

# Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA)

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# Agenda

- Overview of Prior Authorization
  - Electronic Prior Authorization
    - Early and Existing Attempts
    - Multi-SDO Task Group
  - MMA eRx Pilots & ePA
    - Overview
    - Findings
  - Other ePA-related Work
  - eRx Standards Expert Meeting
  - Questions
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# What is Prior Authorization Designed to Accomplish?

- Prior Authorization (PA) is the process of obtaining pre-approval from a payer for specified medications or quantities of medications, with the goals of:
    - Improving patient safety
    - Containing costs
  - Each payer has its own set of PA criteria, which vary by drug, indication, gender and other factors
  - Though commonly thought of as PA, we do not include step therapy or quantity limits in this definition.
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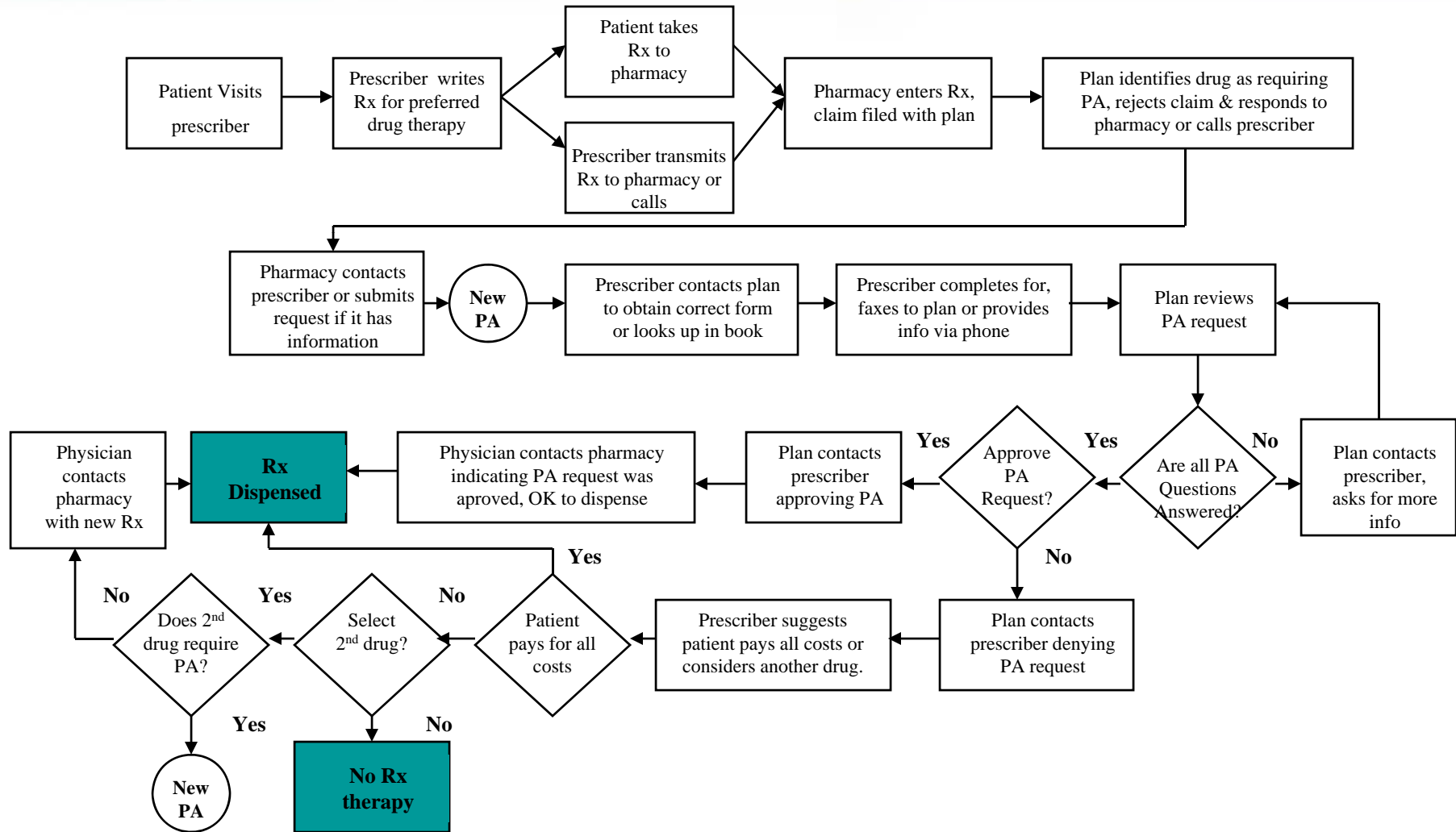
# Prior Authorization Today

