

Electronic Prior Authorization Update

***“Those who cannot remember the past are
condemned to repeat it.”***

- George Santayana, *the Life of Reason*, 1924

NCPDP Workflow-to-Prior AuthTask Group (AKA ePA Task Group)

December 15, 2011

Agenda

- **Pre-Pilot & Pilot Years**
 - Task Group Formation
 - Preparation for Pilots
 - MMA ePrescribing Pilots
- **Post-Pilot Years**
 - Expert Panel & Recommendations
 - New NCPDP xml standard

Pre-Pilot and Pilot Years

NCPDP Workflow-to-Prior AuthTask Group (AKA ePA Task Group)

December 15, 2011

Multi-SDO Task Group

<i>Founded</i>	November 18, 2004 (NCPDP Fall Workgroup Meeting)
<i>Objectives</i>	<ul style="list-style-type: none">• Promote standardized automated adjudication of prior authorization• Coordinate the further development and alignment of standards• Identify additional needed standards
<i>Organizations Participating</i>	Standards Development Organizations: NCPDP, X12, HL7 Health Plans/PBMs: Wellpoint, HealthNet, Excellus BCBS, BCBSMA, Express Scripts, Caremark, Medco, Argus, Prime Therapeutics Physicians/Providers: AAFP, Lifespan Others: Achieve (long-term care); Pfizer; DrFirst; ZixCorp; Allscripts
<i>Task Group Leader</i>	Tony Schueth, Managing Partner, Point-of-Care Partners, LLC

Obtained Physician Perspective

- Most painful formulary-related contact: prior authorization (1999 Medco survey, n=20)
 - Most desired feature of ePrescribing: “decreasing hassles with prior authorization” (2004 SureScripts survey, n=2,391)
 - Most requested ePrescribing feature enhancement of physician software customers: PA (2005 POCP survey, n=20)
 - Findings from 2004 PDR online survey (n=3,529):
 - 63% of prescribers write some Rx's that require PA
 - 71% of Family Medicine/68% of Internal Medicine practitioners have been discouraged from prescribing the most appropriate medication due to pre-auth requirement
 - 91% of MDs surveyed agreed or strongly agreed that PA is frustrating, both for them & patients (2006 NJEPAC n=228)
 - “I hate prior authorizations... because of the time they take.”
 - “Basically, you have to say what the insurance people want to hear. I frequently lie, yell or scream.”
 - “It takes time away from patient care.”
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Obtained Health Plan Perspective

- Findings from survey of AMCP pharmacy directors, 92% of whom manage PA (2004 POCP n=25)
 - 96% support automation of prior authorization to:
 - Increase clinically appropriate prescribing (76%)
 - Decrease administrative costs (76%)
 - Increase member satisfaction (40%)
 - 84% expected no/small ↑ in PA'd drugs as a result
 - Just 44% believed the drugs requiring PA would ↑
 - Barriers to automating prior authorization:
 - Lack of physician office technology (88%)
 - Lack of electronic standards (84%)
 - Lack of PBM business model (60%)
 - Organizational buy-in (24%), Insufficient ROI (36%)
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Obtained Other Perspectives

- “We recommend that there be standards associated with requests or authorization codes” (Medco executive, NCVHS, July 29, 2004)
 - “What’s (complicated) is the discussion on how to qualify the Rx”
 - “The crafters of the MMA took care to insist that ePrescribing pose no undue burden on physicians, but current transactions do little to address some areas where physicians feel the greatest administrative burden (e.g. PA).” (Pfizer exec, NCVHS testimony, July 29, 2004)
 - “Automating processes like PA is what computers were designed for.” (MediMedia exec, NCVHS testimony, Aug 22, 2004)
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Obtained & Analyzed Forms

- Celebrex Observations:
 - Organized by therapeutic category
 - Patient, physician data required should be in vendor system
 - Previous medications (med hx) required
 - Rules included on form
 - Conditions required

