Electronic Drug Prior Authorization Standardization and Transmission

Report to the Minnesota Legislature 2010

Minnesota Department of Health

February 15, 2010

MDH
MINNESOTA
DEPARTMENT OF HEALTH

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Summary

This report is submitted by the Minnesota Department of Health (MDH) in fulfillment of the requirements of Minnesota Statutes, section 62J.497, Subd. 5. The statute requires that

> *The commissioner of health, in consultation with the Minnesota e-Health Advisory Committee and the Minnesota Administrative Uniformity Committee, shall, by February 15, 2010, identify an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions.*

The statute further requires that

> *No later than January 1, 2011, drug prior authorization requests must be accessible and submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.*

The statute was enacted during the 2009 legislative session in response to concerns regarding administrative burdens and costs associated with the current prescription drug prior authorization (PA) process.   Prescription drug prior authorizations are required of prescribers, and in some cases pharmacies, by group purchasers (payers) in order that patients may receive particular prescription drugs. Prescription drugs requiring prior authorization make up only a small fraction of all prescribed medications.[1] However, prior authorization is a "widely adopted method of drug utilization management"[2] and the majority of prescribers submit PA requests.[3]   Both the number of drugs requiring prior authorization and the number of PAs have grown rapidly in recent years.[4]

Despite its growing visibility and importance, the drug prior authorization process is often manual and nonstandard, creating administrative burdens and costs to health care providers and payers.[5] It also may result in patients experiencing delays in getting prescriptions filled, or foregoing medications, leading to potentially adverse health impacts as well.[6]

Health care industry experts and stakeholders have suggested several possible attributes of a "best" approach to standardize drug PA request, including for example:

- Extensive use of direct, computer-to-computer, automated electronic data interchange (EDI), based on well-established, widely-used national standards that are well suited to the drug PA transaction;

- A single, standard list of drugs requiring PAs, and a standard set of questions used by payers to gather supplemental information needed to process PA requests, that are the same across all payers; and,

- Full and effective integration with other health care electronic data exchange, especially electronic prescribing (e-prescribing) and electronic health records (EHRs).

However, many of the suggested characteristics of a "best" PA process are often lacking at this time, and would require time, resources, and changes at the national level that were beyond the scope of this project. Given these challenges and constraints, an interim, alternative approach to meeting the statutory charge was proposed and discussed during the 2009 Minnesota legislative session. Under this approach, MDH would outline high-level, minimum specifications for standard, direct data entry payer web portals, to facilitate drug prior authorization requests from prescribers. The standard web portals would permit prescribers to initiate PA requests in similar ways, and to submit common types of information in consistent, recognizable formats, regardless of the payer. In this manner, a level of information exchange now occurring through a variety of different, payer-specific, separate forms and websites would become more standard and electronic. The approach was proposed to help "fill the gap" until the attributes necessary for a longer term, more optimal PA process can be realized.

MDH contracted with an outside consultant, Advanced Strategies, Inc. (ASI), to assist in planning, data gathering and review, and facilitating structured meetings with stakeholders to help outline the website specifications. We identified a wide variety of stakeholders and subject matter experts, and solicited their participation and input, as well as that of the advisory groups named in statue. A series of meetings, presentations, and information exchanges to obtain input and review were completed during October 2009 – January 2010. These efforts also built upon previous work completed earlier in 2009 in response to a separate statutory requirement to develop a conceptually similar "Uniform Formulary Exception Form."

Despite interests among stakeholders in the direct data entry website approach during the 2009 session, development of the concept has been somewhat controversial. The Minnesota Administrative Uniformity Committee (AUC) and others raised several concerns with the approach. The AUC warned that the concept would result in new administrative costs and burdens, and was a bad investment because it would someday be replaced by national transactions standards that would make the web portals unnecessary. The AUC also recommended:

- That an online fillable form approach should be used instead of the website approach. According to the AUC, this would be less expensive to develop and maintain compared to websites;

- Exploring a new national electronic, standard prescriber-payer drug PA transaction that was recently announced for pilot testing as a basis for more standard, electronic drug PA requests; and,

- Seeking delays in the current statutory requirement to exchange drug PAs electronically by 2011, and the continued ability to submit drug PA requests via fax beyond the current 2011 cut-off date.

In contrast to the AUC position, others pointed out that the recently announced drug PA pilot transaction may not be widely tested or adopted for some time, and that the use of online forms may also have costs. Some also advocated greater standardization of the drug PA process now, including development of a single, common set of questions used by payers to obtain any supplemental information needed to process drug PA requests.

In the remainder of the report, MDH outlines minimum specifications for direct data websites and online fillable forms to standardize the initiation of drug prior authorization requests at this time. As noted, the approach is somewhat controversial and not without tradeoffs. While the proposed website and fillable form specifications are not in and of themselves sufficient to be considered a long term "best" solution, they are presented as an interim option to best meet the statutory directive at this time.

In addition, in the report we also summarize: findings regarding the current PA process; several characteristics suggested by industry experts and stakeholders for an ideal "best" PA request process; existing barriers or constraints to establishing the ideal PA method at this time; and issues and concerns raised during the project.

