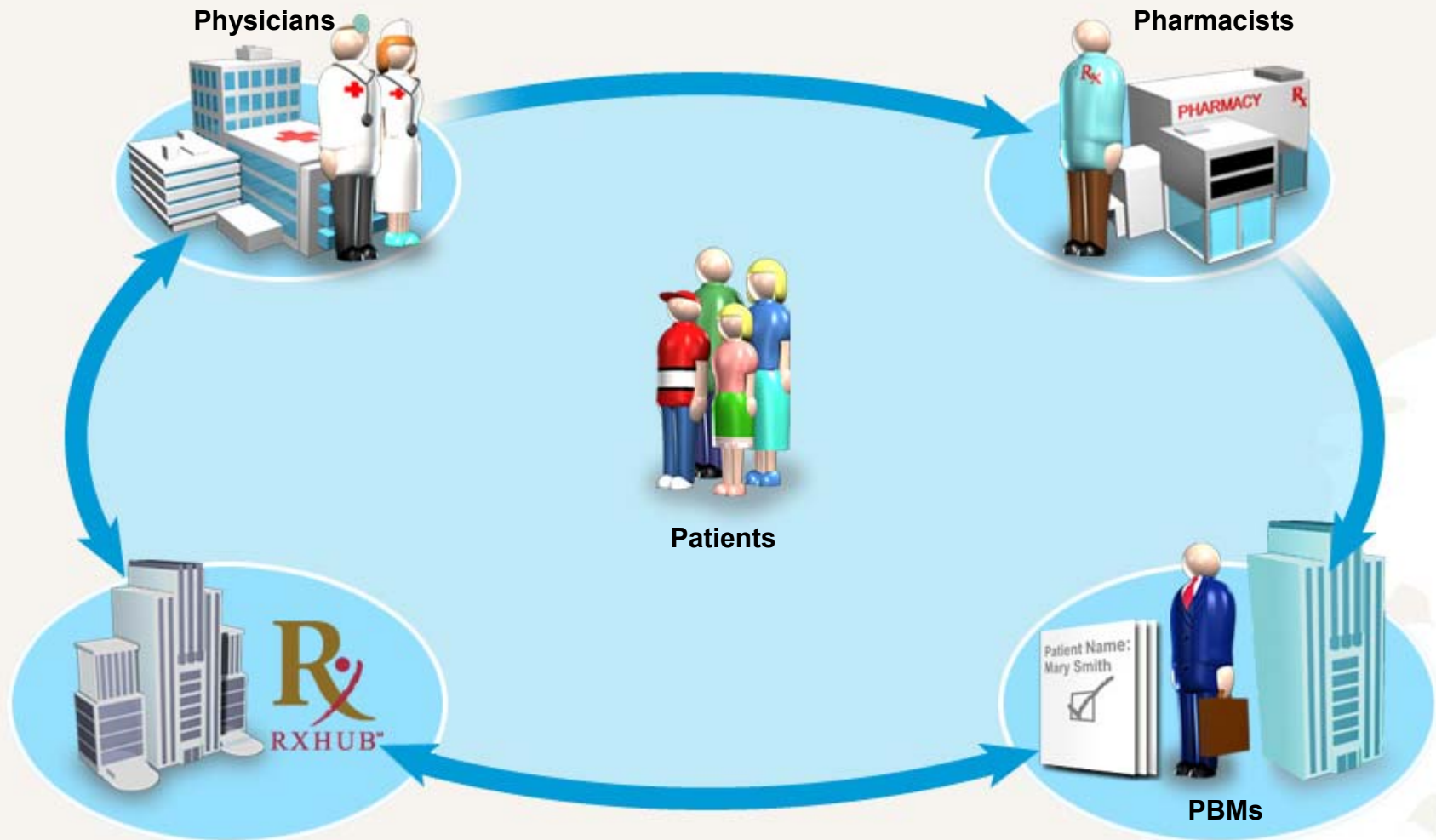
Chelle Woolley
Senior Vice President & Chief
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RxHub

Today's Prescribing Process...

-Needs Improvement

- The prescription is written based on physician-patient decision
but without sufficient information.
- The prescription is delivered to a pharmacy
*in a non-standardized delivery method...
many Rx never get to the pharmacy*
- The prescription is processed at the pharmacy
where much re-work often required.
- When the patient takes the prescription—are they compliant?
is more information needed?