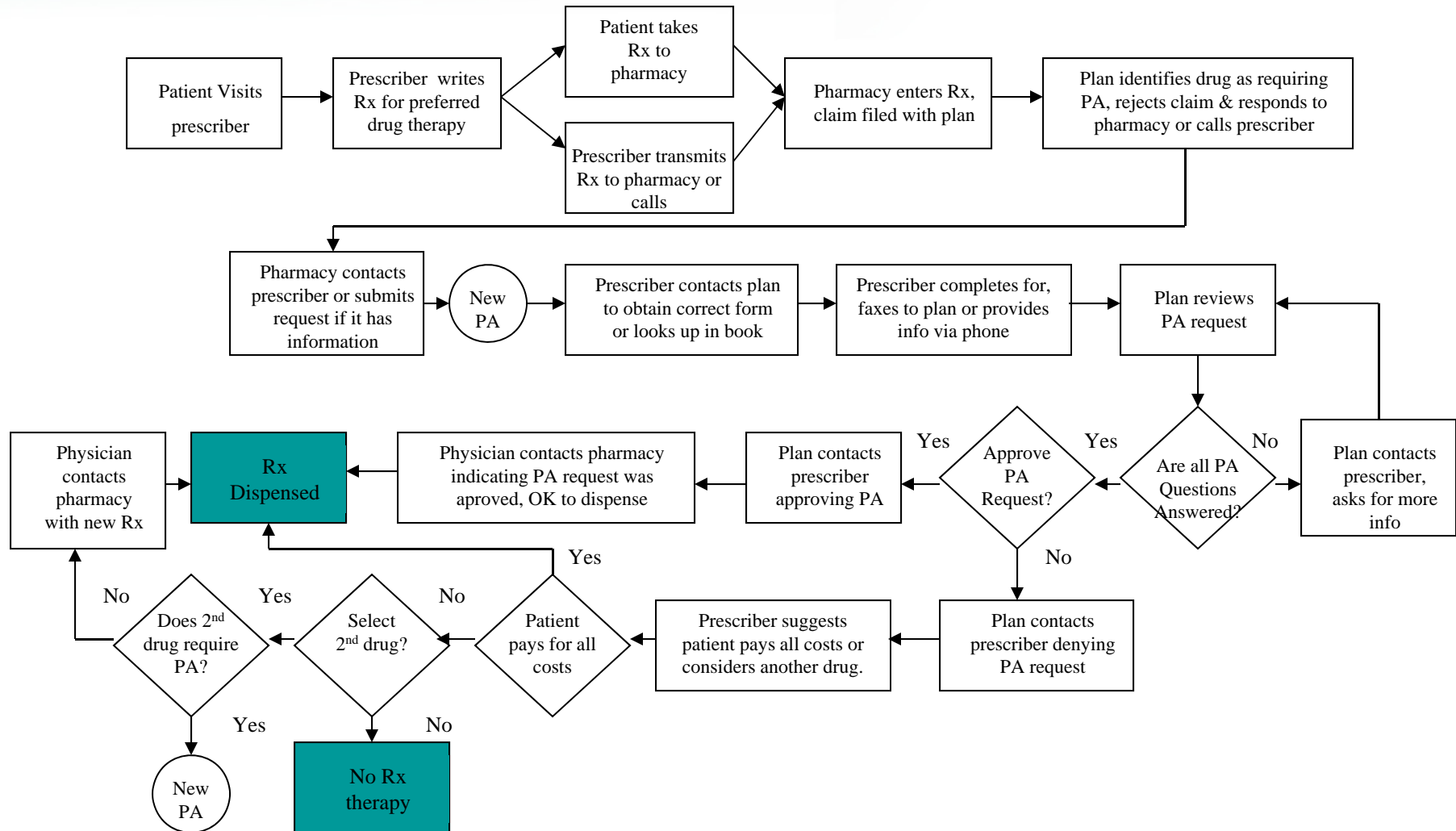
BlueCross of California		CONTAINS CONFIDENTIAL PATIENT INFORMATION			
		Celebrex (celecoxib) Prior Authorization of Benefits (PAB) Form			
		Complete form in its entirety and fax to: Prior Authorization of Benefits (PAB) Center at (888) 831-2243			
1. PATIENT INFORMATION		2. PHYSICIAN INFORMATION			
Patient Name: _____		Prescribing Physician: _____			
Patient ID #: _____		Physician Specialty: _____			
Patient DOB: _____		Physician DEA#: _____			
Date of Rx: _____		Physician Phone#: _____			
Patient is: <input type="checkbox"/> Female <input type="checkbox"/> Male		Physician Fax#: _____			
3. INDICATE DIAGNOSIS					
Diagnosis:	<input type="checkbox"/> Osteoarthritis	<input type="checkbox"/> Rheumatoid Arthritis	<input type="checkbox"/> Primary Dysmenorrhea	<input type="checkbox"/> FAP	
Strength:	Celebrex 200mg	Celebrex <input type="checkbox"/> 100mg	Celebrex 200mg	Familial Adenomatous Polyposis	
Max Qty Limit:	30 per 30 days	60 per 30 days <input type="checkbox"/> 200mg	11 per 30 days	Celebrex 400mg	
	OA or RA: Must meet criteria below in 4A OR 4B OR 4C		Must be female and meet criteria below in 4A OR both 4B AND 4C		60 per 30 days
					Only diagnosis required
4. APPROVAL CRITERIA: CHECK ALL BOXES THAT APPLY					
Any areas that are not filled out will be considered not applicable to your patient AND MAY AFFECT THE OUTCOME OF THIS REQUEST					
A. <input type="checkbox"/> Yes <input type="checkbox"/> No Patient has major NSAID-induced GI complication risk factors: ONE OF THE FOLLOWING MUST BE PRESENT					
<input type="checkbox"/> Yes <input type="checkbox"/> No	Active non-menstrual bleeding or bleeding disorder				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Concurrent anticoagulation therapy Please note: bleeding events and increased prothrombin time have been reported in patients taking COX-2 Selective NSAIDs concurrently with warfarin. INR monitoring is still necessary in COX-2s.				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Patient has previous documented history of NSAID-induced gastropathy				
B. <input type="checkbox"/> Yes <input type="checkbox"/> No Patient has other NSAID-induced GI complication risk factors: TWO OR MORE OF THE FOLLOWING MUST BE PRESENT					
<input type="checkbox"/> Yes <input type="checkbox"/> No	Age ≥ 65 years old				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Chronic major organ impairment _____ (please specify) or active Rheumatoid Arthritis				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Concomitant chronic systemic corticosteroid therapy				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Chronic high-dose NSAID therapy (e.g. 2-3 times the standard dose to achieve therapeutic effect)				
<input type="checkbox"/> Yes <input type="checkbox"/> No	Anti-platelet agents for vascular prophylaxis				
C. <input type="checkbox"/> Yes <input type="checkbox"/> No Patient has documented trial and failure of 2 or more prescription-strength NSAIDs (Must specify trials below)					
NSAID #1: _____		NSAID #2: _____			
5. PHYSICIAN SIGNATURE					
Prescriber or Authorized Signature _____					Date _____
<small>Prior Authorization of Benefits is not the practice of medicine or the substitute for the independent medical judgment of a treating physician, only a treating physician can determine what medications are appropriate for a patient. Please refer to the applicable plan for the detailed information regarding benefits, conditions, limitations, and exclusions.</small>					
IMPORTANT WARNING: This message is intended for the use of the person or entity to which it is addressed and may contain information that is privileged and confidential, the disclosure of which is governed by applicable law. If the reader of this message is not the intended recipient, or the employee or agent of the intended recipient, you should not disseminate, distribute or copy this e-mail. Please notify the sender immediately by e-mail if you have received this e-mail by mistake. Contact your supervisor immediately if you have any questions concerning the above. Thank you for your cooperation.					
<small>05x11 in</small>					

Industry Analysis (NSAIDs/Cox2s)

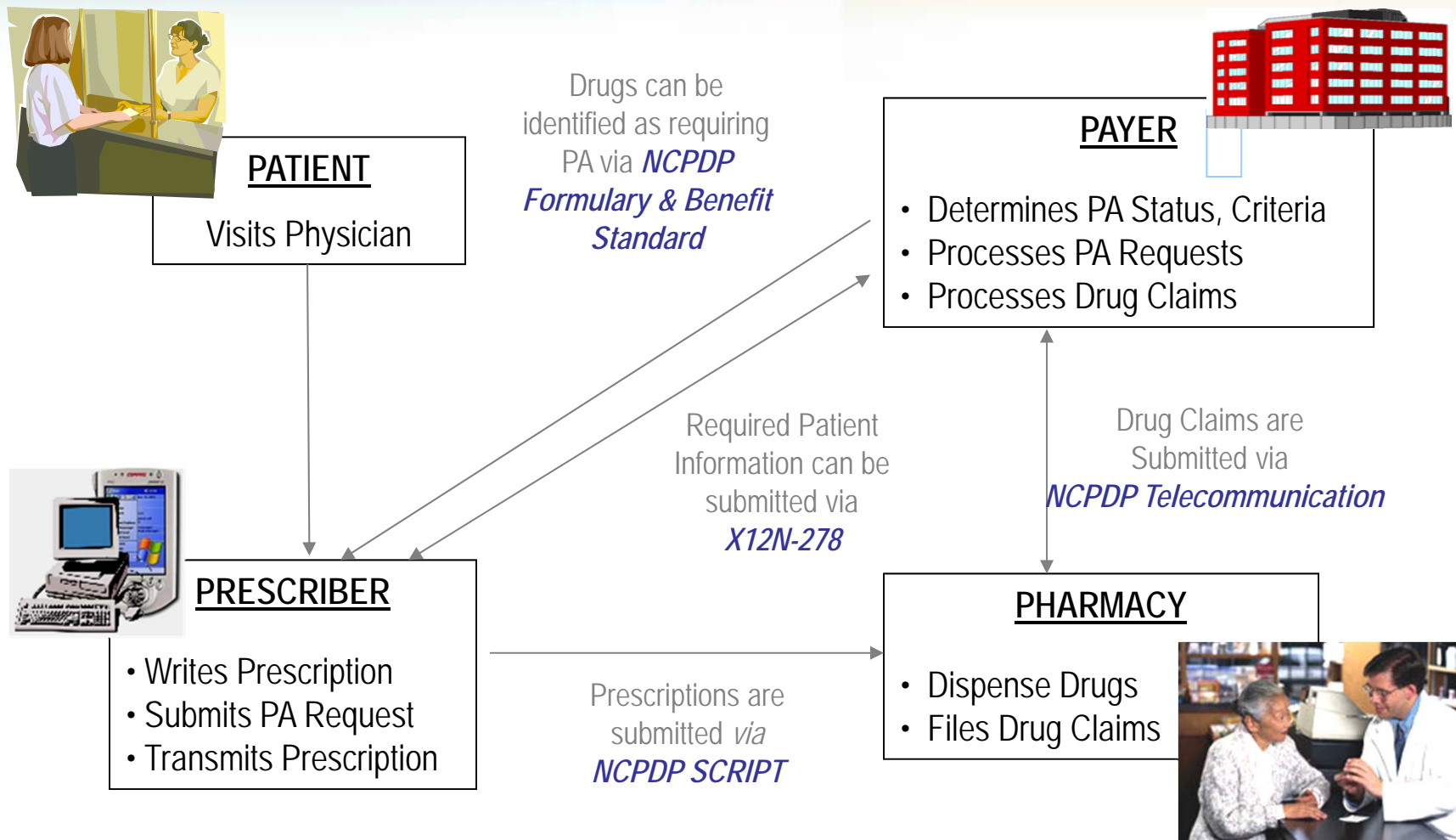
Criteria varies by plan, wording non-standard