Electronic Drug Prior Authorization Standardization and Transmission

I. Overview and Background

A. Statutory Charge

This report is submitted by the Minnesota Department of Health (MDH) to meet the requirements of Minnesota Statutes 62J.497, Subd. 5. The statute requires that

> *The commissioner of health, in consultation with the Minnesota e-Health Advisory Committee and the Minnesota Administrative Uniformity Committee, shall, by February 15, 2010, identify an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions.*

The statute further requires that

> *No later than January 1, 2011, drug prior authorization requests must be accessible and submitted by health care providers, and accepted by group purchasers, electronically through secure electronic transmissions. Facsimile shall not be considered electronic transmission.*

B. Definition of Prescription Drug Prior Authorization (PA) and Current PA Use and Process

A prescription drug prior authorization has been defined as "… the process of obtaining pre-approval from a payer for specified medications or quantities of medications, with the goals of: improving patient safety; and containing costs."[7]

While prescription drugs requiring prior authorization (PA) make up only a small fraction of all medications,[8] studies have also reported that "PA is a widely adopted method of drug utilization management"[9] and prior authorizations are "frequently used to manage the increasing costs of pharmacy benefits."[10] One large online survey found that nearly two-thirds of prescribers write prescriptions that require PA.[11] Over time, prescription drug prior authorizations have become an increasingly more frequent transaction. One study reported that "advances in MTM [medication therapy management], biotechnology, designer drugs, specialty pharmacy, and the cost of the pharmacy benefit, has increased the number of PA'd medications." As a result, "from 2000 to 2006, commercial plans doubled the number of medications requiring PA," and the number "increased steadily" among Medicaid programs.[12]

However, the PA process is often manual, nonstandard, and perceived as burdensome and costly.[13] While some payers have instituted web portals for direct data entry of drug PA requests, and vendors offer web-based solutions, the web portals are not standard across payers. In addition, drug prior authorization "often requires multiple telephone phone calls and facsimiles between pharmacy, practice, and a third party administrator to gain resolution."[14] As described in more detail in a presentation sponsored by the federal Agency for HealthCare Research and Quality (AHRQ):

"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. The payer then evaluates the request, and responds with a faxed approval or denial. Evaluation [of the PA] 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."[15]

Not only is the current drug PA process often administratively burdensome, but it may also result in patients experiencing delays in getting prescriptions filled, or foregoing medications, leading to potentially adverse health impacts as well.[16]

II. Suggested attributes of a "best" prescriber-payer prescription drug prior authorization process and their status at this time

This report's statutory charge requires *"an outline on how best to standardize drug prior authorization request transactions between providers and group purchasers with the goal of maximizing administrative simplification and efficiency in preparation for electronic transmissions."* Health care industry experts and stakeholders have suggested several possible characteristics of a much more efficient, "best" drug prior authorization process, and it is important to understand these attributes when discussing options to address drug PA concerns. However, it is also important to note that many of the desired attributes of a best PA process are often now not present, and would require time, resources, and changes at the national level that were beyond the scope of this project.

A. Need for well-established, widely-used national standard transaction for prescriber-payer exchanges

Prescribers currently often must complete different prior authorization forms for each payer, or access separate websites to submit PA information. The forms must often be completed by hand and submitted via fax. There may be frequent follow-ups with further faxes, phone calls, and messaging, and the process may take up several days to complete.

In contrast to the current PA process, some industry experts and observers maintain that the drug prior authorization process between prescribers and payers would be most efficient if it utilized computer-to-computer electronic data interchange (EDI) of "real-time" (or nearly real-time) transactions, based on well-established national electronic transaction standards. However, an existing national standard for the electronic exchange of prior authorizations that is available for exchanges between prescribers and payers "provides for prior authorization inquiry and response in general" and "provides … limited support for prior authorization of drugs and is not widely used."[17] (Separate, different national transaction standards exist for PAs between pharmacies and payers;[18] MDH was not made aware of similar issues or concerns regarding limitations of the pharmacy PA standard during this project.)

Several national electronic transactions standards-setting organizations have worked in recent years to develop a new electronic transaction to better meet the needs of prescriber-payer PA exchanges. In November, 2009, several months after the conclusion of the 2009 Minnesota legislative session, a federally designated standards organization, the National Council of Prescription Drug Plans (NCPDP),

announced that the new drug PA transaction was available for broader pilot testing.[19] The new transaction, designed to operate in tandem with electronic-prescribing ("e-prescribing"), is available for voluntary testing as a first step prior to potentially being adopted as a new national transaction standard. However, it is unknown at this time: how quickly and widely the testing will occur; what the potential results of the testing may be; or the near-term and long-term potential of the transaction to reduce the underlying burden and costs associated with the current drug prior authorization process.

B. Common lists of drugs requiring prior authorizations, and common questions/criteria used in processing PAs

A further challenge to more standard, efficient drug prior authorizations is that currently payers typically maintain their own unique, individual lists of which drugs require PAs, as well as the specific questions that prescribers must answer as part of a payer's prior authorization processing and determination. Some have suggested then that another precondition for a more standard prescription drug PA process between prescribers and payers would be the development and use of a single set of standard questions or criteria by payers to determine whether to authorize a particular prescription. Previous national-level efforts to standardize these questions and criteria were not successful[20] and were discontinued; no single list of standard drug PA questions or criteria is being advanced at this time.

