Current state of electronic prior authorization (ePA) standards for medications
For the Minnesota Department of Health
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Document goal and sections

This document provides a brief summary of efforts to create an electronic prior authorization (ePA) messaging standard for prescription medications—from initial efforts in the early 2000’s to the NCPDP message specification nearing finalization as a standard today.

It also provides a high-level overview of the NCPDP ePA messaging that introduces certain key aspects of the standard—to serve as a level-set for those new to it.

Document sections:

Section One: Background on Electronic Prior Authorization Standards

This section gives a brief history of industry efforts to develop and pilot electronic prior authorization standard, followed by additional background on the two major industry pilots, including approaches tested and results.

- Brief history of electronic drug prior authorization activities is a high-level timeline of ePA efforts over the past decade.

- ePA pilots and other industry experience summarizes two major industry pilots of electronic prior authorization messaging for prescription medications and also describes proprietary approaches to PA automation tried by individual organizations.

Section Two: The Current NCPDP ePA Standard

This section describes the development of the current NCPDP ePA standard and provides references to the standard’s documentation.

- Development of the current ePA standard describes the effort resulting in the current NCPDP SCRIPT standard containing ePA messaging. The section covers the participants in the effort, alternatives considered, and remaining steps that must take place in order for the standard to gain American National Standards Institute (ANSI) approval—becoming a potential national standard. This section includes a timeline for completion of NCPDP approval steps.

- About the standard gives an overview of the NCPDP ePA messages and provides references to the standard’s documentation.

Section Three: Adoption of the new NCPDP ePA Standard

- Industry acceptance and other success factors is a discussion of findings from past and current pilots, challenges and barriers to broader adoption identified through piloting, and industry acceptance of the current NCPDP ePA standard.

- Path to a named national standard for medication ePA discusses factors that may impact potential inclusion of the ePA standard in the Medicare Part D E-Prescribing Standards (which effectively determine the allowed message types and versions for e-prescribing).

- State rules overviews state-level activities related to prescription ePA.
1. Background on Electronic Drug Prior Authorization Standards

This section provides a brief history of industry efforts to develop and pilot electronic prior authorization standards, followed by an overview of industry experience piloting draft ePA standards and implementing proprietary approaches.

**Brief history of electronic prior authorization activities**

Insurance coverage for prescription medications is sometimes subject to preauthorization requirements, similar to other aspects of a patient’s medical care. Today, providers typically obtain such “prior authorization” by filling out and faxing PA forms to the patient’s pharmacy benefit management company. Because authorization rules vary by medication and because each payer and employer group can determine their own approval criteria, the process of locating the correct PA form and submitting it to the right party can be confusing and time-consuming. This can result in staff costs at the provider’s office and delays in finalizing the patient’s treatment.

The industry has grappled with how to improve the drug PA process through automation for a number of years. Early attempts attempted to standardize the authorization criteria itself, while more recent efforts focused on standardizing the communication between stakeholders while supporting variations in criteria.

Further, states including Minnesota have taken steps to promote electronic prior authorization within their borders. Minnesota, specifically, developed statutes (Section 62J.497, Subd. 5. Electronic drug prior authorization standardization and transmissions) directing the establishment of a standard drug ePA process by 2014 and requiring MN providers and health plans to support ePA by January 2015.

The following table summarizes the industry’s experience at a national level, and also notes Minnesota-specific activities.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug 1996</td>
<td>HIPAA¹</td>
<td>Names X12 278 “prior authorization” transaction standard.</td>
</tr>
<tr>
<td>Nov 2004</td>
<td>NCPDP ePA Task Group formed</td>
<td>HL7 PA Attachment created (2005), which attempts to standardize PA decision criteria using LOINC codes. Designed to be used in conjunction with X12 278 and 275 transactions.</td>
</tr>
<tr>
<td>2006</td>
<td>MMA² E-Prescribing Pilot Tests</td>
<td>X12 278 / X12 275 / HL7 PA Attachment approach tested. Pilots recommend moving to a single PA message standard with needed capabilities: conditionality, ability to tailor criteria. “Analysis shows that, in its current state, this standard is technically unable to convey the information needed to support this function for use in Part D.”³</td>
</tr>
<tr>
<td>2008</td>
<td>CMS / AHRQ Expert Panel</td>
<td>Identified NCPDP as the Standards Development Organization (SDO) to develop ePA standard. Exception to HIPAA resolved (enabling prescription PA using an alternative to the X12 278).</td>
</tr>
</tbody>
</table>
| 2010   | Minnesota statutes related to drug PA                               | Minnesota’s legislature enacted a law that:  
  - Directed the MN Administrative Uniformity Committee (AUC) to publish a drug ePA companion guide by January 2014  
  - Set a requirement for MN providers and payers to support electronic drug prior authorization by January 2015.                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2011   | Renewed Interest                                                    | Industry pilot using a draft enhancement to the NCPDP ePA standard. Legislation in several US states related to ePA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2012/2013 | Updated NCPDP ePA standard                                         | Enhancement of the NCPDP ePA standard based on pilot experience. Stakeholders include NCPDP members, other industry participants. Applicable NCPDP workgroups vote to approve ePA standard in May 2013. Formal NCPDP Board of Trustees approval anticipated in mid-2013. Formal ANSI approval anticipated in mid-late 2013.                                                                                                                                                                                                                                                                                      |
| 2014   | Production use of enhanced NCPDP ePA standard                       | Major industry participants planning 2014 production use of the enhanced NCPDP standard: payers, EHR vendors, networks.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

Some content above was adapted from NCPDP testimony to the NCVHS Subcommittee on Standards, November 2011. http://ncvhs.hhs.gov/111117p15.pdf

ePA pilots and other industry experience

¹ The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) included Administrative Simplification provisions identifying standards for electronic health care transactions among other provisions.

² Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003

Electronic prior authorization standards have been piloted twice in the past decade. In addition, individual organizations have developed proprietary approaches to automate the PA process. These efforts and their outcomes are summarized below.

### 2006 MMA e-prescribing pilot

The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 mandated that all plans and pharmacies participating in the Part D drug benefit support an electronic prescription program. This pilot evaluated a number of information exchange standards being considered for use in that program. HHS provided grants to five pilot sites to test standards for prescription messaging, formulary distribution and prior authorization.

Four of the pilot sites and one information exchange network participated in evaluation of a set of X12 and HL7 messages bundled together support the prescription prior authorization process. Specifically, the pilot tested the use of...

- the X12 278 Health Care Services Request for Review and Response (“prior authorization”) transaction
- used in conjunction with the X12 275 Additional Information to Support a Healthcare Claim or Encounter (“wrapper”) transaction carrying an HL7 PA Attachment document
- which in turn carried a draft HL7 PA Attachment CDA document intended to communicate standardized authorization criteria to the insurer.

The ePA pilot participants were Brigham & Women’s Hospital, Ohio KePRO/UHMP, RAND Corporation, Achieve (a long-term care software vendor), and Surescripts (providing support to other piloters).

### Experience

While preparing for use of the X12/HL7 message combination, pilot participants identified challenges applying the standardized criteria defined in the HL7 PA Attachment to the actual information needs of the health plans participating in the effort.

In particular, the HL7 PA Attachment focused on precise patient characteristics and observations (such as lab results and diagnoses), while the PA forms associated with prescription medications typically contained questions that referred to clinical information in more generalized or informal ways (e.g., referring to condition characteristics such as “exercise-induced asthma”). Due to this mismatch, few of the pre-defined criteria could be used in the pilot.

Further, “real-world” PA forms often included instructions related to the PA process and requests for confirmation by the prescriber of associated clinical risks or required patient follow-ups. Neither of these needs were supported by the HL7 PA Attachment.

Due to these limitations of the pilot standards, some pilot sites augmented the information exchange with approaches for communicating non-standardized PA criteria in a predictable way—similar to techniques underlying the current NCPDP ePA standard. These additional question definition approaches were layered on top of the X12 / HL7 messaging in order to fill gaps not supported by the standards being tested.
Finally, the use of multiple messages created overlaps in content between them. For example, the patient was represented multiple times in different ways across the messages. Piloters had to adopt conventions for populating these multiple instances of the same information in order to avoid confusion regarding the “source of truth” for duplicated information.

Findings

Due to the challenges discussed above, the federal Agency for Healthcare Research and Quality (AHRQ), which compiled results of the pilots, summarized the ePA findings as follows:

“Because the combination of the X12N 278, X12N 275 and HL7 PA Attachment is cumbersome, confusing and requires expertise that may limit adoption, one standard transaction should be considered – one that is specifically designed for medication ePA. This standard should be a) organized by drug, b) support content logic (conditionality), numbering of questions and cardinality, c) provide for educational information and directions, d) support open ended questions and e) uniquely identify the patient.”

2011-13 CVS Caremark pilot

In 2011, CVS Caremark initiated a pilot of an enhanced version of the 2009 NCPDP ePA standard with partners including Surescripts and prescriber system vendors NaviNet and Allscripts. The company stated at the outset its intent to “share both the transactions and the results from the implementation with the market and the appropriate ANSI-accredited standards organizations to help drive the adoption of ePA standards by payers and provider systems.”

The messaging used in this pilot extends the 2009 NCPDP ePA standard, establishing key messaging features that address the weaknesses of earlier standards, including:

- criteria numbering and conditionality, enabling the provider system to dynamically show or hide PA questions based on answers already given
- support for instructions and payer contact information for getting help on completing required information
- concise message format tailored for medication prior authorization.

Experience

The pilot has operated in production settings for over a year, and participants report that the messaging was straightforward to implement and met business needs. The pilot messaging was used within different workflows in the participating provider systems, including within the medication ordering workflow of one system and in a provider portal for resolving PAs identified during claims processing in another system.

As planned, the pilot contributed its message definitions and experience to be used as a starting point for an enhanced NCPDP ePA standard. The 2013 version of the NCPDP standard builds on and refines the features introduced by this pilot.
Findings

While the pilot participants reported that the ePA messaging they used met business needs, the technical structures were based on a previous version of the NCPDP standard and needed to be updated to match the standard’s current version.

In addition, the pilot transactions’ support for an appeal process (enabling the provider to respond in cases when authorization is denied or has undesirable restrictions) was limited. The 2012 NCPDP ePA task group expanded support for this workflow in the final 2013 version of the standard.

Proprietary approaches to ePA

Over the past decade, payers and independent software and service providers have developed their own proprietary solutions for making medication prior authorization forms more readily available to providers.

A number of payers provide PDF versions of PA forms on online portals, which reduces the clinic time needed to locate and complete the forms. Also, vendors such as Cover My Meds have partnered with payers to warehouse PA forms and make them available in an online-fillable format.