Drug/Criteria	Health Plan A	Health Plan B	Health Plan C	Health Plan D	Health Plan E	Health Plan F	Health Plan G
NSAIAs							
<i>[Celebrex, Bextra] - COX2 Inhibitors</i>							
Drug				N/A			
Strength	•	•					•
Dose	•	•					•
Diagnosis	•	•			•	•	•
Expected duration	•	•			•	•	•
Previous therapy and dates	•	•			•	•	•
Response to previous therapy (inadequate response, adverse effects, comments)	•				•	•	•
Pt age: 65 or older					•	•	•
Pt has documented Hx of ulcer disease or prior evidence of GI hemorrhage (ICD-9 if available)	•					•	•
Pt has concurrent use of corticosteroids		•			•	•	•
Pt has concurrent use of anticoagulants or antiplatelets (Ticlid, Aggrenox, Plavix)	•	•			•	•	•
Pt has concurrent use of NSAIDs	•	•			•	•	•
Pt has anti-ulcer agent (H.Pylori eradication agents) - Helidac or Prevpac		•					
Pt requires NSAID use > 21 days (list drug and dose)	•						
Pt previously unable to tolerate 2 different NSAIDs	•					•	•
Shrt-trm Tx (<21d) hi-risk pts NSAID induced adv GI event w/2 different	•				•		
Shrt-trm Tx (<21d) hi-risk pt anticoag, antiplatelet, chronic oral corticosteroid	•						
Hx of PUD, NSAID-related ulcer or clinically significant GI bleed	•					•	•
Pt has hereditary or acquired coagulation defect (eg: hemophilia or Von Willebrand's, protein C or S deficiency, thrombocytopenia or chronic renal failure)	•				•		
Celebrex coverage for reducing number of adenomatous colorectal polyps in pts w/Familial Adenomatous Polyposis (FAP)	•						•
Coverage not provided for prevention of cancer, prev or tx of Alzheimer's or in presence of ASA >325 mg/day	•						
Benefit approval duration: 12 months (grandfather existing users)	•						

Mapped ePA Workflow



ePA-Related Standards (2005)



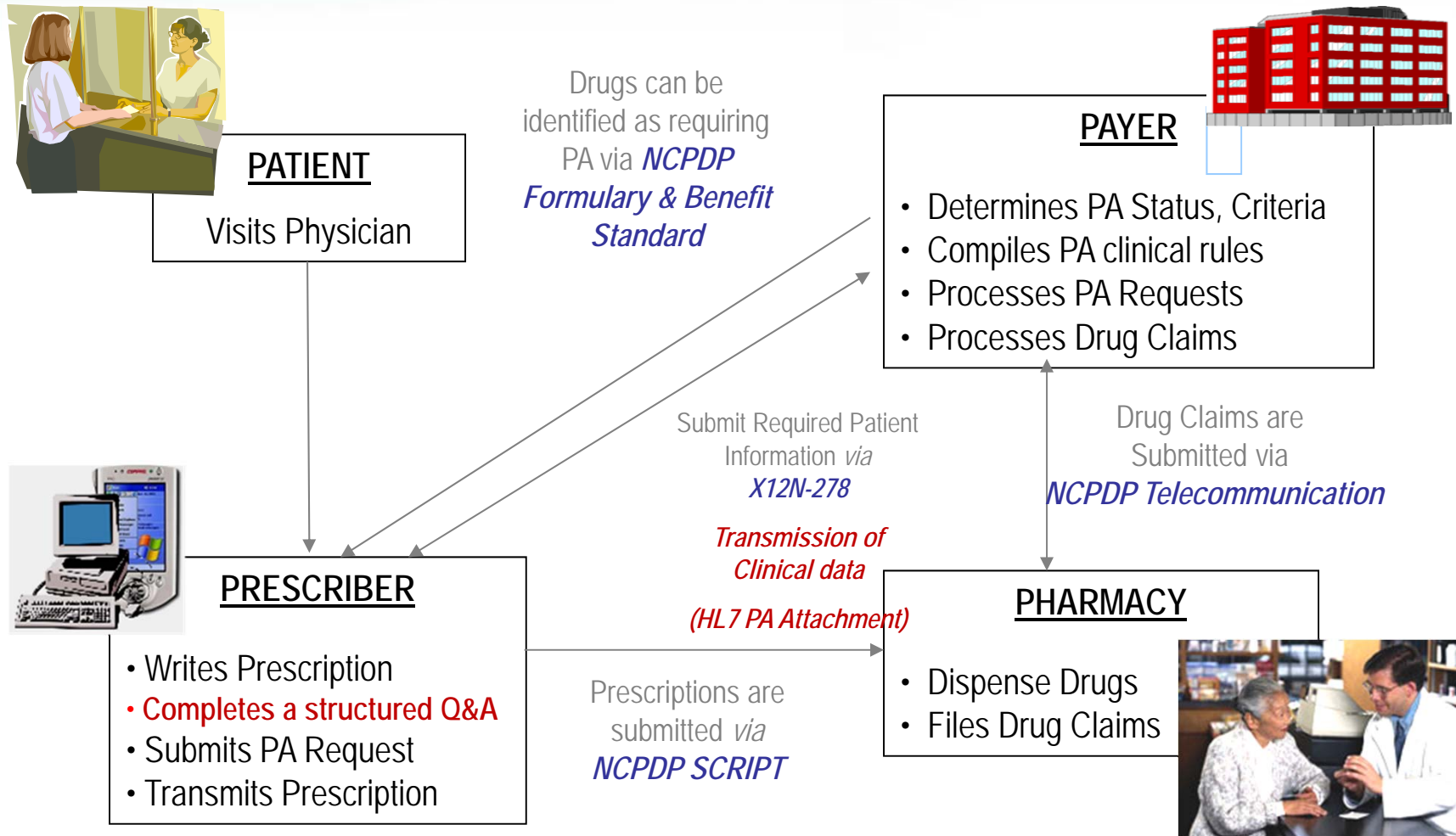
Solicited model = eRx software makes request, payer id's criteria and responds; 2nd request is made

Unsolicited model = eRx software provides criteria/form and request is made to payer