C. PA process as part of e-prescribing and Electronic Health Record (EHR) work flow

Prescribers often now do not know that a PA is required for a drug until they have written the prescription for a patient, and the patient takes it to a pharmacy to be filled. When the pharmacy submits a claim for a prescription that must first be prior authorized, the claim will likely be rejected, notifying the pharmacy of the need for a PA. When this occurs, either the pharmacy or the patient typically must contact the prescriber regarding the need for a PA request.

In contrast to the current drug PA process, e-prescribing holds promise for alerting prescribers to the need for drug prior authorizations before completing a prescription. Knowing that a PA is needed in advance would allow the prescriber to consider other alternative medications that did not require prior authorization, or to request a PA prior to completing the prescription, thus saving all parties involved unnecessary delays and administrative costs. According to some, if a PA were needed, the "best" PA process would also integrate fully with the prescriber's e-prescribing and electronic health record (EHR) capabilities to auto-populate data needed for the PA request, and thereby reduce the amount of manual data entry and potential opportunities for mistakes or errors.

Minnesota has mandated that prescribers use electronic prescribing (e-prescribing) by January 1, 2011, and implement interoperable electronic health records (EHRs) by 2015. In addition, the federal government is implementing rules for financial incentives for providers to make "meaningful use" of EHRs, starting in 2011.

However, not all e-prescribing systems are currently taking advantage of the full formulary and benefit functionality needed to signal prescribers that a prescription must be authorized in advance. It is unclear whether this will continue to be an issue, or whether use of the functionality may increase in response to the federal meaningful use incentives. In addition, not all Pharmacy Benefit Managers (PBMs) and payers provide formulary and benefit information at the individual level at this time.[21] As a result, even when prescriptions are sent electronically through an e-prescribing application, prescribers and patients may not be informed in advance that a prior authorization is needed.

Finally, even if prescribers receive a PA alert before writing the prescription, they often cannot process the PA request electronically using only their EHR or e-prescribing systems. Instead, the prescriber may

often still have to submit the PA request by hand keying (or even hand writing) data to a particular form that is specific for a particular payer, and sending it to the payer via fax, where it may be subject to additional iterations of manual responses, clarifications, error corrections, and other steps.

D. Interim "best" drug PA method at this time given existing constraints

Given the overall challenges and constraints of meeting several important preconditions above for an ideal PA solution at this time, as well as project time and resource constraints, MDH outlined an interim "fill-the-gap" approach to meeting the statutory requirements that was discussed with stakeholders and legislators during the 2009 session. This interim approach focused on the development of common, high-level, minimum specifications for direct data entry website portals to be implemented by payers to facilitate the prescription drug PA process.

Under this approach, payers would make available websites meeting common, minimum specifications that could be accessed by prescribers to submit information in a more standard, electronic way to initiate prior authorization requests. Some payers currently already make web portals available for prescribers to submit PA requests, and vendors provide a range of web-based solutions, but these websites may vary in their content, appearance, and other features across payers. The goal of MDH's outline was to provide high level, minimum website specifications so that prescribers would then be able to initiate PA requests in a similar fashion, and provide common background information in similar ways, regardless of the payer. In this manner, a level of information exchange now being undertaken through a variety of separate, different forms or websites would be made more standard and electronic.

III. Project Scope and Process

A. Focus on prescriber-payer exchange of information to initiate drug PA request

In early discussions with the Minnesota Administrative Uniformity Committee (AUC) and other interested parties, MDH defined the focus of the project as outlining high level, minimum specifications for interim direct data entry websites as described above. In particular, MDH focused on the PA transaction between prescriber and payer, and especially, the exchange of common information needed to initiate the transaction. While pharmacies may sometimes make drug PA requests, most often, the pharmacy must notify the prescriber of the need for a PA, and the prescriber must provide information needed for the prior authorization. Given the project's focus and the time and resources available, MDH did not undertake to: standardize the kinds of additional information being requested by payers to process a prior authorization request; determine which drugs should be subject to prior authorization; or complete an in-depth analysis of the recently announced new pilot PA transaction, as these steps were considered beyond the scope of the project.

B. Project consultant

MDH contracted with Advanced Strategies, Inc. (ASI), a consulting group with significant experience working with state governments, including Minnesota state government, as well as the private sector, in documenting and evaluating business needs as they relate to technology applications. ASI assisted with project planning, data gathering and review, and in facilitating two, structured, full-day working meetings with stakeholders. It reviewed initial example PA requests and processes, mapped the prescription PA process and work flow, documented PA information needs, and provided summaries of issues and options explored with stakeholders during meetings and feedback to MDH.

C. Solicitation of input and participation

The Department solicited input and participation in the project through:

- Communications, reports, updates, and discussions with the AUC and the Minnesota e-Health Advisory Committee;

- Notices and contacts with other interested parties, including those that had previously participated in a similar MDH project in mid-2009 to develop a Uniform Formulary Exception Form, as well as other national payers, Pharmacy Benefits Managers (PBMs), and representatives of national designated standards organizations (National Council of Prescription Drug Programs; Accredited Standards Committee X12N/TG2/WG10); and,

- Frequent website updates and general informational notices.