However, in these solutions the clinic’s input is still typically submitted to the payer in PDF or fax format for manual processing. As a result, overall processing time may not be significantly reduced by these approaches. An additional challenge encountered by third-party vendor solutions is maintaining a complete and up-to-date inventory of PA forms for a wide range of payers, plan groups and medications. Minnesota enacted requirements in 2009 for the development and use of a single PA form in 2010 by Minnesota prescribers, to be accepted by payers. However, as noted below, while the standardization of PA forms provides some benefits, they are not a true ePA solution. The Minnesota requirements did not include compliance and enforcement provisions, and anecdotal evidence indicates that use of the single PA form varied in practice.

In an October, 2011 ePA focus group coordinated by NCPDP, participating physicians commented on the need to bring the PA process up-stream, into the physician’s workflow. Existing PDF and third-party solutions typically require that the appropriate PA form be located manually, reducing the opportunity for the prescriber to initiate PA during the ordering process where she could potentially resolve a PA requirement before transmitting the prescription to the pharmacy.

Current third-party web-based systems and online payer PA form portals provide benefits over a paper and faxed-based process, but the challenges identified above prevent them from being strong long-term solutions. It may be evidence of the limitations of web and PDF-based solutions that organizations with these systems in place were early pilots of fully electronic, message-based ePA processing.
2. The Current NCPDP ePA Standard

This section discusses how the current NCPDP ePA standard was developed, gives a high-level overview of how the standard works and provides references to the standard’s documentation.

**Development of the current ePA standard**

**Process and timeline for approval**

**NCPDP task groups and participating stakeholders**

NCPDP convened two task groups to serve as forums supporting enhancement of the NCPDP ePA standard:

- ePA Workflow to Transactions Task Group
- ePA XML Sub Task Group.

Both task groups reported to NCPDP’s Workgroup 11, which manages the organization’s e-prescribing standard, SCRIPT. Participation in both groups was open to non-NCPDP members, and participants included individuals from a range of organizations and perspectives.

The ePA Workflow to Transactions Task Group provided a forum for determining the approach to be taken and to address non-technical topics such as regulatory and privacy considerations. The ePA XML Sub Task Group delved into the detailed information and workflow needs of stakeholders and produced the technical specifications for the resulting ePA messages. The outputs of the Sub Task Group were reviewed and approved by the main Workflow to Transactions task group, to which it reported.

The ePA Workflow to Transactions Task Group was an existing working group that re-commenced meetings in late 2011 and typically met every two weeks through the first three quarters of 2012, during which the current NCPDP ePA standard was being developed.

The ePA XML Sub Task Group’s efforts ramped up in the second quarter of 2012 after the Workflow task group agreed that an enhanced NCPDP ePA standard should be developed. The group typically met weekly through the summer and fall of the year, and produced the specification and implementation guide for the standard, working closely with NCPDP staff.

Both the ePA Workflow to Transactions Task Group and the ePA XML Sub Task Group included participants from a range of organizations with different perspectives on the prior authorization process, including:

- physician groups (American Medical Association, provider organizations)
- pharmacies (retail chains, independent, long-term care / institutional, pharmacy organizations)
- payers / processors (health plans, pharmacy benefit managers, state Medicaids)
regulatory representatives (CMS)

- system vendors (prescriber systems, pharmacy systems, exchange networks)
- pharmaceutical manufacturers
- other interested parties.

**Approval process**

NCPDP is an ANSI-accredited standards body, and follows a standards development process that typically begins with the identification of an opportunity to extend or adjust an NCPDP standard and ends with ANSI-approval of the resulting new or modified message specification. The steps from idea to final ANSI standard are summarized below:

(a) The idea for the modification or addition of a message is typically raised at an NCPDP Workgroup meeting, and a task group is frequently created to flesh out the idea and produce a concrete proposal.

(b) A request describing the proposed change or addition (a Data Element Request Form, or “DERF”) is formally submitted for the Workgroup to evaluate during a quarterly Workgroup meeting. The NCPDP members present at the meeting vote to either:

- Approve the DERF, sending it to be voted on during the period before the next Workgroup meeting
- “Pend” the DERF, allowing additional time for the proposal to be adjusted or to educate stakeholders before bringing it to the next quarterly Workgroup meeting to be reevaluated, or
- Deny the DERF, requiring that the proposal be resubmitted for consideration in a future Workgroup meeting.

(c) When a DERF is approved for ballot, the change or addition it proposes gets combined with other approved DERFs in a ballot version of the standard, which is voted on prior to the next Workgroup meeting. NCPDP members and non-members may vote on the ballot and may provide comments suggesting changes to the balloted version of the standard.

(d) During the Workgroup meeting following the ballot, comments submitted during voting are adjudicated:

- Minor or editorial adjustments may be accepted by those attending the Workgroup meeting to immediately be applied to the approved standard.
- Substantive changes, if approved by the Workgroup, cause another ballot cycle, with voting taking place prior to the following Workgroup meeting.
- Comment found to be non-persuasive by the Workgroup are not applied to the standard and do not count against approval.
The ballot is considered approved by the Workgroup if it receives the required number of affirmative votes and if no comments force an additional ballot cycle.

(e) Other NCPDP entities approve ballot: Maintenance and Control, Standardization Committee, and the Board of Trustees.

(f) ANSI confirms that the appropriate process was followed during the process resulting in the new version of the standard, and if so, also gives its approval.