Guiding Principles

- Leverage existing standards for two reasons:
 - Felt constrained by HIPAA; specifically, that there is only one named standard for PA (ASC X12 278 – Health Care Services Review – Request & Response, v4010, May 2000)
 - Believed we could move faster by modifying existing standards vs building new ones
 - Objective was to streamline & standardize the mechanism for ePA, not usurp the plan's coverage decisions
 - Needed to be done with the cooperation of multiple SDOs, and in a consensus-based environment
 - Actively sought out the involvement of multiple relevant stakeholders (especially MDs, payers), so that work wouldn't be challenged by unrepresented stakeholders
 - While admittedly a challenge, believed it was possible to create and maintain a master-set of standard criteria
 - Aggressively worked to get ready for the 2006 pilots.
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Straw Model



Red letters = gaps in existing standards



MMA eRx Pilots – ePA Overview

Overview

- RFAs released in September 2005
 - Key components:
 - Must be conducted in CY 2006
 - \$6M available, no more than 9 funded, no award > \$2M
 - Cooperative agreements (coalitions)
 - Proposals evaluated by peer group
 - At least 25% of population Medicare-eligible
 - Testing EDI (vs fax) is critical
 - Test the interoperability of Foundation and Initial Standards
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Foundation & Initial Standards

Foundation Standards

- SCRIPT (new Rx, renewal, change, cancel, admin functions)
- ASC X12N 270/271
- NCPDP
Telecommunication

Initial Standards

- Medication History
- Formulary & Benefits
- Structured & Codified SIG
- Prior Authorization (X12N 278)
- RxNorm (new Rx, renewal, cancel)
- SCRIPT (fill status)

eRx Pilot Profiles

Lead	Award	Software Vendors	Switche(s)	Pharmacies	Other Organizations
RAND Corporation	\$1.8 M	Allscripts, iScribe	RxHub, SureScripts	Walgreens	Horizon, Caremark, UMDNJ, Point-of-Care Partners
Brigham & Women's	\$1.0M	B&W Hospital	RxHub, SureScripts	"Community of pharmacy chains"	CareGroup Health Sys (MA), MA-Share
Achieve	\$1.1M	Achieve Healthcare Information Technology	RxHub	Preferred Choice Pharmacy	Benedictine Health System, RNA Health, Prime Therapeutics, BCBSMN
Ohio KePro	\$896K	InstantDx, NDC Health	RxHub, SureScripts	CVS, Walgreens, Rite-Aid	NEO/Univeristy Hospitals System, Primary Care Physicians, Qual-choice, Aetna, Univ. of MN, MGMA
SureScripts	\$1.9M	Allscirpts, MedPlus/ Quest Diagnostics, DrFirst, GSM, Zix	SureScripts	Ahold, Brooks, Albertsons, CVS, Duane Reed, Rite Aid, Walgreens, Walmart, Kerr, Longs	Brown University, Midwestern University, Chain Pharmacy Advisory Council, Independent Pharmacy Advisory Counsel

Focus of Initial Standards Testing

Standards	Description	Testing Requirements
Medication History (NCPDP SCRIPT)	Dispensed/Claims Hx fx of NCPDP SCRIPT	Determine readiness
Formulary & Benefit (NCPDP v.1.0)	Form status & alternative drugs, copay	Determine if should be adopted
Fill Status Notification (Fxn of NCPDP SCRIPT)	Informs when Rx filled, not filled or partially filled	Assess business value & clinical utility
Structured & Codified SIG	Patient instructions incl. dose, route, freq., etc.	Test standards development org formats
RxNorm Clinical Drug Terminology	Std drug nomenclature meant to be intralingua	Determine if RxNorm translates to NDC
Electronic Prior Authorization Messages	Provider request, payer response to PA criteria	Determine if standards are ready for adoption

eRx Standards Summary By Pilot Site

Standards	Achieve	B&W	OH KePro	RAND	SureScripts
Medication History (NCPDP SCRIPT)	No	Yes-live	Yes-live	Yes-live	Yes-live
Formulary & Benefit (NCPDP v.1.0)	Yes-live	Yes-live	No	Yes-live	Yes-live
Fill Status Notification (Fxn of SCRIPT)	Yes-live	Yes-eval only	Yes-using MedHx	Yes-live	Yes-using MedHx
Structured & Codified SIG	No	Yes-lab	Yes-lab	Yes-lab	Yes-lab
RxNorm Clinical Drug Terminology	No	Yes-lab v12/21/06	Yes-lab	v12/21/06	Yes-lab v8/2/06
Electronic PA Messages	Yes-live <i>unsolicited</i>	Yes-lab <i>unsolicited</i>	Yes-live <i>unsolicited</i>	Yes-live <i>unsolicited</i>	No

Pilot Limitations

- Pilots are based on very limited data, for the following reasons:
 - Got started late 2006 due to delays in contract awards and funding
 - Only a few therapeutic categories were “standardized”
 - Even though these were cooperative agreements, there were limited numbers of payers in each
 - Since the pilot was not dedicated to PA, payers were chosen for reasons other than PA (ie they may not have had a large number of PA’d medications)
 - Timing (generally 4th quarter) was suboptimal
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MMA eRx Pilots – ePA Findings

NCPDP Formulary & Benefit Standard

- Modifications were required to F&B to enable the payer to distribute questions
 - Refinements needed to be made to the ePA process with meds with quantity limits or step therapy, so prescribers will only be prompted to fill out an ePA form when necessary
 - Not all payers provide group-level coverage limitations, which resulted in a number of PA opportunities being misidentified
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Use of the 275/278 Transaction Standards

- Investigators agreed with the Multi-SDO task group that the HIPAA-named PA standard – the X12N 278 **v4010** – is not adequate to support drug PA because it was designed for procedure or DME PA.
 - Content redundancy is problematic
 - Elements cannot be identified easily as common between standards
 - Same data needs to be transmitted multiple times
 - The 278 does not have a mechanism for providers to request and explain reasons for a quality dosing override.
 - The 278 does not limit diagnosis codes. This is a challenge for clinicians, who must select from hundreds of options, most of which are not appropriate. Clinicians prefer only those codes that are relevant to a drug in a drop-down list.
 - For “off-label,” an optional text field was required
 - All pilots indicated the need for the PBM’s unique member ID and cardholder ID, both for back-end processing and display
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Use of HL7 PA Attachment

- Designed to define the allowable and/or required content for the PA request and the structure for the infrastructure for the transmission of the content so that a health plan or PBM can approve or deny request.
 - Challenge is that it does not support content rules (including conditionality) or question sequence, so vendors cannot make questions mandatory.
 - Ensures that information is complete and reduces the back-and-forth between PA reps and prescribers
 - Investigators also found that there was no way to enable the use of payer-defined questions when appropriate pre-defined questions were not available.
 - The standard did not provide the ability to provide general information or instructions, rather than questions
 - Investigators found that it would be helpful to be able to provide a title for each electronic PA form (e.g. “Plan A Celebrex PA Form”), mimicking what is on the top of the current paper PA form.
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Use of LOINC

Logical Observation Identifiers, Names and Codes

- Does not contain all of the ?s that payers require to conduct PA
 - Asks questions that are not currently required by the payers, and forces payers to ask a predefined set of questions that are not necessarily relevant
 - Inconvenient and creates extra work for payers, prescribers and pharmacies
 - Impossible to map current forms used by payers
 - Does not allow payers to
 - ask for additional information
 - authorize new drugs that may be developed in the future
 - Does not contain rules that explain how to limit an iso+ set of “unit” choices available in the dropdown menus for questions that require numbered responses.
 - For numbered entries, the message format includes a value and a unit the code set for those units is large and appears generally irrelevant to clinicians.
 - The standard does not define rules for limiting those choices using predefined criteria, thereby creating a cumbersome experience
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Use of LOINC