In soliciting input and participation, MDH especially sought information and clarification to aid in developing the following website characteristics:

- Data collection needs regarding patients, patient clinical information, provider information, prescription drug information, insurer/payer information and other data;

- Privacy and security, including registration, authorization, and authentication of system users;

- Website content, organization, and display; and,

- Other related data, data exchange, and response considerations.

D. Meetings, presentations, reviews

Several meetings, presentations, and discussions were conducted in the early stages of the project. MDH issued a request to interested parties for relevant background studies, information, examples and related material. Two full-day structured, facilitated meetings were held with stakeholders, including representatives of the AUC and the e-health Advisory Committee, to discuss the website characteristics and specifications. An additional half-day follow-up meeting was held and a preliminary draft report was circulated among project participants and interested parties for review and comment prior to preparation of this final report. Numerous other literature searches and specific follow-up research, discussions, and clarifications were ongoing throughout the project.

IV. Project Outcomes and Results

A. Prescriber-payer drug PA work flow and process

The meetings and study process described above resulted in discussions and documentation of the current workflow and process steps in prescription drug PAs. This work flow was summarized and diagrammed by ASI to aid in better visualizing the process, and is attached as Appendix A following this report.

B. Data needs to initiate the prescriber-payer drug PA

The project examined several models of PA and inventoried information requested by payers on a recurring basis to initiate the PA process. The project also reviewed the outcomes of earlier work in developing a Uniform Formulary Exception Form (UFEF) in 2009 pursuant to Minnesota Statutes 62J.497, Subd. 4, as the UFEF has several components in common with prior authorization.

Approximately 70 data elements were identified initially as needed to initiate a PA request and provide commonly requested routine information to identify the prescriber, patient, the drug for which the PA was required, and relevant clinical information. Following additional review and discussion at the meetings above, the list was reduced to approximately 50 elements. MDH subsequently reviewed the list and provided additional specificity for the purposes of establishing common website specifications.

The list of the PA initiation data elements is incorporated in the website specifications section of the report (section V below).

C. Website security considerations

In its meetings with stakeholders, MDH discussed security and safeguards to protect patient information and maintain appropriate data privacy. A brief, summary outline of overall website security considerations and best practices provided at the working meetings is provided in Appendix B.

D. Concerns and issues

In the meetings and reviews above, several members of the AUC and others expressed concerns that the creation of direct data entry web portals would add costs and administrative and burdens. In addition, concerns were raised that: the websites would require significant re-keying and manual entry of data, particularly of data already available through electronic health records (EHRs); and, that the direct data entry portal concept was too narrowly focused on only the initiation phase of PAs and did not standardize payers' questions and responses back to prescribers. Concerns were similarly raised that investments in the web portals might be relatively short term and may not be recouped if they were later replaced by the adoption of a new, recently announced transaction standard for electronic exchange of PA requests.

However, concerns were also reiterated by others during the project regarding the current burdens and costs of the exiting PA process and work flow. It was noted that a great deal of re-keying or manual entry of data is now sometimes common in current drug PA requests, and that this is compounded by the lack of standard PA review processes and questions that must be addressed. It was also observed that developments expected to improve the PA process, such as the recently announced pilot drug PA transaction, might take much longer to test or implement on a broad basis than perhaps was initially expected.

The AUC recommended that instead of requiring payers to establish and maintain websites that special, standard fillable forms be made available by payers. These forms would be designed to be sent securely and electronically and were recommended as being less expensive to develop and maintain compared to websites. The AUC also recommended seeking delays in the current statutory requirement to exchange drug PAs electronically by 2011, and to allow continued use of faxes for drug PA requests beyond 2011. The AUC findings and recommendations submitted to MDH are included as Appendix C.

The participants in the project process brainstormed during one of the full-day sessions regarding possible other alternatives to the current fax-based, manual entry prescriber-payer PA exchange, but did not reach consensus on other preferred options.

The following section of the report outlines minimum specifications for direct data entry portals or online fillable forms to facilitate a more standard, electronic drug prior authorization request initiation between prescribers and payers at this time.

Note: The minimum specifications outlined below are similar to those for a "Minnesota Uniform Formulary Exception Form" (UFEF) created and posted by MDH in 2009, pursuant to Minnesota

Statutes, section 62J.497, Subd. 4. Requests for exceptions from group purchaser (payer) formularies are requests to make nonformulary prescription drugs available to a patient as a formulary drug. Minnesota Statutes § 62J.497, Subd. 4 also requires that "No later than January 1, 2011, the uniform formulary exception form must be accessible and submitted by health care providers, and accepted and processed by group purchasers, through secure electronic transmissions. Facsimile shall not be considered secure electronic transmissions."   Further information regarding the UFEF is available at: http://www.health.state.mn.us/asa/form.html.

Because of the close similarities between the UFEF and the drug PA website and fillable form minimum specifications, MDH encourages payers to adapt the specifications to also meet the UFEF requirements. Payers providing a single website, or online fillable form, for both the initiation of drug PA requests and formulary exceptions, should clearly state that this is the case, and provide appropriate directions or instructions accordingly.