Approval timeline

- **Nov. 2011**: NCPDP task groups created to gather input and define proposed ePA messages
- **Nov. 2012**: Draft ePA DERF discussed by Workgroup 11 and pended to allow time to finalize the XML schema and implementation guide
- **Feb. 2013**: Proposed ePA messaging approved by NCPDP Workgroup 11 and sent to ballot
- **May 2013**: Ballot was completed with sufficient affirmative votes; comments were adjudicated by Workgroup 11 without the need for an additional ballot cycle. Approved also by the NCPDP Maintenance and Control Workgroup
- **Summer 2013**: Approval by the NCPDP Standardization Committee and Board of Trustees
- **Summer / Fall 2013**: Approval as an ANSI standard

**Other ePA alternative considered: X12/HL7 messaging**

At the outset of NCPDP ePA task group discussion in 2012, stakeholders including the American Medical Association suggested that the industry should adopt X12 transactions for pharmacy prior authorization, rather than developing a new ePA standard. The rationale is understandable: that use of a single standard for prior authorization of all types of medical services—including prescription medications—might simplify adoption by electronic medical record vendors and other stakeholders.

X12 messaging is widely used to retrieve patient eligibility for both medical and pharmaceutical benefits, and in the processing of medical claims. (Pharmaceutical claims, however, are processed using a separate HIPAA-named NCPDP D.0 transaction). The X12 standard also contains transactions supporting authorization for services and the exchange of related information, though these are not as widely used as the eligibility or claims messages, and are currently only used in relation to medical services.

The approach suggested by the AMA was very similar to the one piloted in the 2006 MMA e-prescribing pilots (described above). In a November, 2011 presentation to the National Committee for Vital and Healthcare Statistics standards subcommittee, the AMA described this approach as follows:

... the 275 provides the metadata (envelope) around the clinical information with HL7 Clinical Data [sic] Architecture (CDA) carrying the clinical information. Thus, we will use both the terms “275” and “275/HL7” to refer to this transaction. ...
The 275/HL7... can be used ... to send clinical information as part of obtaining an ASC X12 278 prior authorization approval from a payer. ... It can be sent in parallel with the 278 transaction as supporting information. ... Future versions of the 275 could contain specific coded information ... related to the specific services being requested.

The table below identifies the specific X12 and HL7 transactions used in the approach proposed by the AMA to the NCPDP ePA task group:

<table>
<thead>
<tr>
<th>Transaction</th>
<th>Current adoption for pharmacy benefits</th>
<th>Current adoption for medical benefits</th>
<th>Function / Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC X12 ver. 5010 278 Health Care Services Request for Review and Response</td>
<td>Not used</td>
<td>Some use</td>
<td>HIPAA-named standard for medical authorizations</td>
</tr>
<tr>
<td>ASC X12 ver. 5010 275 Additional Information to Support a Healthcare Claim or Encounter</td>
<td>Not used</td>
<td>Little use</td>
<td>Provides a standard “envelope” in which additional messages / attachments / standard data structures may be conveyed. Not named in HIPAA rules.</td>
</tr>
<tr>
<td>PA Attachment based on the HL7 Clinical Document Architecture (CDA)</td>
<td>Not yet developed</td>
<td>Not yet developed</td>
<td>This approach proposes use of a new HL7 CDA-based PA attachment that has not yet been developed. There is currently no HL7 working group actively pursuing this development.</td>
</tr>
<tr>
<td>Alternative to HL7 PA Attachment: Proprietary web portal process</td>
<td>n/a, not standard</td>
<td>n/a, not standard</td>
<td>The AMA has suggested use of a “URL portlet to a website; or an active HTML form that would carry PA questions specific to the authorization request direct to the physicians desktop” as an interim alternative to a standard HL7 PA attachment *</td>
</tr>
</tbody>
</table>


This approach was given much discussion during a number of NCPDP Prior Authorization Task Group meetings in the first half of 2012, with representatives of the AMA and X12 presenting their perspective. A point-by-point comparison between the X12 combination message approach and the proposed NCPDP messaging was developed and discussed by the group.

A vote was ultimately taken within that task group, with representation from a number of non-NCPDP members such as individuals from the AMA, X12 and other organizations. The group’s decision, by a wide margin, was to complete development of a dedicated NCPDP standard rather than pursuing the alternative approach. Key considerations in that decision included:
• work has not begun on an HL7 CCDA document for carrying authorization-related details

• current adoption of the HL7 275 message by the industry is low

• negative findings by participants in 2006 CMS-sponsored pilots of a similar use of a 278/275/attachment model for prescription prior authorization

• industry experience with weaknesses of proprietary web portal-based PA solutions, and

• the positive outcome of a 2011/2012 pilot of NCPDP-based ePA messaging.

Representatives from the AMA continued to participate in the development of the NCPDP ePA messages after the group’s decision to proceed with development of NCPDP messaging and provided valuable input which was incorporated into the final standard.

**Overview of the NCPDP ePA standard**

This section provides an overview of the NCPDP ePA standard and references to its documentation.

**How ePA relates to the current “paper” PA process**

ePA messaging...

• follows the same basic workflow as today’s non-electronic prior authorization process

• supports the same ability for PBMs/payers to request information from providers to support the PA decision process (which is currently done using paper or PDF prior authorization forms)

• does not define standard PA questions nor does it identify the information that should apply to specific drugs. Each payer determines the information it needs and how it asks for it

• does provide a data format and framework that all payers can use to convey their “PA form questions” in a common way, enabling the provider system to present the questions and capture the provider’s responses in a consistent manner, regardless of who the payer is

• also enables the provider system vendor to systematically retrieve needed PA information from the patient’s electronic chart, when the payer includes optional “coded references” with its PA questions.