Logical Observation Identifiers, Names and Codes

- Health plans can be very particular about the wording of questions, and their clinicians may not agree with the standardized LOINC questions
 - *“These questions go through multiple reviews by both the PBM clinical team and the health plan/client clinical team. Trying to standardize the questions themselves will expend more effort with little assistance in adoption of ePA. Since not all prescribers are going to be connected, health plans will need to support both an electronic and paper process. These two processes must present the same criteria. By trying to standardize specific wording, these standards are effectively asking health plans to standardize the way they implement PA across the board.”*
 - Employs free text for prior therapy drug entry.
 - However, providers have requested dropdown menus that limit options.
 - A common content LOINC question is prior therapy for diagnosis.
 - This question involves a free text drug name, a coded entry drug code and information on why the drug was discontinued
 - Provider groups prefer that the payer specify relevant drugs for prior therapy via coded entry.
 - Step therapy meds are included with the formulary standard, but are not selections under prior therapy in the LOINC standard
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Use of LOINC

Logical Observation Identifiers, Names and

Codes

- Implementation issues that need to be addressed to make LOINC sustainable in the future
 - Very large library of LOINC questions will have to be created to support ePA, ensure standardization of questions and reduce administrative time so that plan administrators would not have to reinvent the wheel each time they wanted to ask new questions or modify existing ones.
 - There is currently no way to create or fund a library to capture the questions that have already been asked. This library would have to be actively maintained, and there is currently no clearly identified entity to undertake this task.
 - There is no clear process for a quick and easy way to update questions. Health plans and other clients review and update PA criteria on an ongoing basis and the standards need to accommodate that process.
 - Flexibility would have to be built into the system so that the questions could be added on an interim basis, and modifications would have to be made more rapidly than the typical consensus-based SDO timeline
 - The need to use LOINC may delay the process of creating new codes for months, while some payers may want to implement within days
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Use of LOINC

Logical Observation Identifiers, Names and Codes

- Physicians prefer auto-population of PA forms. However, such functionality will be difficult to implement using the current LOINC standard.
 - Medical assistants (MAs) – not physicians – often complete payer requests for additional information. Currently, the questions defined in LOINC are too clinical for MAs to complete accurately, and too general to be autopopulated. Therefore, physicians will need to assume a greater role in the PA process, or additional training of MAs will be required
 - One pilot found that prior therapies and diagnoses are accessible to the health plan using claims data. Additionally, processing the test scenarios in the PA user interface demonstrated that fewer denials were granted than were expected.
 - **Therefore, plans may not need all of the information they request through their PA forms.**
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Diagnoses and ICD-9

- The tested standards assumed vendors have ICD-9 codes and they will be used to answer questions about diagnoses. Issues include:
 - Specificity of ICD-9 codes is inconsistent across PA categories, combining the request for diagnosis and co-morbidities in one question, and questions on broad conditions. For example ...
 - The single code for multiple sclerosis is too broad to address the five specific MS questions asked on typical PA forms
 - In contrast, the ICD-9 codes for various types of mycosis are precisely matched to the PA questions
 - Multiple codes would be necessary to replace a simple yes/no answer
 - PA questions on broad conditions could be associated with a range of diagnosis codes, and it would be impossible to know which ones the physician would actually choose. For example ...
 - The simple question on whether the patient has cancer could be associated with several hundred codes in the range between 140 to 239.
 - Even a more focused question on breast cancer could be associated with as many as nine (9) ICD-9 codes
 - Not all payers or PBMs use ICD-9s, so the work they need to do to retrofit ICD-9 to the ePA process diminishes the potential ROI.
 - Several vendors – especially eRx (vs EMR) – do not use ICD-9s, so adding the code set to their software would be add'l work and cost

Provider Implementation Issues

- Asynchronous communication in ePA process may create delays overall
 - If a doctor is on vacation or the contact person is unavailable, additional info questions may not be answered in a timely manner
 - This is less of a problem if PA is real-time
 - Access must be flexible because different offices have unique processes for managing PA
 - Sometimes the doctor does it, other times RN or medical assistant, often a combo
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Implementation Issues for Patients

- Patient notification is important to complete the ePA loop, but current ePA standards do not include a mechanism for this.
 - If a payer has implemented real-time authorization, patient notification will not be an issue
 - However, when real-time authorization is not possible, an electronic patient notification process will need to be devised
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Implementation Issues for Pharmacies

- The standards do not provide guidance for communicating pharmacy information used in the eRx workflow.
 - Information about each pharmacy, such as name and address, must be known to the ePrescribing application to support selection of the pharmacy to which the electronic transaction will be delivered.
 - The SureScripts and RxHub implementation guides differ in how this information is exchanged, complicating the prescriber system interfaces.
 - A standard for this data would be useful in ensuring consistency of implementation and in reducing the complexity of communication with multiple business partners.
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Implementation Issues for Payers


- Adopting ePA will require substantial modifications to the payer back-end PA processing system
 - The ROI will depend on the degree to which ePA could improve efficiency by reducing call-backs to the physicians, and the degree to which it could be ultimately automated.
 - Until all physicians are interacting electronically, it will be necessary to support both an electronic and a paper PA process.
 - Payers will need to be clear about necessary patient-level information and other required circumstantial data, to ensure that ePA is processed only when needed
 - Provider willingness to adopt ePA will be adversely affected by the frequency w/ which PA requests turn out to be unnecessary
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Other ePA Work

Other ePA-related Work

- NCPDP Formulary & Benefit Task Group created a data model to facilitate communication of prior authorization requirements and added PA lists
 - Found that coverage subtype lists (e.g. quantity limits, step edits) may require significant modifications to facilitate relation of coverage limitations and PA forms
 - Research continued on GELLO, with input from the Federal Drug Administration (FDA), National Library of Medicine (NLM), Department of Defense (DoD), Oracle, and HL7 Technical Committees. The team found:
 - In comparison to four other clinical language queries, GELLO was found to 1) a provided a platform-independent, object-oriented data model that is compatible with the HL7 v3 RIM and 2) be used to retrieve patient data as part of clinical decision support content used across a broad range of applications
 - The HL7 Query Mechanism was found to be an effective tool for mapping non-compliant patient data into a virtual medical record (vMR).
 - The HL7 Patient Care Provision Domain fulfills the requirements of the ePA process.
 - The HL7 GELLO coding of six drug therapeutic categories was successfully recoded to the HL7 Patient Care Provision with several limitations.
 - An ePA Roadmap Overview and Detailed Concept diagrams and text annotations were developed to illustrate the life cycle of GELLO expressions in the context of ePA.
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Task Group Accomplishments through 2006

Task Group Accomplishments

- Mapped paper prior authorization workflow
 - Ambulatory Environment
 - Long-term Care (LTC) Environment
 - Leveraged AHRQ grant to analyze PA forms
 - Created database to support analysis
 - 350 forms / 1,750 questions / 53 payers
 - Leveraged additional AHRQ grant to normalize data in the following therapeutic categories:
 - Erectile Dysfunction
 - Growth Hormones
 - Unspecified
 - *Focused on commercial, high-volume, low-cost*
 - AntiFungals
 - PPIs
 - NSAIDs/Cox2s
 - Opioid Agonists
 - Formed separate task group to address PA in LTC
 - Responded to CMS NPRM in support of claims attachments
 - Developed guidance document, cross-reference for MMA pilots
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Task Group Accomplishments (cont.)