Information at Every Point of Care



ePrescribing: A Comprehensive Approach

- Access to information of clinical decision support
- Building (incrementally) of a patient database that is transportable and accessible to all parties deemed by the patient to require information in their care
- Long-term intention of realizing safety gains realized by the more integrated systems
- Reducing cost and increasing practice efficiency

Essentials of a Medicare ePrescribing Program

- Eligibility (accurate identification of patient)
- Benefits (including formulary and tiered formulary structure & requirements for prior authorization).
- Information on the drug being prescribed or dispensed, other drugs listed on medication history.
- Information on the availability of lower cost, therapeutically appropriate alternatives.

Update on ePrescribing Standards

- Eligibility- ASC X12N 270/271 named foundational standard in recommendation from NCVHS and the NPRM.
- Medication History, SCRIPT 8.0 – is now an NCPDP Standard It was passed by the NCPDP Board of Trustees early August . The standard has been submitted to ANSI in parallel and indications are ANSI is very close to blessing it.
- Formulary and Benefit File Load V1.0 – Passed the re-circulation ballot at NCPDP early August. Final review of comments and 30 day appeals period during which the Board will approve. The standard has been submitted to ANSI in parallel.

Pre-emption: A Must for Broad Adoption

- Uniform Standards
- Deemed preemptive—in place not later than September 1, 2005
- Preempt any state law or regulation
- Safe Harbor provisions

Impact on Health Plans

What do health plans participating in Part D have to do about e-prescribing?

Answer: The Medicare Prescription Drug Benefit final rule, published on January 28, 2005, contains provisions related to e-prescribing. It requires that Part D sponsors, including Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) Organizations offering Medicare Advantage Prescription Drug (MA-PD) plans ***must support and comply with electronic prescribing standards relating to covered Part D drugs for Part D enrollees once final standards are in effect.***

Requirements for Participation

Solicitation for Applications from Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug Plans (MA-PD)

January 21, 2005

(as Revised on March 9, 2005)