**The two ePA workflow “models”: Solicited and Unsolicited**

In today’s paper-based prior authorization process, the payer generally maintains a set of PA forms for its various member plans and for different medications. When the prescriber learns that one of their patient’s prescriptions requires PA, they notify the patient’s payer and are sent the appropriate PA form to be completed and returned. Or, they may visit the payer’s website and download the form from there.

In today’s process, the provider could hold on to a PA form and file it for future use, rather than “soliciting” a new form each time a PA is needed. However, ePA enables a system to quickly request
and receive the correct PA “form” for their specific patient and medication—which eliminates any benefit the provider might get today by maintaining a local file of PA forms. In addition, by initiating the process with the payer before filling out a PA form, the provider will avoid unnecessary work if it turns out that the patient does not actually require PA in the particular situation, which is a common occurrence.

Solicited workflow

Because of the ease of requesting the correct PA form in the electronic PA process, and because of benefit of avoiding unnecessary work when PA is ultimately not required, the mainstream of the industry is promoting a “solicited” workflow in which the PA process always begins with an initiation step, in which...

- the provider system sends a PAInitiationRequest message to the payer, containing the patient and medication for which PA is desired

- the Payer then responds with a PAInitiationResponse message that contains either:
  - the correct electronic PA “form” for the patient and medication, or
  - a message indicating that PA is not required for the patient/medication combination, or
  - a message indicating that an exception situation exists, for example, the patient’s coverage has expired.

If PA is required for the patient, the provider system gathers the information requested in the PAInitiationResponse and continues on to the next ePA message: PARequest, with which the actual request for authorization is made. The payer then responds with a PAResponse message containing its determination.

Unsolicited workflow

In this workflow model, the provider system skips the step of asking the patient’s payer for the appropriate PA form. The PAInitiationRequest and PAInitiationResponse messages are not used in this workflow. Instead, the provider system jumps to the step of collecting information that it predicts or has learned previously will be needed by the payer, and submits it in a PARequest message to the payer

The payer responds with a PAResponse message that may or may not include a PA determination as follows.

- If the payer is able to make a PA determination based on the information submitted, the PAResponse contains an indication of approval or denial.
- If the provider system did not include needed information in its request, the PAResponse will contain an electronic PA “form” indicating additional information needed.
- If another situation exists (e.g., patient not recognized, PA isn’t required, etc.) the PAResponse will contain that information.
**Patient privacy considerations**

Because the unsolicited workflow will in some cases involve sending patient healthcare information to the payer when it is not needed (e.g., if PA isn’t needed for the particular medication), this model raises patient privacy considerations that are avoided by the initiation step of the solicited model. This concern has been cited by several payers as a reason for their support of the solicited model.

**ePA Message Types**

The ePA standard is made up of messages that support four basic steps in the prior authorization process: *initiation* of the process, the actual *request* for PA, *appeal* of a PA determination, and *cancelation* of the process by the prescriber.

<table>
<thead>
<tr>
<th>PA step</th>
<th>NCPDP ePA message type</th>
<th>Sender / receiver</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>PAInitiation Request</td>
<td>Prescriber or other party (“initiating party”) sends this message to the patient’s payer or PBM</td>
<td>Starts the PA process. Required in the “solicited” model, but not used in the “unsolicited” model.</td>
</tr>
<tr>
<td></td>
<td>PAInitiation Response</td>
<td>The payer/PBM returns this message to the initiating party</td>
<td>• Supplies the PA questions to be completed&lt;br&gt; • Or indicates that PA isn’t required&lt;br&gt; • Or indicates an exception situation exists</td>
</tr>
<tr>
<td>Request</td>
<td>PAResquest</td>
<td>Initiating party to payer/PBM</td>
<td>Contains the information requested by the payer and a request for approval.</td>
</tr>
<tr>
<td></td>
<td>PAResponse</td>
<td>Payer/PBM to initiating party</td>
<td>• Contains either Approval of PA&lt;br&gt; • Or Denial of PA&lt;br&gt; • Or a request for additional info&lt;br&gt; • Or an indication that the PA case has been closed (e.g., if the patient’s coverage has expired since initiation of the PA process)</td>
</tr>
<tr>
<td>Appeal</td>
<td>PAAppeal Request</td>
<td>Initiating party to payer/PBM</td>
<td>Submitted if the provider desires a change to the PA determination. May be submitted in response to an approval as well as denial, e.g., if the approval contained limitations on quantity or number of fills.</td>
</tr>
<tr>
<td></td>
<td>PAAppeal Response</td>
<td>Payer/PBM to initiating party</td>
<td>• Contains either Approval of the appeal request&lt;br&gt; • Or Denial of the appeal request&lt;br&gt; • Or a request for additional info&lt;br&gt; • Or an indication that the PA case has been closed (e.g., if the patient’s coverage has expired since initiation of the PA process)</td>
</tr>
</tbody>
</table>
**Common content in the ePA messages**

**Core content: patient, medication, prescriber, other**

The prescriber, patient and medication, and other context elements that make up the PAInitiationRequest (below) are echoed in all later PA messages that the provider and payer exchange.

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<table>
<thead>
<tr>
<th>PA step</th>
<th>NCPDP ePA message type</th>
<th>Sender / receiver</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancel</td>
<td>PACancel Request</td>
<td>Initiating party to payer/PBM</td>
<td>Submitted if the provider wishes to stop the PA process, e.g., if they've decided to switch to an alternative medication</td>
</tr>
</tbody>
</table>
|         | PACancel Response      | Payer/PBM to initiating party | Contains either:  
  - Indication that the payer was able to cancel the process before it completed  
  - Indication that the PA process couldn’t be cancelled, e.g., because it had already completed before the cancellation request was processed |

---

This identifier is assigned by the initiating provider when sending the PAInitiationRequest, and is echoed back in all subsequent messages in this PA “conversation.”