- Chose five additional therapeutic categories for analysis/normalization (but never finished)
 - Antineoplastics
 - Autonomic & CNS Medications
 - Genitourinary Drugs
 - Respiratory Agents
 - Topical Agents
- Supported MMA ePrescribing pilot project PA initiatives
 - Held training session for how to read HL7 attachments & walk-through of PA Attachment
 - Encouraged and Facilitated Plans, PBMs joining task group
 - Production testing of PA trans in MMA pilots
- Supported modification of X12N 278, 275
- Adjudicated ballot for HL7 PA Attachment
- Evaluated NCPDP F&B Standard for ability to carry criteria from plan to physician software system
 - Separate task group worked on this
- Set out to normalized additional therapeutic categories/drug sets, but ran out of time
 - Asked CMS to provide list of its high-volume, low-cost
 - CMS also asked that we look at high-cost, low-volume

Other Standardization Activities

- AHRQ-sponsored initiatives to research viability of using HL7 ANSI-accredited standard, Guideline Expression Language – Object-Oriented (GELLO) for:
 - Presentation of prior authorization criteria (structured Q&A)
 - Query mechanism to extract clinical data from EMR
 - Ad hoc team from Harvard, InferMed, POCP, Pfizer working with input from the FDA, National Library of Medicine, Department of Defense, Oracle, HL7
 - One concept being tested: extracting criteria from the Structured Product Label (SPL)
 - Payers & PBMs continue to designate which drugs require PA, define information prescribers must submit
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Post-Pilot Years

NCPDP Workflow-to-Prior AuthTask Group (AKA ePA Task Group)

December 8, 2011

The Expert Panel



U.S. Department of Health & Human Services



National Resource Center for Health Information Technology

Agency for Healthcare Research and Quality

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Participants

- **Frank McKinney**, Achieve
- **Ross Martin, MD**, Bearing Point
- **Bruce Wilkinson**, CVS Caremark
- **Seth Joseph**, CVS Caremark
- **Reid Coleman**, MD, Lifespan
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- **Mark Gingrich**, RxHub
- **Tim McNeil**, RxHub
- **Terri Byrne**, T. Byrne & Associates
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- **Avi Ehrlich**, Wellpoint
- **Stuart Kersky**, RPh, Walgreens Health Solutions

Organizers: **Jon White, MD**, AHRQ; **Drew Morgan**, CMS; **Prashila Dullabh**, National Resource Center; **Jonathan Moore**, National Resource Center

Facilitator: **Tony Schueth**, Point-of-Care Partners

5-Year Assumptions

- Most prescribers will be using e-prescribing
 - ePA should happen
 - We should be rethinking the process – it doesn't make sense to automate a bad process
 - Policy makers will support this work and make it happen
 - Multiple connectivity devices
 - Market demands support ePA
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5-year Vision for ePA

- Every stakeholder will want to be engaged in ePA
 - Implementation will be fully functional
 - There will be a clear ROI for all stakeholders
 - Providers will be given the information they need to make the right decision
 - Right drug will be provided to the right patient at the right time
 - It'll be easy to transmit information between providers and PBM/plans
 - There will be a clear method for creating standardized Q&A
 - At a very minimum, demographics should be standardized
 - There will be a tool to automate the population of as much data as possible
 - There will be a real-time benefit check that verifies the relevance of PA for the patient
 - Some ePA will be automatically processed
 - There will be mechanisms to support automation in both the MD office & at the payer
 - There will be a mechanism for notifying a member or his/her agent of the status of the PA request
 - PA request will processed in real-time and at the POC
 - There will be a mechanism to alert pharmacy of the PA status
-

Roadmap

2008

- *Real time benefit check (being developed by RxHub)
- *Use resource links in Script to provide some short-term ePA support
- *Requesting no legislation around ePA standards
- *Identify funding sources for additional research, pilots
- *Modify Formulary & Benefit standard for step medication & quantity limits
- Fully understand the industry business models that need to be supported
 - Study value proposition for each key stakeholder
- Identify regulatory burdens impacting ePA
- Pilot planning
 - Identify which standards should be pilot tested (create and modify ePA transactions)
 - Determine pilot participants and involve them in planning
 - Establish metrics for success
 - Establish timeframe and timeline for pilots

** Priority areas*

Roadmap cont..

2009

- Phase 1 of ePA pilot
 - Pilot test transactions (end-to-end, but format-only)
- Analysis of standardized clinical questions

2010

- Complete Phase 1 of ePA pilot
 - Analyze findings
 - Report outcomes
- Begin planning of Phase 2 of ePA pilot
 - Establish timeframe, success criteria
 - Establish owner of repository
 - Understand business model for all participants/key stakeholders
 - Determine pilot participants and involve in the process

2011

- Phase 2 of ePA Pilot
 - Pilot test standardized clinical questions

2012

- Complete Phase 1 of ePA pilot
 - Analyze findings
 - Report outcomes
 - Take standards to industry
-

Additional Areas of Research

- *Value proposition for different stakeholders (MDs, payers, pharmacies)
- *Identify regulatory hurdles to ePA
 - Feedback loop to patients
- Evaluate how coverage data and presentation/UI impacts outcomes
- How may ePA questions be answered from data from EMR

** Priority areas*

Electronic Prior Authorization (ePA) Expert Panel Recommendations

~~August 6, 2008~~

Updated: November 5, 2008



U.S. Department of Health & Human Services



National Resource Center for Health Information Technology

Agency for Healthcare Research and Quality

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Background

- HIPAA's code set and final rule clearly specifies the X12 278 as the transaction for medication prior authorization.
 - The 2000 regulation specifies the 278 as a “request to ... obtain an authorization for health care”
 - Elsewhere, the regulation defines “health care” as “sale or dispensing of a drug ... in accordance with a prescription”
 - One finding of the 2006 MMA ePrescribing pilots was that the X12 278 v4010 prior authorization standard (PA), created for service or procedure PA, was insufficient for drug PA.
 - Workarounds were possible but not ideal because developers would be using fields for which they were not originally intended
 - The piloters tested a combination of the X12 278, X12 275 and the HL7 PA attachment (modeled after the claims attachment), and found them to be cumbersome and require redundant information.
 - Piloters recommended the multi-standard solution be abandoned for one standard
 - One of the concerns is that the combination of standards requires expertise in – and sometimes participation in – two SDOs, an expensive proposition for most companies
-

Background

- Some (but not much) work was completed on drug ePA since the conclusion of 2006 pilots
 - Formulary and Benefit (F&B) standard is being modified to better manage step therapy, quantity limits and other restrictions to reduce false-positives
 - F&B could be used as a means of getting criteria to the eRx or EHR system in the case of the “unsolicited model”
 - In 2006, a DRA segment was added to v5050 of the X12 278 to accommodate drug ePA.
 - According to X12, this segment will accommodate ~80% of drug PAs
 - More work still needs to be done to accommodate “solicited” model
 - Recognizing that there are some challenges to F&B (static file, etc) and that the ambulatory technology infrastructure is advancing, the **industry is in the process of building a real-time benefit check** to improve accuracy, reduce false-positives and enhance efficiency in community formulary and benefit info.
-