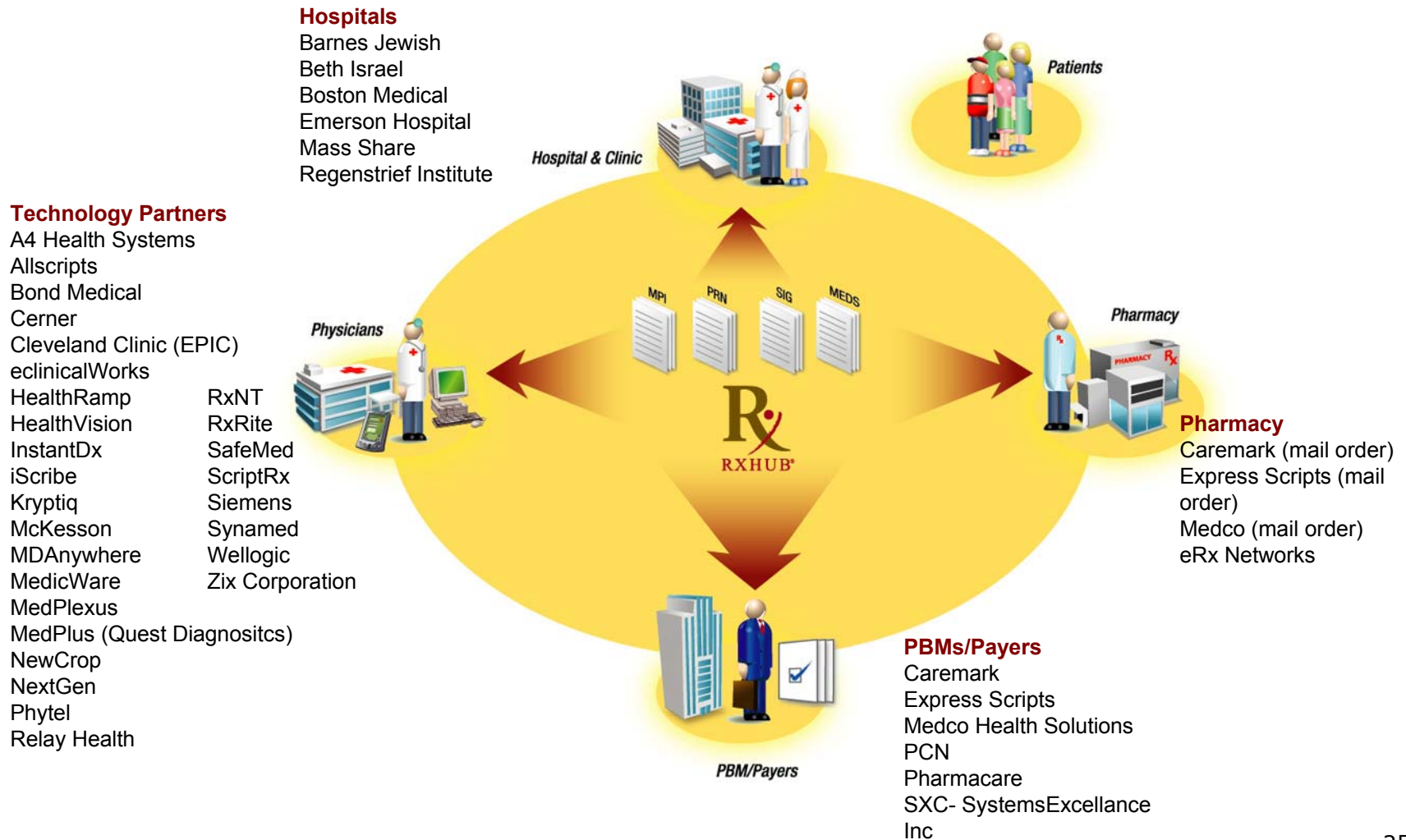
3.2.5 Electronic Prescription Program

A. Complete the table below:



APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PDP CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN. YES NO1. Once electronic prescribing standards are published and in effect, the Applicant agrees to have an electronic prescription program that supports electronic prescribing with pharmacies as well as physicians.

RxHub Connectivity



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Ken Whittemore, Jr.
VP, Professional and
Regulatory Affairs

September 8, 2005

Prescription Routing: NCPDP SCRIPT Standard (a proposed foundation standard)

- SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, intermediaries and payors
- The current standard supports messages regarding new prescriptions, prescription changes, refill requests, **prescription fill status notification** and prescription cancellation
- Enhancements have been added for DUR alerts, formulary information and medication history
- While most organizations have implemented NCPDP SCRIPT 4.2 or earlier, the standard is now at v8.0