- Today's PA is not automated, requiring the prescriber and pharmacy to determine the patient's benefit plan and identify its drug-specific PA form.
  - Once the appropriate form is obtained, the prescriber must fill it out and fax a paper copy to the payer, often with the assistance of pharmacy or facility staff.
  - Once obtained, the payer's PA staff must sort thru the information provided. More often than not, mandatory information is omitted. Sometimes the handwriting cannot be read. Other times, info must be clarified.
    - One plan estimates that 80% of PA requests require follow-up
    - Another estimates that 20% of their staff is dedicated to PA
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# Prior Authorization Today (cont.)

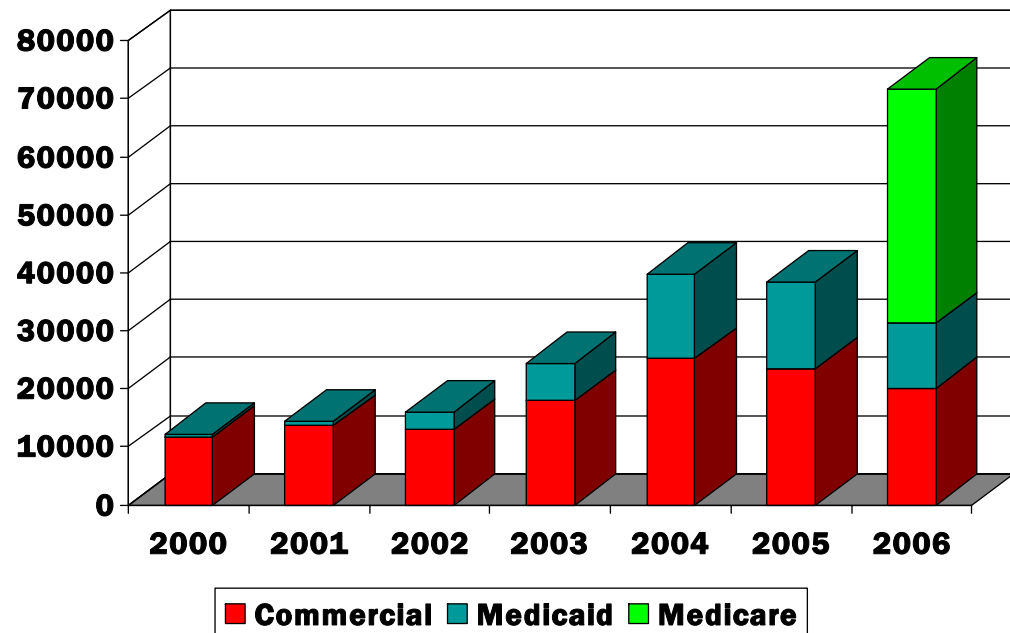
- The payer then evaluates the request, and responds with a faxed approval or denial
    - Evaluation is often done by non-clinical staff
    - More complex cases may be brought to a clinician or, in some cases, a committee
  - If approved, the PA drug will be covered, and a pharmacy claim will process successfully.
    - The process can take several days to complete
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# Prior Authorization Today (cont.)