V. Outline of minimum specifications for direct data entry web portals and fillable forms to facilitate drug PA request initiations between prescribers and payers

A. Minimum website specifications

i. General specifications

1. Navigation between different sections or pages of the portal must be clear and allow for forward/back movement between pages/sections, as well as up/down movement between sections on the same page.

2. Pre-populating of data fields is encouraged. For example, the PA authorizing entity may prepopulate prescriber information into the request based on the login and password of the prescriber.

3. Drop down menus, check boxes, and other means of reducing data entry are encouraged.

4. The entity maintaining the web portal must provide a unique confirmation/receipt number to the prescriber upon conclusion of the transaction. The prescriber must be able to view on the website with appropriate security any messages or additional information regarding the uniquely identified transaction.

5. All data fields should be appropriately and consistently labeled as shown below.

6. The portal should be consistent with standards and best practices promoting the greatest accessibility possible. See for example several guides and tips at sources such as:
▪ Usability.Gov (http://www.usability.gov/)
▪ Web Accessibility Initiative (WAI) (http://www.w3.org/WAI/)

7. Note: The additional minimum specifications outlined below are similar to those for a "Minnesota Uniform Formulary Exception Form" (UFEF) created and posted by MDH in 2009, pursuant to Minnesota Statutes, section 62J.497, Subd. 4. Further information regarding the UFEF is available at: http://www.health.state.mn.us/asa/form.html. Because of the close similarities between the UFEF and the minimum specifications below, MDH encourages payers

to adapt the drug PA website and fillable form specifications to also meet the UFEF requirements. Payers providing a single website, or online fillable form, for both the initiation of drug PA requests and formulary exceptions, should clearly state that this is the case, and provide appropriate directions or instructions accordingly.

ii. Prescriber log in and password

1. The portal must have sufficient security to provide adequate safeguards for the data being exchanged.

2. See Appendix B with additional best practices and considerations for website identification, authentication, authorization, integrity, non-repudiation, confidentiality, integrity checks, validation, business rules, and privacy.

iii. Patient information

Patient Information Data Fields		
Ref. no.	Field name/label	Format/comments/other instructions
1	Patient name	
	i. Last Name	
	ii. First Name	
	iii. Middle	
2	Patient date of birth	[MM/DD/YYYY]
3	Patient address, including:	
	i. Street (one)	
	ii. Street (two)	
	iii. City	
	iv. State	Provide a pull-down menu of state options
	v. Zip code	Must accept either five-digit or nine-digit zip codes
4	Patient Gender	Provide radio buttons (options buttons) for: ▪ Male ▪ Female ▪ Unknown
5	Patient Health Plan or Pharmacy Plan Name	
6	Patient health plan #ID (or Pharmacy Plan ID# if different than Health Plan ID#)	This field is to also include the following explanatory information: [Note: If the patient has pharmacy benefits that are separate or "carved out" from the health plan benefits, provide the patient's pharmacy benefit card ID number (the "cardholder

Patient Information Data Fields		
Ref. no.	Field name/label	Format/comments/other instructions
		ID"). If the patient's pharmacy benefits are integrated with the health plan coverage (if there is no separate pharmacy benefit ID number), provide the patient's health plan ID number.]

iv. Prescriber Information

Prescriber Information Data Fields		
Ref. no.	Field name/label	Format/comments/other instructions
1.	Prescriber name	
	i. Last	
	ii. First	
	iii. Middle	
2.	Prescriber National Provider Identifier (NPI)	
3.	Prescriber Phone Number	[_ _ _ - _ _ _ - _ _ _ _]
4.	Point Of Contact (POC) Name (If different than the prescriber)	[Last, First, MI]
5.	POC Phone Number (If different than the prescriber)	[_ _ _ - _ _ _ - _ _ _ _]
6.	Clinic Name	
7.	Clinic Address:	
	i. Street (One)	
	ii. Street (Two)	
	iii. City	
	iv. State	Provide a pull-down menu of state options
	v. Zip code	Must accept either five-digit or nine-digit zip codes
8.	Prescriber Business Address (If different than clinic address)	
	i. Street (One)	
	ii. Street (Two)	
	iii. City	
	iv. State	Provide a pull-down menu of state options
	v. Zip code	Must accept either five-digit or nine-digit zip codes
9.	Prescriber fax number	[_ _ _ - _ _ _ - _ _ _ _]

v. Pharmacy information

The following data fields were suggested for PA requests submitted to the Minnesota Department of Human Services (DHS).