Patent information is sent in the PAInitiationRequest and repeated in all subsequent messages in the conversation. The BenefitsCoordinating composite holds the patient’s unique PBM member ID.

The prescriber composite represents the clinician that prescribed the medication for which PA is desired. (Note that a different party may initiate the PA process... see the Provider composite below)

The MedicationPrescribed composite holds the medication for which PA is desired.

The Provider composite is used when a person other than the prescriber initiates the PA process and acts as the contact for related communication. The composite holds the contact person’s name and contact information.
PA Question Set

The Question Set concept in the ePA standard represents the information needed by the payer in order to process the PA request. The same basic Question Set structure is used in multiple messages in the standard, though with variations based on the particular function of each message.

For example, the Question Set in response message types (PAInitiationResponse, PAResponse, PAAppealResponse) contain only the question definition, whereas Question Sets in the PARequest and PAAppealRequest also include elements that hold the prescriber’s answers and other information required to process the authorization request.

The diagrams below illustrate the Question Set structure.

*High-level information structure:*

---

The Header contains information pertaining to the entire set of questions, including an ID for the set, a title, a description, and contact information at the payer.

Each Question composite represents a single question on the PA “form”. A QuestionSet must have at least one question.
Data associated with every question:

Certain details apply to every question, regardless of whether it is a True/False question, multiple choice question, etc.:

- **QuestionID**: ID assigned by the payer to identify the question.
- **SequenceNumber**: Sequence number to indicate the order of questions. Answers should be displayed in this order.
- **QuestionSetGroup**: Indicates that all questions with this ID are related.
- **QuestionText**: Best practice is to not support compound questions.
- **CodedReference**: An optional composite that gives an industry terminology-based ID (or multiple IDs) that can be used by the provider system to retrieve the desired information from the patient's electronic chart.

Data associated with each question type:

- **Select**: The Select question type is used for True/False and multiple choice questions. Content includes the answers the user can choose from, a flag that indicates whether more than one answer can be chosen, etc.

- **Date**: Date questions request answers in the form of a date or datetime.

- **Numeric**: The numeric question type includes elements that enable the payer to specify different questions to ask next, based on whether the answer is above/below/within or outside of a numeric range.

- **FreeText**: FreeText questions ask for a simple textual answer.
**Response composites**

Each step in the PA process is supported by a pair of ePA messages, one of which is a *request* sent by the provider and the other which is a *response* returned by the payer/PBM.

While the particulars of the response composite differs in each of the steps, the same basic structure is used across the response messages:

- **ReferenceNumber** (used only when communicating via a mailbox)
- **ResponseStatus**, with two or more status types that apply in the given step:
  - Open
  - Closed
  - Approved
  - Denied

Additional elements are included within the status-level composites, based on the message type and particular ResponseStatus. For example, an Approved status includes an Authorization ID field.
Below is a high-level comparison of the response options in each of the ePA response-type messages:

Documentation

The ballot package that holds the implementation guide and XML specification for the SCRIPT version containing the ePA messaging standard is available to NCPDP members at the location below. This documentation will be removed after the approved standard is made available in the Standards section of the NCPDP website.


Follow the link to My Voting History and click the Download the Maintenance Package link for Ballot WG110053.
3. Adoption of the new NCPDP ePA Standard

This section identifies factors related to industry adoption of the ePA standard.

Industry acceptance and other success factors

Industry consensus on the NCPDP ePA standard

Interest in electronic prior authorization has increased significantly in the past three to four years, due to several factors including...

- experience with the limitations of web portals and other proprietary approaches
- maturation of the systems of stakeholders and increased experience with real-time electronic messaging in other areas of e-prescribing
- state-level rules mandating electronic prior authorization processes or problematic alternatives such as “uniform” PA form requirements, and
- economic and other factors.

The NCPDP task group process that produced its current ePA standard reflected a broad-based interest in moving forward with adoption of a standard electronic process. While a number of topics prompted lively debate among participants, and alternative approaches were compared and passionately argued, the group came to consensus and worked collaboratively to produce the final standard. The steps following submission of the ePA DERF have encountered remarkably little opposition, and approval of the ePA ballot occurred in the first round of voting, with only minor adjustments made to the standard.

Adoption timing expectations

While not all stakeholders have yet indicated support for the NCPDP ePA standard (notably, it appears the AMA is continuing to advocate for its alternative approach), the organizations representing the overwhelming majority of prescribers, health plans—and hence patients—have indicated they expect to implement the NCPDP standard. The largest e-prescribing network has announced its plans to be production-ready for ePA at the start of 2014, and large payer and provider system vendors have also indicated they would be up-and-running on the standard in the 2014/2015 timeframe.

In recent informal discussions between the author and a number of potential ePA implementers (provider system vendors, payers/PBMs), the key timing drivers identified were:

- state-level ePA rules;
- competition from Meaningful Use requirements (a factor that may slow adoption); and
- eventual naming of ePA as a Medicare Part D standard.
Path to a named national standard for medication ePA

The Medicare Part D E-Prescribing Standards (established according to the Medicare Modernization Act / MMA) effectively determine the message types and versions that e-prescribing participants must implement in their systems. The Part D standards do not, in and of themselves, require any party to engage in e-prescribing, but they do dictate the message standards that those who do e-prescribe must use when caring for Medicare Part D beneficiaries.