# Growth in PA

- Advances in MTM, biotechnology, designer drugs, specialty pharmacy, and the cost of the pharmacy benefit, has increased the number of PA'd medications
- From 2000 to 2006, *commercial* plans doubled the number of medications requiring PA.
- Among *Medicaid* programs, the number increased steadily.
- But the most dramatic impact was in *Medicare* Part D plans that designated more than 40K drugs as requiring PA



Source: MediMedia analysis of formulary database, October 2006

# 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.”
  - More than 80% of respondents requested an ability to fill out PA online and receive real-time responses as highly attractive (2008 SEMI n=500).
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# 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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# 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 the 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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# In Summary: The Problem

- Patient hassle and treatment delay
    - No one knows drug requires PA until patient has already left prescriber's office
    - Treatment might be delayed for days
  - Pharmacy hassle
    - Pharmacy must call prescriber's office, and sometimes the plan
  - Prescriber hassle and disruption
    - Gets called back from pharmacy, must call plan, wait for faxed form, completes form and sends it back
    - Turnaround time can be 48 hours or more
  - Healthplan inefficiency
    - Expensive and labor intensive process that creates animosity
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# Electronic Prior Authorization (ePA)

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# Component of Formulary Database

- For years, formulary aggregators (RxHub, MediMedia, Epocrates) have provided a PA flag
- ePrescribing, EMR companies use it to alert prescribers
- Vendors use different, symbols
- Some PBMs don't supply this data
- Sometimes data is at the group level

The screenshot shows the Allscripts ePrescribing interface for patient Bell, Douglas. The patient's information includes MRE: AHS060727162853730, Sex: Male, Age: 35 Years, DOB: 07/01/1971, AKA: Douglas, Allergy: Unknown, Directives: No Restricted Data, and FVL: [EVI]. The interface displays a 'New Rx' section with a 'Medication' table. A callout box highlights the 'Medication' column, showing a list of drugs with their respective PA flags (green smiley face for non-PD, red 'PA' for PD).

Medication	SIG	Days	Qty	Ref	daw
Amoxicillin 250 MG Capsule					
Increlex 40 MG/4ML Solution					
Percocet 10-325 MG Tablet					
Percocet 2.5-325 MG Tablet					
Viagra 100 MG Tablet					

# Custom, Non-Standard Solutions

- There are solution providers who have created custom, non-standard solutions for health plans
- Initially failed b/c not in prescribing workflow
- Simple html forms
- Print pdf's

NaviNet - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address C:\Demos\Dean\RootDocument.htm

msn Search Highlight Options Pop-ups Allowed Hotmail Messenger My MSN

NaviMedix Plan Central Office Central Action Items Customer Service Online Training Log Off

Drug Prior Authorization > Member Search > Provider/Drug Selection > Request Form

Drug Prior Authorization Information

Submission Status: Incomplete  
Receive Date: 05/04/2005  
Date of Service: 05/04/2005  
Drug Name: Flolan (Epoprostenol)

Please answer the following questions prior to submission:  
If you need an option not listed in the form below, please provide additional information in the text box at the bottom of the page.

What is the prescriber's specialty?

Cardiology   
Pulmonology   
Other (If other, please provide additional information in the text box at the bottom of the page)

Does the patient have primary pulmonary hypertension?  Yes  No  
Does the patient have secondary pulmonary hypertension?  Yes  No

Please list the treatments tried and their associated outcome.

Does the patient have primary pulmonary hypertension?	<input type="radio"/> Yes	<input type="radio"/> No
Does the patient have secondary pulmonary hypertension?	<input type="radio"/> Yes	<input type="radio"/> No
Please list the treatments tried and their associated outcome		
Anticoagulants	<input type="checkbox"/>	
Effectively treated condition	<input type="checkbox"/>	
Ineffectively treated condition	<input type="checkbox"/>	
Unacceptable side effects	<input type="checkbox"/>	