	Pharmacy Information Data Fields	
Ref. no.	Field name/label	Format/comments/other instructions
1.	Pharmacy Name	
2.	Pharmacy National Provider Identifier (NPI)	
3.	Pharmacy Phone Number	[_ _ _ - _ _ _ - _ _ _ _]
4.	Pharmacy Address	
	i. Street (One)	
	ii. Street (Two)	
	iii. City	
	iv. State	Provide a pull-down menu of state options
	iv. Zip code	Must accept either five-digit or nine-digit zip codes

vi. Prescription Drug Information

	Prescription Drug Information Data Fields	
Ref. No.	Field name/label	Format/comments/other instructions
1.	Name of Requested Drug	
2.	Strength (Medication "strength" is usually expressed in milligrams, e.g., 30 mg, 15 mg/ml, etc.)	
3.	Quantity	
4.	Dosing Schedule (Medication "dosing schedule" is used to report how often the patient will take/use the medication, e.g., daily, four times per day, every four hours, as needed, etc.)	
5.	Date Therapy Initiated	[DD/MM/YYYY]

Prescription Drug Information Data Fields		
Ref. No.	Field name/label	Format/comments/other instructions
6.	Authorization start date	[DD/MM/YYYY]
7.	Clinical Trial Drug Request	Provide radio buttons (options buttons) for: ▪ Yes ▪ No
8.	Is Dispense As Written (DAW) specified?	Provide radio buttons (options buttons) for: ▪ Yes ▪ No
9.	Rationale for DAW	
10.	Is Patient Currently Being Treated With the Requested Drug?	Provide radio buttons (options buttons) for: ▪ Yes ▪ No

viii.   Patient Clinical Information

Patient Clinical Information Data Fields		
Ref. No.	Field name/label	Format/comments/other instructions
1.	Diagnosis (Include ICD-9 codes when available)	
2.	Drug Allergies (If relevant to this request)	
3.	Other Medications Tried And Explanation of Results (if relevant to request)	Provide method to repeat this set of fields as needed
	i. Drug name	
	ii. Length of time on drug	
	iii. Explanation of results	
4.	Patient Height, in inches (if relevant to this request)	
5.	Patient Weight, in pounds (if relevant to this request)	

Patient Clinical Information Data Fields		
Ref. No.	Field name/label	Format/comments/other instructions
6.	Other Pertinent Clinical Information	

B. **Minimum fillable form specifications**

i. General specifications

1. Navigation between different sections or pages of the form must be clear and allow for forward/back movement between pages, as well as up/down movement between sections on the same page.

2. Pre-populating of data fields is encouraged. For example, the PA authorizing entity may prepopulate prescriber information into the request based on the login and password of the prescriber.

3. The entity maintaining the form must make a unique confirmation/receipt number of the PA request transaction available to the prescriber upon conclusion of the transaction. The prescriber must be able to use the unique confirmation/receipt number of the transaction with appropriate security to access status information and updates regarding the transaction, and to access messages or additional information regarding the uniquely identified transaction.

4. The form should be made available and maintained so as to be consistent with standards and best practices promoting the greatest accessibility possible. See for example several guides and tips at sources such as:
- Usability.Gov (http://www.usability.gov/)
- Web Accessibility Initiative (WAI) (http://www.w3.org/WAI/)

5. Note: The example "Minnesota Prescription Drug Prior Authorization (PA) Request Form" in section iii below is similar to the "Minnesota Uniform Formulary Exception Form" (UFEF) created and posted by MDH in 2009, pursuant to Minnesota Statutes, section 62J.497, Subd. 4. Further information regarding the UFEF is available at: http://www.health.state.mn.us/asa/form.html. Because of the close similarities between the UFEF and the Drug PA Request Form, MDH encourages payers to adapt the Drug PA Request Form to also meet the UFEF requirements. Payers providing an online fillable form for both the initiation of drug PA requests and formulary exceptions should clearly state that this is the case, and provide appropriate directions or instructions accordingly.

ii. Security and data protection

1. The portal must have sufficient security to provide adequate safeguards for the data being exchanged.

2. See Appendix B with additional best practices and considerations for website identification, authentication, authorization, integrity, non-repudiation, confidentiality, integrity checks, validation, business rules, and privacy.

iii. <u>Example fillable form</u>

An example fillable form follows on the next two pages.

Example Minnesota Prescription Drug Prior Authorization (PA) Request Form (side 1)

Instructions

Important: Please read all instructions and information before completing the form.

This form is made available to facilitate exchanges of information between prescribers and group purchasers as part of prescription drug prior authorization (PA) requests. This form will not change frequently. The form version number and most recent revision date are displayed in the lower left hand corner.

Definitions and instructions

- o Prescription drug prior authorization requests are requests for obtaining pre-approval from a payer for specified medications or quantities of medications.

- o The term "health care provider" is defined in Minnesota Statutes, section 62J.03, Subd. 8; the term "group purchaser" (payer) is defined in Minnesota Statutes, section 62J.03, Subd. 6 (see https://www.revisor.leg.state.mn.us/statutes/?id=62J.03.)

- o This form is made available for use by prescribers to initiate prescription drug PA requests with group purchasers.

- o Group purchasers may request additional information or clarification needed to process PA requests.

- o Group purchasers may supply additional instructions or other relevant or legally required information with their response.

- o For Section A. - Patient Information: If the patient has pharmacy benefits that are separate or "carved out" from the health plan benefits, provide the patient's pharmacy benefit card ID number (the "cardholder ID"). If the patient's pharmacy benefits are integrated with the health plan coverage (if there is no separate pharmacy benefit ID number), provide the patient's health plan ID number.