Below is an overview of the process by which the NCPDP ePA messages may eventually be added to the Part D e-prescribing standards, and the author’s understanding of possible timing and considerations, based on informal conversations with involved stakeholders.

Process

The Centers for Medicare and Medicaid Services (CMS) typically determines the standards to be named for use in the Part D program based on industry input and the recommendations of the National Committee on Vital and Health Statistics (NCVHS), which serves as an advisory body to the Department of Health and Human Services on health data, statistics and health information policy.

The broad steps involved in adding or adjusting the set of Part D standards are:

- Industry testimony to the NCVHS standards subcommittee;
- A recommendation by NCVHS to the Secretary of HHS to add or change a Part D standard; and
- Rulemaking steps led by CMS, including formal public notice of the proposed change, a comment period, and a subsequent establishment of the final rule.

Status and possible timing

CMS representatives have participated in an ongoing discussion with the industry regarding experience with potential ePA standards, readiness for adoption of ePA and other considerations including compatibility with HIPAA-named administrative standards. NCVHS has also received testimony periodically on the status of ePA standards.

CMS appreciates the urgency for a national ePA standard, due in part to increasing activity to establish state level rules in this area. Also, efforts such as the 2009 AHRQ ePA Expert Panel have reported that the issue of compliance with HIPAA requirements has been discussed and resolved in principle among the necessary parties, enabling an NCPDP ePA standard to be named for use in medication prior authorization.

Representatives of CMS have informally indicated an interest in moving forward quickly with the process to add the NCPDP ePA messages to the Part D standards. Once initiated, the rulemaking steps identified above could be completed in approximately two years.

State rules related to medication prior authorization

Several states have enacted or are in the process of enacting rules related prior authorization for prescription medications. In several cases, the rules establish non-electronic “uniform PA forms” that can
be submitted by electronic or non-electronic means. But other states including Minnesota are making efforts to put in place electronic prior authorization processes using data exchange standards.

Below is a sampling of state-level activities as of May 2013. While not exhaustive, it gives an overview of efforts taking place today.