Expert Panel Concerns

- The HIPAA-named ePA standard, the ASC X12 278, is an EDI transaction, which cannot accommodate a real-time transaction, such as the real-time benefit check, which is what the industry is evolving to.
 - The DRA segment was added to X12 v5050. Time-to-market could be more than 10 years, based on history of HIPAA process to get a new version of a X12 HIPAA transaction approved
 - v4010 is now what's HIPAA-approved
 - The process is cumbersome and time-consuming, involving unanimous adoption by SDO -> NCVHS hearings -> HHS recommendation -> notice and comment rule-making by CMS
-

Recommendation

- Create a new, xml-based drug ePA transaction based on the X12N 278 (but not in X12):
 - Leverage the multi-SDO taskgroup, which involves X12 and HL7
 - Use the Context Inspired Component Architecture (CICA), ASC X12's framework for developing international data exchange message formats using reusable syntax-neutral components
 - Rationale:
 - compatibility with the real-time benefit check
 - faster time-to-market (due to not being constrained by HIPAA)
 - better able to maintain because of the nature of membership
 - ePA criteria tends to be clinically based and X12 tends to have participation of financial and administrative staff
 - X12 had asked for NCPDP's help in the past because of this
-

Next Steps

- Develop a new xml-based standard:
 - Likely for prior authorization, in general, vs. for medication prior authorization, in particular
 - Take it through the HIPAA Exceptions Process. As spelled out in §162.940 of the Transactions & Code Sets final rule, this involves:
 - Pilot testing under a detailed set of requirements
 - Must be supported by an ANSI-accredited SDO
 - Needs to prove less costly, improve efficiency and effectiveness and not impose additional administrative burden
-

Prior Authorization Workflow-to-Standards Task Group

February 13, 2009



Proposed Objectives

- ▶ Leverage previous work by the task group, SDOs, pilots, AHRQ and other sources to understand PA workflow in physicians office, plan, long-term care and pharmacy to:
 - ▶ Facilitate the creation of the structure to allow for the adjudication of electronic prior authorization
 - Create a new XML-based standard that will communicate necessary data elements to adjudicate electronic prior authorization of prescriptions/medications
 - ▶ Participate in the development of and monitor the HITSP electronic prior authorization use case.
 - Members of the task group will/are already serving on both



Principles for Building New Standard

- XML-based transaction/standard incorporating lessons learned from research done before 2006 and the 2006 pilots
- Leverage the NCPDP SCRIPT standard EDI and XML syntax
- Consider CICA design rules and the X12 prior authorization
- Involve multiple SDOs and stakeholders
- Ensure interoperability with electronic medical records
- Consider HITSP use case
- Support both “solicited” and “unsolicited” models



Where Are We Today?

NCPDP Workflow-to-Prior AuthTask Group (AKA ePA Task Group)

December 15, 2011

Where We Are (per ONC)



U.S. Department of Health & Human Services | www.hhs.gov

HealthIT Buzz

The Latest on Health Information Technology from ONC

Home > From the ONC Desk > E-Prescribing and Standards for E-Prior Authorization

E-Prescribing and Standards for E-Prior Authorization

May 2, 2011, 9:59 am
Dr. Coop Frosma | Director Office of Standards and Interoperability

Recently, colleagues have raised questions about pending state legislation related to electronic prescribing (e-prescribing) and in particular the concept of electronic prior authorization (ePA) for medications. We thought it would be helpful to discuss what we know about the current state of e-prescribing and ePA. E-prescribing provides significant advantages in contrast to its paper analog. Coupled with other complementary technologies, such as drug-drug interaction checking, e-prescribing can improve patient safety, increase prescribing accuracy and efficiency, and lower costs by notifying providers of generic or preferred drug list alternatives.

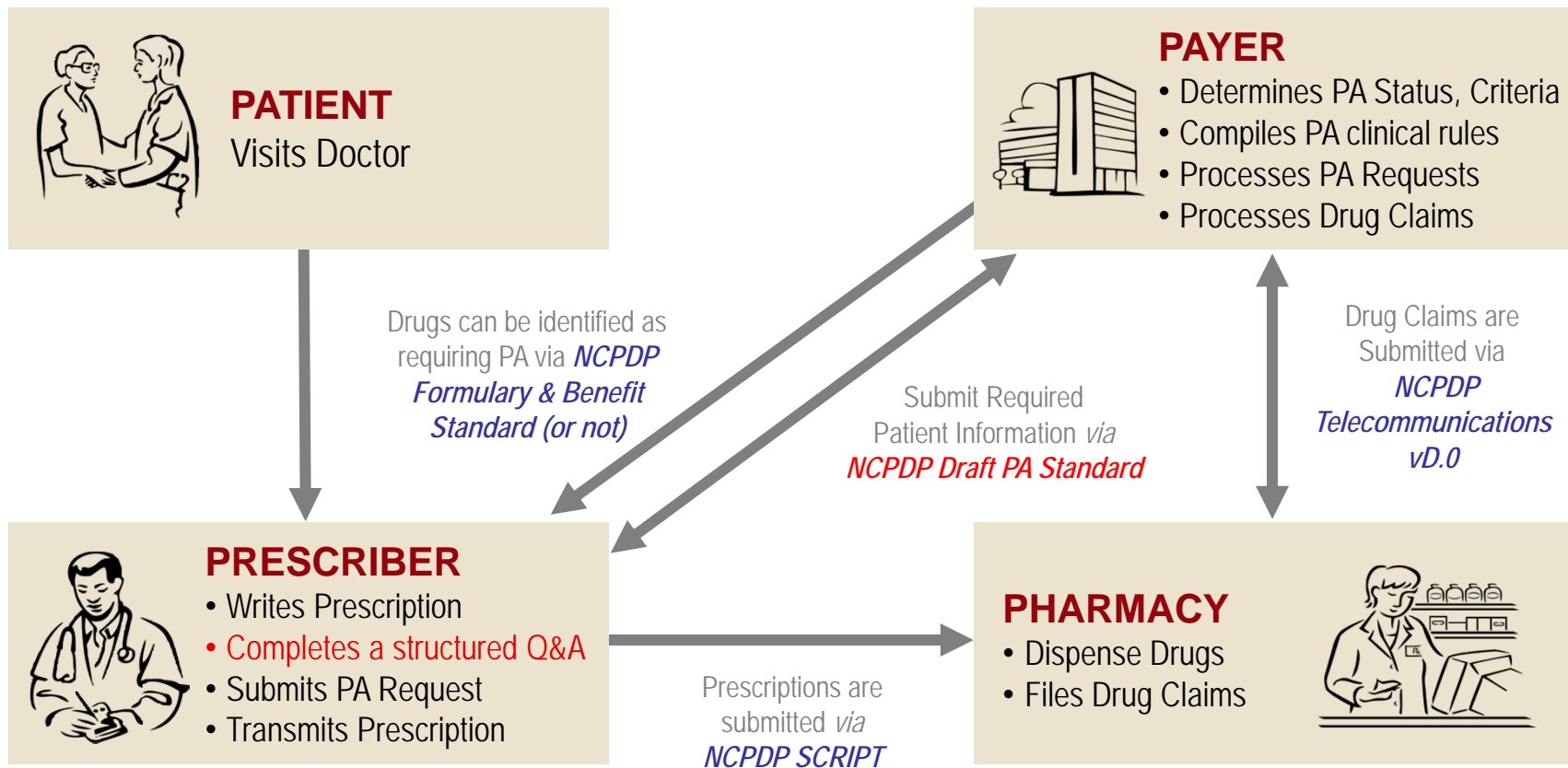
Over the past three years, Congress has signaled its support for e-prescribing by promoting its use in two major laws: Medicare Improvements for Patients and Providers Act of 2009 (MIPPA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act covers certain eligible professionals seeking to become meaningful users of certified electronic health record (EHR) technology in the Medicare and Medicaid EHR Incentive Programs. The HITECH Act specifically identified e-prescribing as a requirement for eligible professionals participating in the EHR incentive programs, and therefore it is part of the "core set" of meaningful use objectives and measures (which also includes objectives and associated measures for using computerized provider order entry (CPOE), maintaining active medication and medication allergy lists, and implementing clinical decision support). MIPPA focuses on Medicare eligible professionals to encourage e-prescribing with a separate incentive program requiring use of a qualified e-prescribing system. Below are a few points that address some of the questions raised by our state colleagues as they consider e-prescribing related legislation.