- o In Sections C and D, medication "strength" is usually expressed in milligrams, e.g., 30 mg, 15 mg/ml, etc. Medication "dosing schedule" is used to report how often the patient will take/use the medication, e.g., daily, four times per day, every four hours, as needed, etc.

- o Note: This "Minnesota Prescription Drug Prior Authorization (PA) Request Form" is similar to the "Minnesota Uniform Formulary Exception Form" (UFEF) created and posted by the Minnesota Department of Health (MDH) in 2009 pursuant to Minnesota Statutes, section 62J.497, Subd. 4. Further information regarding the UFEF is available at: http://www.health.state.mn.us/asa/form.html. Because of the close similarities between the UFEF and the Drug PA Request Form, MDH encourages payers to adapt this Form to also meet the UFEF requirements. Payers providing an online fillable form for both the initiation of drug PA requests and formulary exceptions must clearly state that this is the case, and provide appropriate directions or instructions accordingly.

Revision History:
V 1.0 2/15/10

MINNESOTA
MDH
DEPARTMENT of HEALTH

Example Minnesota Prescription Drug Prior Authorization (PA) Request Form (side 2)

This **Minnesota Prescription Drug Prior Authorization (PA) Request Form** is made available for use by prescribers to initiate prescription drug PA requests with group purchasers. **Additional information and instructions are on the first page of this form.**

A. Patient Information

Patient Name (Last, First, MI):	DOB (mm/dd/yyyy):
Patient Address:	City, State, ZIP
Gender: ☐ Male ☐ Female ☐ Unknown	Patient Health Plan ID# (or Pharmacy Plan ID# if different than Health Plan ID):
Health Plan or Pharmacy Plan:	

B. Prescriber Information

Prescriber Name: (Last, First, MI)	National Provider Identifier (NPI)	Prescriber Phone Number
Prescriber contact name (if different than prescriber)	Prescriber contact phone number (if different than prescriber)	
Prescriber Business Address:	Prescriber City, State, ZIP:	Prescriber Fax Number:
Clinic Name	Clinic Location	

C. Prescription Drug Information

Requested drug name	Requested Drug Strength (e.g., 30 mg, 15 mg/ml, etc):	Dosing Schedule:
Date Therapy Initiated	Authorization Start Date	
Clinical Trial Drug request? ☐ Yes ☐ No		
Is "Dispense as Written" (DAW) specified? ☐ Yes ☐ No	Rationale for DAW	
Is patient currently being treated with the drug requested? ☐ Yes ☐ No		

D. Patient Clinical Information

Diagnosis related to medication request (include ICD-9 codes when available):

Drug Allergies (if relevant to this request):	Height (if relevant to this request):	Weight (if relevant to this request):

Previous Therapies Tried / Failed

Drug Name	Date Prescribed	Dosing Schedule	Strength	Duration	Describe adverse reaction or efficacy failure

Other pertinent clinical information:

E. Pharmacy Information (for PA requests to the Minnesota Department of Human Services (DHS)

Pharmacy Name:	National Provider Identifier (NPI)	Pharmacy Phone Number
Pharmacy Address:	Pharmacy City, State, ZIP:	

MINNESOTA MDH DEPARTMENT of HEALTH

Appendix A

Summary Advanced Strategies, Inc. (ASI) flow chart, Prescription Drug Prior Authorization

The following definitions, notes, and flow charts are provided as an informational summary, excerpted from the ASI work product, "Prescription Drug Prior Authorization Standardization and Transmission Project Workflow Diagrams and Notes, DRAFT, December 15, 2009."

Key to Symbols

PRESCRIBER   A closed box is a data store, which is either source of information, or a destination to which information is sent. No further action is taken with the data. The slash marks on the upper left corner indicates a duplicate of this data store exists elsewhere on the diagram.

Complete PA Request   A circle is a process, an activity that transforms an input into a different output.

Requested Different Drug   A solid line with an arrowhead represents an information flow; input flows point into processes; output flows point away from processes.
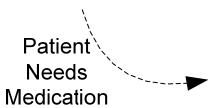
Patient Needs Medication   A dotted line is a trigger; this is some event that initiates a process.

A   The small circle containing a letter indicates that the flow comes from or goes to somewhere else on the page; look for another small circle with the same letter.

D   The pentagon shape is an off-page connector; it signifies that the flow starts on or goes to another page; look on the other page for a pentagon with the same letter.
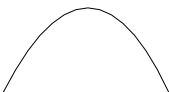
The thicker line is a boundary separating in-scope from out-of-scope processes.

Diagram Notes

There are two work flow diagrams presented here. The first is a candidate "To Be" workflow for provider-initiated Prior Authorization (PA) Requests. The second is a description of the current work flow when pharmacists initiate PA requests.