<table>
<thead>
<tr>
<th>State</th>
<th>Scope</th>
<th>Status as of May 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>• Prescriptions&lt;br&gt;• Establish study committee on ePA&lt;br&gt;• Create recommendations on electronic PA&lt;br&gt;• Uniform drug PA form</td>
<td>In process&lt;br&gt;Last action 3/28/2013</td>
</tr>
<tr>
<td>Arkansas</td>
<td>• Prescriptions&lt;br&gt;• Uniform drug PA form&lt;br&gt;• Electronic submission (vague)</td>
<td>Passed&lt;br&gt;Delivered to Governor 3/13/2013</td>
</tr>
<tr>
<td>Arkansas</td>
<td>• E-Prescribing study committee</td>
<td>Died 2011</td>
</tr>
<tr>
<td>California</td>
<td>• Prescriptions&lt;br&gt;• Standard electronic prior auth. “form”&lt;br&gt;• Process / timing&lt;br&gt;• Electronic submission required&lt;br&gt;• State must consider CMS PA forms and ePA standards</td>
<td>Passed 2011, 2012</td>
</tr>
<tr>
<td>Colorado</td>
<td>• Prescriptions&lt;br&gt;• Process / timing&lt;br&gt;• Uniform PA form&lt;br&gt;• Defines electronic as via internet portal&lt;br&gt;• Workgroup to develop standard ePA process&lt;br&gt;• Must consider national standards</td>
<td>Sent to the Governor 5/14/2013</td>
</tr>
<tr>
<td>Connecticut</td>
<td>• Prescriptions, labs, imaging, other treatment&lt;br&gt;• Uniform PA forms&lt;br&gt;• Process / timing&lt;br&gt;• Does not require electronic PA&lt;br&gt;• Forms / PA process defined by the state must be consistent with national standards</td>
<td>In process&lt;br&gt;Last action 3/11/2013</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>• Prescriptions, tests, treatment&lt;br&gt;• Standard electronic prior auth. “form”&lt;br&gt;• Process / timing&lt;br&gt;• Electronic submission required&lt;br&gt;• State must consider CMS PA forms and ePA standards</td>
<td>Introduced 3/5/2013</td>
</tr>
<tr>
<td>Florida</td>
<td>• Medicaid managed care plans must post formularies&lt;br&gt;• Managed care plans must accept pre-auth. requests electronically</td>
<td>Passed 2011</td>
</tr>
<tr>
<td>Georgia</td>
<td>• Prescriptions&lt;br&gt;• Electronic messaging standard (NCPDP)&lt;br&gt;• Payers required to support ePA&lt;br&gt;• Optional for prescribers to use ePA process</td>
<td>Passed 2012</td>
</tr>
<tr>
<td>Hawaii</td>
<td>• Working group to recommend ePA approach</td>
<td>2011 passed</td>
</tr>
<tr>
<td>Hawaii</td>
<td>• Uniform PA form</td>
<td>2012 APPEARS NOT PASSED</td>
</tr>
<tr>
<td>State</td>
<td>Scope</td>
<td>Status as of May 2013</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>Iowa</td>
<td>Prescriptions, Uniform PA form, Process / timing</td>
<td>Introduced 2/14/2013</td>
</tr>
<tr>
<td>Kentucky</td>
<td>E-Prescribing rules, Directs state to consider NCPDP ePA standard</td>
<td>Passed 2012</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Establishes legislative working group</td>
<td>Senate, House established workgroup 2011</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Prescriptions, Medicaid only, Uniform PA form</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Last action: 5/13/2013</td>
</tr>
<tr>
<td>Maine</td>
<td>Prescriptions, Timing, Step therapy</td>
<td>Introduced 3/12/2013</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Prescriptions, labs, other treatment, Standard PA forms, Process / timing, Required electronic acceptance by payer. Optional electronic submission by provider</td>
<td>Passed, signed by Governor – 2012</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Uniform PA form (medical, prescription)</td>
<td>Died 2011</td>
</tr>
<tr>
<td>Michigan</td>
<td>Prescriptions, Process / timing, Electronic / web submission, Uniform form (separate from electronic process)</td>
<td>Approved by Governor 5/14/2013</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Prescriptions, Uniform form (single standard form), Process / timing, Electronic availability / submission (vague)</td>
<td>Passed, signed by Governor 4/23/2013</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Working group to establish electronic PA process, Establish e-prescribing rules</td>
<td>Died 2011</td>
</tr>
<tr>
<td>Missouri</td>
<td>Established ePA working group</td>
<td>Approved by Governor in 2012</td>
</tr>
<tr>
<td>Nevada</td>
<td>Establishes a state HIE, Standards for prescription ePA, Workgroup to determine standard electronic PA</td>
<td>Approved by Governor in 2011</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Prescriptions, Uniform PA form</td>
<td>Introduced 2/1/2013</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Prescriptions, Uniform form (single standard form), Electronic availability / submission (vague), Process / timing</td>
<td>Passed 2013</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Set steps to establish standard process for ePA</td>
<td>Died 2011</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Directed legislative committee to hold hearing on ePA standards</td>
<td>Passed 2011</td>
</tr>
<tr>
<td>State</td>
<td>Scope</td>
<td>Status as of May 2013</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>New York</td>
<td>• E-prescribing software req’ts</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Prescription PA</td>
<td>Last action 1/29/2013</td>
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<tr>
<td></td>
<td>• Electronic PA transmission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Process / timing</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>• E-Prescribing</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Ability to initiate PA from the eRx system</td>
<td>Last action 4/2/2013</td>
</tr>
<tr>
<td></td>
<td>• Electronic signature</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• “Real time” access to info the provider must supply for PA</td>
<td></td>
</tr>
<tr>
<td>North Carolina</td>
<td>• E-Prescribing</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Ability to initiate PA from eRx system</td>
<td>Last action 3/20/2013</td>
</tr>
<tr>
<td></td>
<td>• Submit PA electronically</td>
<td></td>
</tr>
<tr>
<td>North Dakota</td>
<td>• Prescriptions</td>
<td>Passed, signed by Governor 4/10/2013</td>
</tr>
<tr>
<td></td>
<td>• Electronic submission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Does not include uniform PA form rules</td>
<td></td>
</tr>
<tr>
<td>Oklahoma</td>
<td>• E-Prescribing</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Prescription ePA</td>
<td>Passed House. Last action 3/21/2013</td>
</tr>
<tr>
<td></td>
<td>• Medication history, current patient med list</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Process / timing</td>
<td></td>
</tr>
<tr>
<td>Oklahoma</td>
<td>• Prescriptions</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Uniform PA form</td>
<td>Last action 5/8/2013</td>
</tr>
<tr>
<td>Oregon</td>
<td>• Prescriptions</td>
<td>In process</td>
</tr>
<tr>
<td></td>
<td>• Uniform PA form</td>
<td>Last action 5/7/2013</td>
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<tr>
<td></td>
<td>• Electronic submission (non-specific)</td>
<td></td>
</tr>
<tr>
<td>Texas</td>
<td>• Prescriptions</td>
<td>In process. HB 1032 last action 4/26/2013</td>
</tr>
<tr>
<td></td>
<td>• Uniform PA form (single form)</td>
<td>SB 644 last action 5/20/2013 – placed on general state calendar</td>
</tr>
<tr>
<td></td>
<td>• Process / timing</td>
<td></td>
</tr>
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<td></td>
<td>• Electronic transmission</td>
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</tr>
<tr>
<td>Utah</td>
<td>• Prescriptions</td>
<td>Passed, signed by Governor 4/1/2013</td>
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<tr>
<td></td>
<td>• Working group</td>
<td></td>
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<tr>
<td></td>
<td>• Standard PA form</td>
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<tr>
<td></td>
<td>• National standards</td>
<td></td>
</tr>
<tr>
<td>Vermont</td>
<td>• Prescriptions and other medical service</td>
<td>Introduced 1/22/2013 (Senate), 1/24/2013 (House)</td>
</tr>
<tr>
<td></td>
<td>• Uniform PA form or electronic submission</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Approval statistical reporting</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Electronic submission</td>
<td></td>
</tr>
<tr>
<td>Vermont</td>
<td>• Prescription PA</td>
<td>Passed 2011. (Report issued Feb 2012)</td>
</tr>
<tr>
<td></td>
<td>• Working group</td>
<td></td>
</tr>
<tr>
<td>Washington</td>
<td>• Prescriptions, procedures, tests</td>
<td>Signed by the Governor 5/10/2013</td>
</tr>
<tr>
<td></td>
<td>• Electronic transmission</td>
<td>(Effective date 7/28/2013)</td>
</tr>
<tr>
<td></td>
<td>• Uniform PA forms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Process / timing</td>
<td></td>
</tr>
</tbody>
</table>