The ePrescribing Gateway allows for true end-to-end electronic prescribing

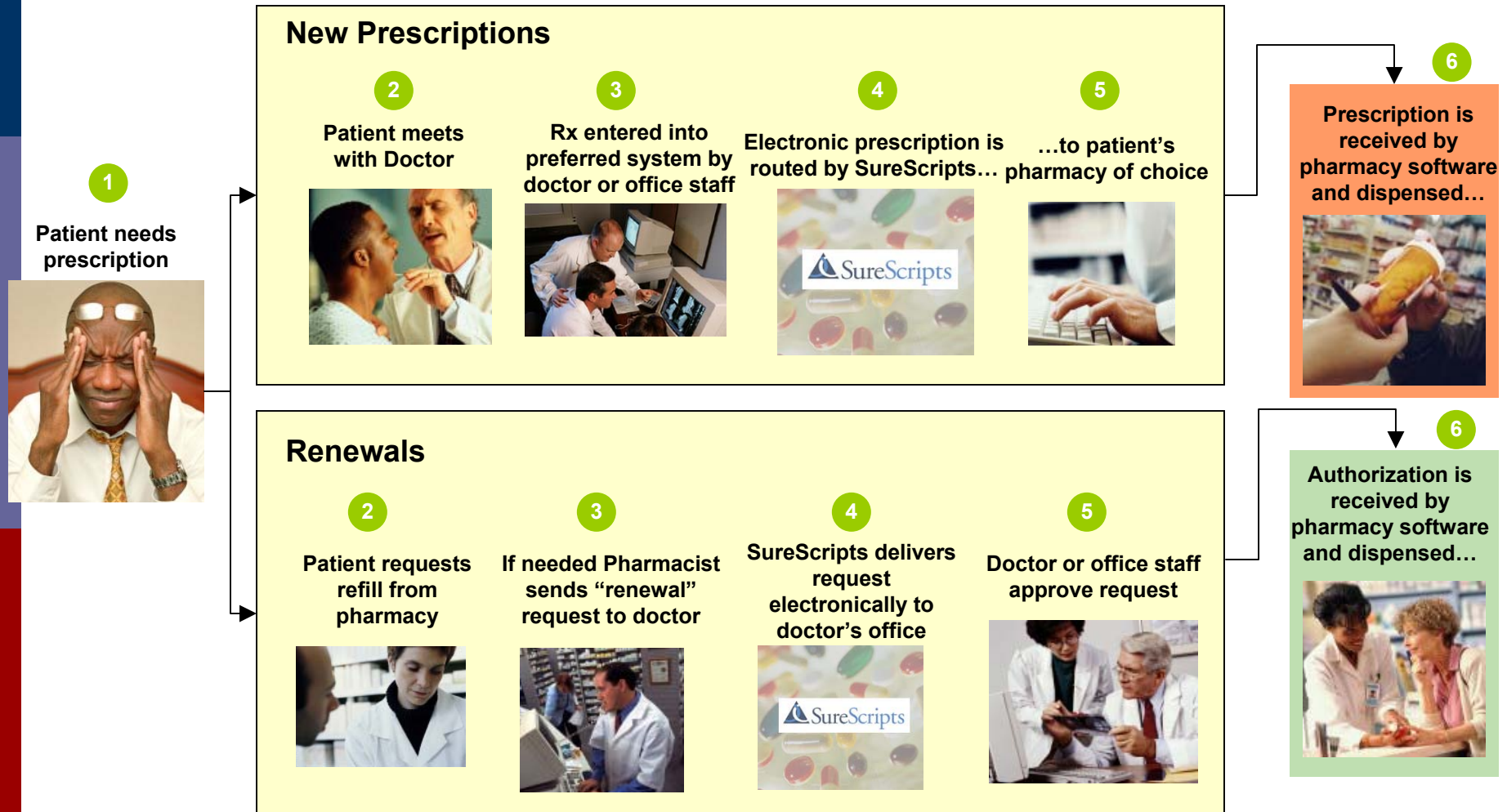


- ◆ Physicians need electronic prescribing software that is certified with the ePrescribing Gateway (EPG)
- ◆ Works on existing computers or new tablets/PDAs
- ◆ Automate prescribing only or more functions like an EMR
- ◆ Send new prescriptions and respond to renewal requests

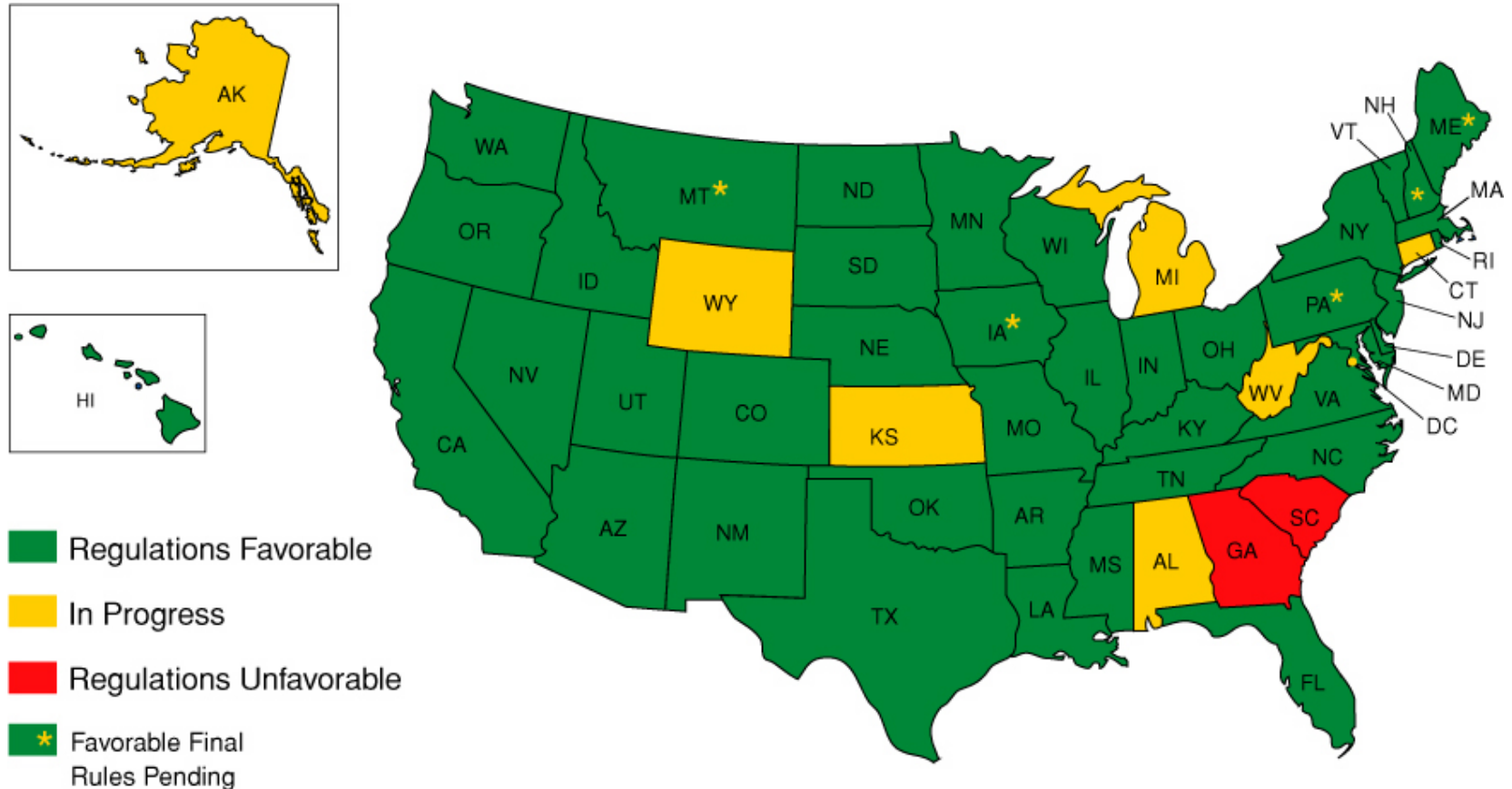
- ◆ The ePrescribing Gateway (EPG) provides application to application connectivity
- ◆ The EPG certifies that the software applications that physician practices and pharmacies deploy work properly
- ◆ Most EPGs do not charge physician practices for connectivity to pharmacies