Computer 9:37 PM

# Multi-SDO Task Group

<b><i>Founded</i></b>	November 18, 2004 (NCPDP Fall Workgroup Meeting)
<b><i>Objectives</i></b>	<ul style="list-style-type: none"><li>• Promote standardized automated adjudication of prior authorization</li><li>• Coordinate the further development and alignment of standards</li><li>• Identify additional needed standards</li></ul>
<b><i>Organizations Participating</i></b>	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; Dr. First; ZixCorp; Allscripts
<b><i>Task Group Leader</i></b>	Tony Schueth, Managing Partner, Point-of-Care Partners, LLC

# Industry Analysis (NSAIDs/Cox2s)

Drug/Criteria	Health Plan A	Health Plan B	Health Plan C	Health Plan D	Health Plan E	Health Plan F	Health Plan G
<b>NSAIDs</b>							
<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)	•						

Criteria varies by plan, wording non-standard

# Sample Form: 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

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
Strength:	Celebrex 200mg	Celebrex <input type="checkbox"/> 100mg	Celebrex 200mg
Max Qty Limit:	30 per 30 days	60 per 30 days <input type="checkbox"/> 200mg	11 per 30 days
	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
			<input type="checkbox"/> FAP Familial Adenomatous Polyposis Celebrex 400mg 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.  Yes  No Patient has major NSAID-induced GI complication risk factors: ONE OF THE FOLLOWING MUST BE PRESENT**

Yes  No Active non-menstrual bleeding or bleeding disorder

Yes  No Concurrent anticoagulation therapy Please note: bleeding events and increased prothrombin time have been reported in patients taking COX-II Selective NSAIDs concurrently with warfarin. INR monitoring is still necessary in COX-II.

Yes  No Patient has previous documented history of NSAID-induced gastropathy

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**B.  Yes  No Patient has other NSAID-induced GI complication risk factors: TWO OR MORE OF THE FOLLOWING MUST BE PRESENT**

Yes  No Age ≥ 65 years old

Yes  No Chronic major organ impairment \_\_\_\_\_ (please specify) or active Rheumatoid Arthritis

Yes  No Concomitant chronic systemic corticosteroid therapy

Yes  No Chronic high-dose NSAID therapy (e.g. 2-3 times the standard dose to achieve therapeutic effect)

Yes  No Anti-platelet agents for vascular prophylaxis

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**C.  Yes  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 \_\_\_\_\_

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.

**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 receipt, use or disclosure of this e-mail.

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# Sample Form: Growth Hormones

- Add'l Observations
  - Laboratory test results required
  - Data that might be in EMR, but not ePrescribing, solution requested

**CONTAINS CONFIDENTIAL PATIENT INFORMATION**  
**Growth Hormone Prior Authorization of Benefits (PAB) Form**  
 Complete form in its entirety and fax to:  
 Prior Authorization of Benefits Center at (888) 723-5479



BlueCross  
of California

**1. PATIENT INFORMATION**

Patient Name: \_\_\_\_\_

Patient ID #: \_\_\_\_\_

Patient DOB: \_\_\_\_\_

Date of Rx: \_\_\_\_\_

**2. PHYSICIAN INFORMATION**

Prescribing Physician: \_\_\_\_\_

Physician Specialty: \_\_\_\_\_

Physician DEA#: \_\_\_\_\_

Physician Phone#: \_\_\_\_\_

Physician Fax#: \_\_\_\_\_

**3. MEDICATION REQUESTED (Maximum quantity limit allowed: 28 injections per 28 days)**

<input type="checkbox"/> Genotropin	<input type="checkbox"/> Humatrope	<input type="checkbox"/> Nutropin, Nutropin AQ	<input type="checkbox"/> Serostim	<input type="checkbox"/> Tev-Tropin
<input type="checkbox"/> Geref	<input type="checkbox"/> Norditropin	<input type="checkbox"/> Protropin	<input type="checkbox"/> Saizen	<input type="checkbox"/> Zorbtive

**4. DIAGNOSIS**

<input type="checkbox"/> Short Stature	<input type="checkbox"/> Prader-Willi Syndrome	<input type="checkbox"/> Short Bowel Syndrome
<input type="checkbox"/> HIV Wasting Syndrome	<input type="checkbox"/> Panhypopituitarism	<input type="checkbox"/> Turner's Syndrome
<input type="checkbox"/> Idiopathic Growth Hormone Deficiency		
<input type="checkbox"/> Other (please specify): _____		