- It is useful to keep apprised of the technical requirements (capabilities and technical standards) that are currently part of Federal health IT programs to ensure consistency and avoid potential conflicts.
- While ONC requires as a condition of certification (for the purposes of meaningful use) that EHR technology be capable of generating and transmitting electronic prescriptions, certification does not require that EHR technology also be capable of performing electronic prior authorization.
- We are not aware of a widely adopted, common, industry transaction standard that has been demonstrated to support real-time ePA, nor are we aware of a common or universal electronic format that has been demonstrated to facilitate distribution of prior authorization forms. We are aware of work that has been done by the National Council for Prescription Drug Programs (NCPDP) to create an XML-based ePA messaging standard and a real-time eligibility check messaging standard. We understand that these are draft standards that have not yet been tested in pilots and have not been fully "balloted" (voted on) through NCPDP's process or been finalized as American National Standards Institute (ANSI)-accredited standards.
- There is a lack of established and fully vetted standards to support ePA and the current lack of capability to support ePA in implemented EHR systems. Therefore, requiring real-time electronic prior authorization as a prerequisite technical capability before health care providers could e-prescribe and/or access drug formulary information may be difficult to implement, and could otherwise prevent providers from being able to e-prescribe. If such requirements prevent providers from being able to e-prescribe, it could also keep them from being able to participate in the incentive programs noted above.

“We are not aware of a widely adopted, common, industry transaction standard that has been demonstrated to support real-time ePA, nor are we aware of a common or universal electronic format that has been demonstrated to facilitate distribution of prior authorization forms. We are aware of work that has been done by the National Council for Prescription Drug Programs (NCPDP) to create an XML-based ePA messaging standard and a real-time eligibility check messaging standard.”

“Therefore, requiring real-time electronic prior authorization as a prerequisite technical capability before health care providers could e-prescribe and/or access drug formulary information may be difficult to implement, and could otherwise prevent providers from being able to e-prescribe. ... it could also keep them from being able to participate in the incentive programs noted above.”

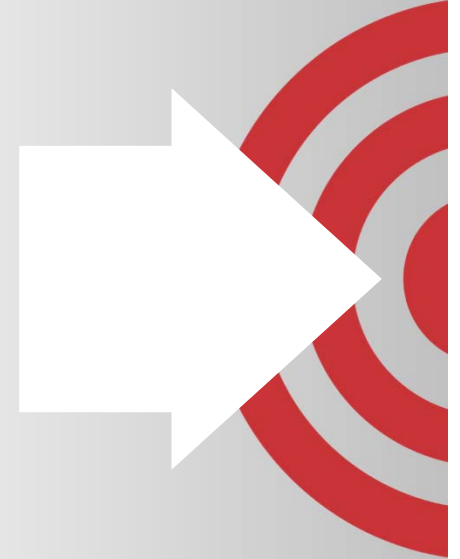
Proposed Standard



Red = gaps in existing standards

Blue = existing standards

NCPDP ePA Focus Group



POINT-OF-CARE PARTNERS
HIT Strategy & Management Consultants

Meeting Overview



Meeting Date	October 6, 2011
Location	NCPDP Headquarters, Scottsdale, AZ
Stated Objectives	<ol style="list-style-type: none">1) To identify basic needs and issues for the industry related to electronic Prior Authorization.2) To implement a pilot project that uses the NCPDP standards that will address the concerns of all affected parties.3) To come away from this meeting with a basic project plan to create an ePA pilot.
Moderator	Rick Sage, Emdeon (NCPDP Workgroup 11 Co-Chair)
Presenters	Tony Schueth, Point-of-Care Partners (former Leader, NCPDP Prior Authorization-to-Workflow Task Group)
Pre-meeting Materials	<ul style="list-style-type: none">• Minnesota Department of Health work on ePrior Auth (current)• ONC Statement on ePrior Authorization standards (May, 2011)• “ePA Pilot Preparation Report,” by Point-of-Care Partners for AHRQ, (Feb, 2009)• Draft NCPDP ePrior Authorization Standards (2009)• Flow Diagrams (2009)• ePA Expert Recommendations (Feb, 2008)

NCPDP Facilitated Focus Group

<i>Date/Location</i>	October 6, 2011 NCPDP Headquarters, Scottsdale, AZ
<i>Objectives</i>	<ul style="list-style-type: none"> • To identify basic needs and issues for the industry related to electronic Prior Authorization. • To implement a pilot project that uses the NCPDP standards that will address the concerns of all affected parties. • To come away from this meeting with a basic project plan to create an ePA pilot.
<i>Organizations Participating</i>	<p><u>PBMs/Payers</u></p> <ul style="list-style-type: none"> • CVS Caremark, Express Scripts, Medco, Catalyst, Argus, SXC <p><u>Vendors</u></p> <ul style="list-style-type: none"> • DrFirst, CoverMyMeds, Armada, Agadia, Ibeza, RxEOB <p><u>Intermediaries</u></p> <p>Surescripts, Emdeon, RelayHealth</p> <p><u>Physicians/Organizations</u></p> <p>AMA, Am College of Rheumatology, Heart & Vascular Center of Arizona</p> <p><u>Government</u></p> <p>CMS, AHRQ, Minnesota Department of Health</p> <p><u>Other</u></p> <p>Pfizer, Lilly, Center for Healthcare Transformation, AMCP</p>
<i>Facilitator/ Speakers</i>	<ul style="list-style-type: none"> • Rick Sage, VP Clinical Services Emdeon; Co-Chair, NCPDP Workgroup 11 – ePrescribing & Related Transactions • Tony Schueth, CEO & Managing Partner, Point-of-Care Partners; former leader, NCPDP ePA Task Group

Key Takeaways



- New energy around standardized electronic prior authorization
- Recommendation to reform Task Group
- View that NCPDP standard was draft but that it could be modified to accommodate shortcomings
- CVS Caremark agreed to take concerns, lessons learned back to the task group to inform standards modifications
- Pioneer piloters (Humana/Agadia, Relay Health/CoverMyMeds) willing to share lessons learned and contribute to process

Next Steps/Action Items



- Checking to see if Surescripts will share the format for the Real-time Benefit Check (RTBC)
- Need to make announcement that NCPDP will reform the ePA task group
- NCPDP should consider making the RTBC a standard (if we're going to recommend use within the ePA standard, need to make sure the format is "standard.")
- Humana/Relay, CVS Caremark to compare formats, communicate the deltas
- Need to figure out how to provide a status back to the pharmacy and patient
- Consider other entry points to ePA such as the pharmacy