- ◆ Pharmacy management system communicates via the EPG with physician practices
- ◆ Sending renewals directly to computers in physician practices instead of faxes and phone calls
- ◆ Receiving new prescriptions electronically too

The prescription process is greatly simplified with true end-to-end electronic prescribing



The state legal and regulatory environment allows for true electronic prescribing in the majority of states today



* As of June 1, 2005

Over 85% of the nation's community pharmacies have systems certified to connect to the SureScripts electronic prescribing network



Just some of the pharmacies connected to the SureScripts Electronic Prescribing Network.

Community pharmacies are managing electronic prescriptions in over 40 states



Physician technology vendors now contracted with or connected to *SureScripts* (27 EMRs)

■ **Electronic Medical Record (EMR) Solutions**

- ◆ **A4 Health Systems ***
- ◆ **Allscripts ***
- ◆ **ASP.MD ***
- ◆ **Bond Medical ***
- ◆ Cerner
- ◆ **ChartConnect***
- ◆ Companion Technologies
- ◆ **DOCS* (SOAPware)**
- ◆ **Epic***
- ◆ **eClinicalWorks***
- ◆ **Health Systems Research***
- ◆ iMedica
- ◆ InteGreat
- ◆ **Medical Communication Systems ***
- ◆ MediNotes
- ◆ **McKesson***

■ **Electronic Medical Record (EMR) Solutions**

- ◆ MedicWare
- ◆ MedNet System
- ◆ **MedPlexus ***
- ◆ MOST LLC
- ◆ NextGen Healthcare Information Systems
- ◆ Physician Micro Systems
- ◆ Polaris Management, Inc.
- ◆ Smart EMR/VIPA Health
- ◆ Spring Medical
- ◆ **Synamed ***
- ◆ Wellogic

* = Completed SureScripts certification & registered as a SureScripts Certified Solution Provider™

Physician technology vendors now contracted with or connected to *SureScripts*

Electronic Prescribing Solutions

reative Socio-Medics Corp.

AW Systems

rFirst *

old Standard Multimedia *

ealthRamp *

nstantDx *

ighthouseMD*

Danywhere Technologies

Other Services

- Athenahealth
- **Axolotl ***
- **Cleveland Clinic***
- HEALTHvision
- Kryptiq
- ScriptRx
- **UNC Health System ***

There are currently 26 SureScripts Certified Solution Providers (CSPs) with a target of 35 by end of 2005!

* = Completed SureScripts certification & registered as a SureScripts Certified Solution Provider™

A “Whole Product” is necessary to drive adoption and utilization