**5. PROVIDE THE FOLLOWING INFORMATION AS APPROPRIATE Please note: Any areas that are not filled out will be considered not applicable to your patient AND MAY AFFECT THE OUTCOME OF THIS REQUEST**

Date:	List and attach copy of Growth Hormone Stimulation Test Results and Reagents Used	
Patient's Height:	Reagent 1:	Reagent 2:
Patient's Bone Age:	Results #1:	Results #1:
Patient's Chronological Age:	Results #2:	Results #2:
Growth Velocity:	Results #3:	Results #3:
IGF-1 Results:	Results #4:	Results #4:
	Results #5:	Results #5:

**6. PHYSICIAN SIGNATURE**

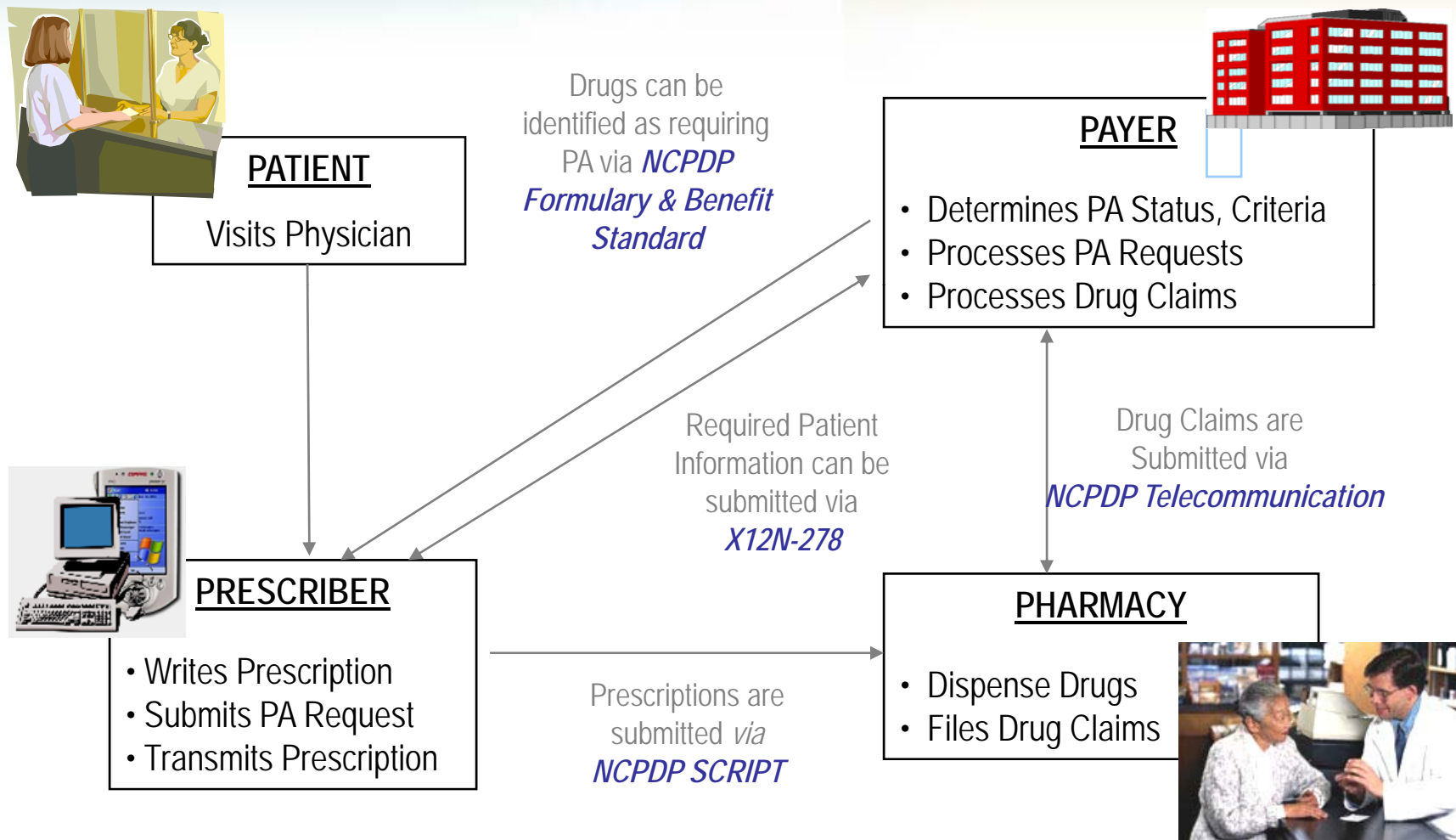
Prescriber or Authorized Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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.

# 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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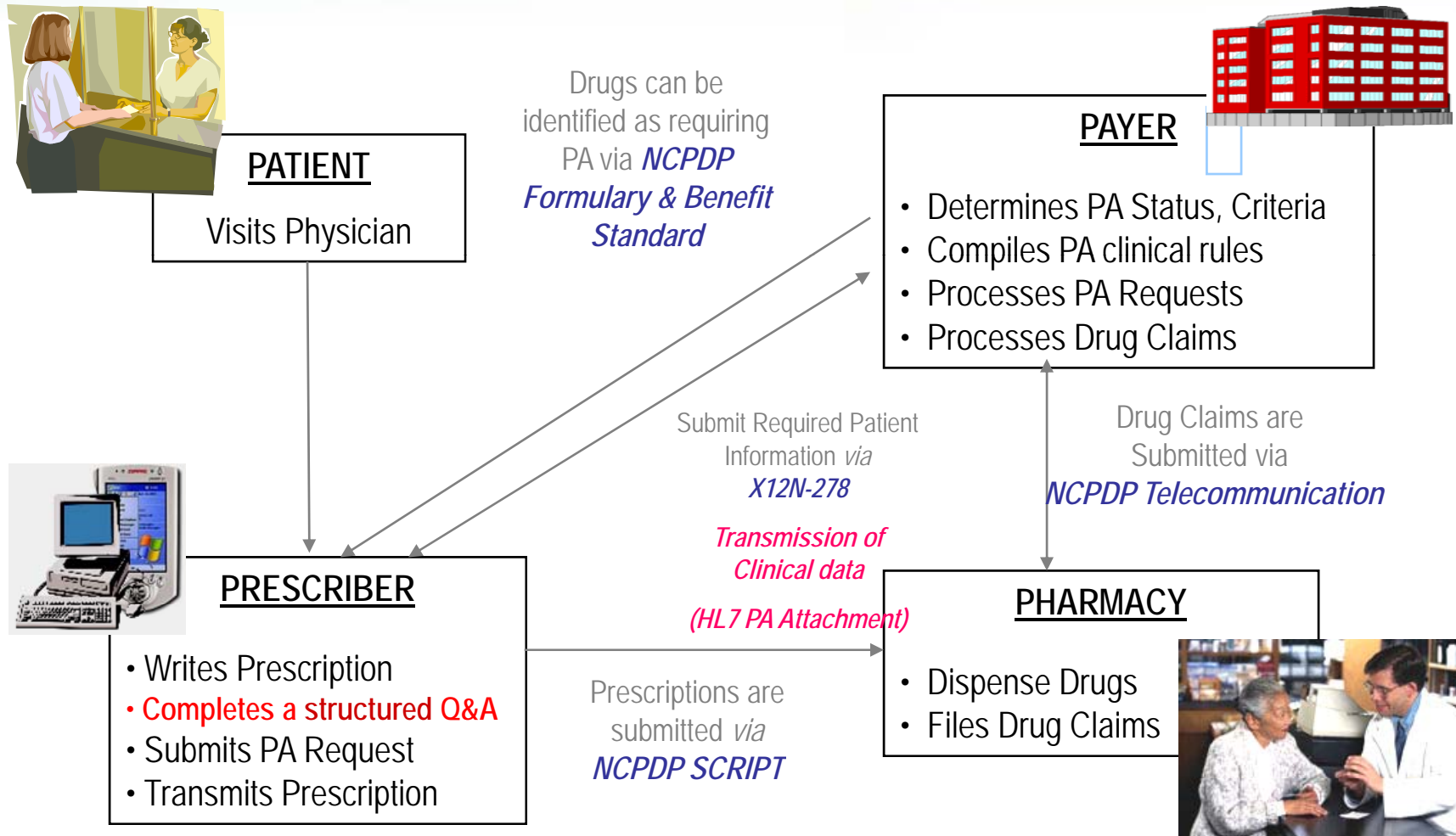
# ePA-Related Standards (2005)



**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

# Straw Model



*Red letters* = gaps in existing standards

# 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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# MMA eRx Pilots – ePA Overview

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# 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
<b>RAND Corporation</b>	\$1.8 M	Allscripts, iScribe	RxHub, SureScripts	Walgreens	Horizon, Caremark, UMDNJ, Point-of-Care Partners
<b>Brigham &amp; Women's</b>	\$1.0M	B&W Hospital	RxHub, SureScripts	"Community of pharmacy chains"	CareGroup Health Sys (MA), MA-Share
<b>Achieve</b>	\$1.1M	Achieve Healthcare Information Technology	RxHub	Preferred Choice Pharmacy	Benedictine Health System, RNA Health, Prime Therapeutics, BCBSMN
<b>Ohio KePro</b>	\$896K	InstantDx, NDC Health	RxHub, SureScripts	CVS, Walgreens, Rite-Aid	NEO/Univeristy Hospitals System, Primary Care Physicians, Qual-choice, Aetna, Univ. of MN, MGMA
<b>SureScripts</b>	\$1.9M	Allscripts, 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
<b>Medication History</b> (NCPDP SCRIPT)	Dispensed/Claims Hx fx of NCPDP SCRIPT	Determine readiness
<b>Formulary &amp; Benefit</b> (NCPDP v.1.0)	Form status & alternative drugs, copay	Determine if should be adopted
<b>Fill Status Notification</b> (Fxn of NCPDP SCRIPT)	Informs when Rx filled, not filled or partially filled	Assess business value & clinical utility
<b>Structured &amp; Codified SIG</b>	Patient instructions incl. dose, route, freq., etc.	Test standards development org formats
<b>RxNorm Clinical Drug Terminology</b>	Std drug nomenclature meant to be intralingua	Determine if RxNorm translates to NDC
<b>Electronic Prior Authorization Messages</b>	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
<b>Medication History</b> (NCPDP SCRIPT)	No	Yes-live	Yes-live	Yes-live	Yes-live
<b>Formulary &amp; Benefit</b> (NCPDP v.1.0)	Yes-live	Yes-live	No	Yes-live	Yes-live
<b>Fill Status Notification</b> (Fxn of SCRIPT)	Yes-live	Yes-eval only	Yes-using MedHx	Yes-live	Yes-using MedHx
<b>Structured &amp; Codified SIG</b>	No	Yes-lab	Yes-lab	Yes-lab	Yes-lab
<b>RxNorm Clinical Drug Terminology</b>	No	Yes-lab v12/21/06	Yes-lab	v12/21/06	Yes-lab v8/2/06
<b>Electronic PA Messages</b>	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 4<sup>th</sup> quarter) was suboptimal
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# MMA eRx Pilots – ePA Findings

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# 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

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# 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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# e-Prescribing Expert Standards Meeting

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# **e-Prescribing Standards Expert Meeting**

- **Develop a set of next steps for each of the standards**
  - **Prioritize ideas for needed technical work**
  - **Prioritize ideas for needed areas of study (including study questions)**
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# QUESTIONS

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**THANK YOU**

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