About the Candidate "To Be" Prescriber Workflow Diagram:
- A "candidate" diagram is put forward for consideration, but it not necessarily a recommendation.
- A "To Be" diagram attempts to describe a future state, but does not specify details of the transition, including cost, length of time, intermediate steps, etc.
- A "High-Level" diagram is one that does not specify all of the details that might occur in the work setting.
- A "High-Level" diagram is intended to be generic; it does not specify any particular enabling medium (e.g., web site or secure transmission) nor does it describe physical, implementation details such as the order of information entry, use of drop-down menus versus radio buttons, etc.
- The diagrams are based on discussions at meetings sponsored by the Minnesota Department of Health on November 19 and December 1, 2009.
  - The diagrams are the work of the consultant and not necessarily a consensus diagram or a preferred option of the Minnesota Department of Health.
- Other prescribers or payors that did not participate in discussions might have provided different information, resulting in a different set of workflows.
- The project focused on the transactions portion of the PA request; time and resources precluded re-engineering the entire PA process.
- The internal processes of the payors were considered out of scope; also deemed out of scope were formulary decisions, decisions about which drugs require PA, and the criteria for approving or denying PA requests.
- Prescribers indicated a desire to complete as much of the PA process in one electronic session as possible.
- Prescribers would also like real-time decisions from payors.
  - Payors do not think that they can answer all PA requests in real-time; some cases require additional consideration.
- The workflow diagram can apply to two future scenarios
  - Scenario A: The provider is able to supply all needed information to needed by the payor to process a drug-specific PA request in one electronic session, at the time the prescription decision is made; most requests are decided on in real time.
  - Scenario B: The prescriber is able to complete a drug-specific PA request in one session; the payor acknowledges receipt of the request, and processes the PA using its current process; the decision on the PA request occurs after some lag.
- The workflow diagram allows for three responses by the payor: approved, denied, or more information needed.

About the Pharmacist Workflow Diagram:
- Prescriber-Initiated and Prescriber-Initiated PA Requests are shown separately
  - Most PA requests come from the prescriber, except for MN Medical Assistance, where a larger percentage of PA transactions are pharmacist-initiated.
  - Participants suggested that while any new system should be flexible enough to allow pharmacists to initiate a PA request, the primary focus should be on prescriber-initiated PA requests.
  - The group did not focus enough on the pharmacist workflow to support construction a "to be" diagram. A "to be" workflow for pharmacists would need to reflect the impact of licensure scope of practice on decisions and processes available to pharmacists, as distinct from prescribers.
    - The pharmacist workflow is therefore a description of current reality.

- Definitions
  - "Patient Identifier Info", "Patient Clinical Info", "drug Info", and "Prescriber Info" are described [in the information elements table in section V of the main body of the MDH "Electronic Drug Prior Authorization Standardization and Transmission" report].
  - "Other Supporting Info" is any information supplied by the prescriber in response to specific follow-up questions from the payor.
  - "Authorizing Entity Formulary" is a list of all drugs covered by a payor, identifying which drugs require prior authorization
    - Some payors also list cost information on their web sites
  - "Authorizing Entity PA Process Requirements" consists of questions and process steps that the payor requires to make a decision on the requested drug; this may include drug-specific questions, requests for information on other drugs tried, etc.
  - "Patient Medical Record" is the information on the patient's identifier information, medical history and health plan membership that is kept by the prescriber.
  - "Patient Prescription History" is the information kept by a pharmacist about prescriptions filled and claims processed for an individual patient.

Request Prescription Drug Prior Authorization

Candidate "To Be" High Level Work Flow- Prescriber Initiates PA

Minnesota Department of Health

Date Created:	11/28/2009
Last Updated:	12/15/2009
Notes:	

Filename: Request PA-Updated New Work Flow.vsd

PATIENT MEDICAL RECORD (CLINIC)

Patient Coverage Info

Determine Drug Authorizing Entity

Determined Drug Authorizing Entity

Determine Need for Prior Authorization

Determined Need for Prior Authorization

Patient Identifier Info

Patient Clinical Information

Other Supporting Information

Additional PA Justification

Select Desired Drug

Patient Needs Medication

Desired Drug

Prior Authorization Is Needed

AUTHORIZING ENTITY FORMULARY

Supply Patient Identifier Info

Supply Patient Clinical Information

Supply Other Supporting Information

Acknowledge Receipt of PA Request

Acknowledged PA Request

<Authorizing Entity>

PRESCRIBER

Requested Different Drug

A

Supply Desired Drug Info

Supplied Desired Drug Info

AUTHORIZING ENTITY PA PROCESS REQUIREMENTS

AE Required Info

Supplied Patient Identifier Info

Supplied Patient Clinical Information

Supplied Other Supporting Information

Complete PA Request

Completed PA Request

Send PA Request

Sent PA Request

Supplied PA Justification

Additional PA Justification Needed

Decide on PA Request

<Authorizing Entity>

PA Request Decision

Notify Patient Of PA Approval

Patient PA Decision Notice

PATIENT

Notify Prescriber Of PA Decision

<Authorizing Entity>

PA Request Approved

PA Request Denied

<Prescriber>

Notify Pharmacy of Approval

<Pharmacist>

Approval Notice

PHARMACIST

Supply Prescriber Info

Supplied Prescriber Info

Informed Prescriber

PRESCRIBER

Prescriber Info

B

Supply Additional PA Justification

Informed Prescriber

D

Request A Different Drug

Requested Different Drug

A

Pharmacist PA Denial Info

C

Notify Patient Of Denial

Patient Notice of Denial

PATIENT

NOTES:

--This diagram must be read in conjunction with notes for complete understanding

--Gray processes are out of scope
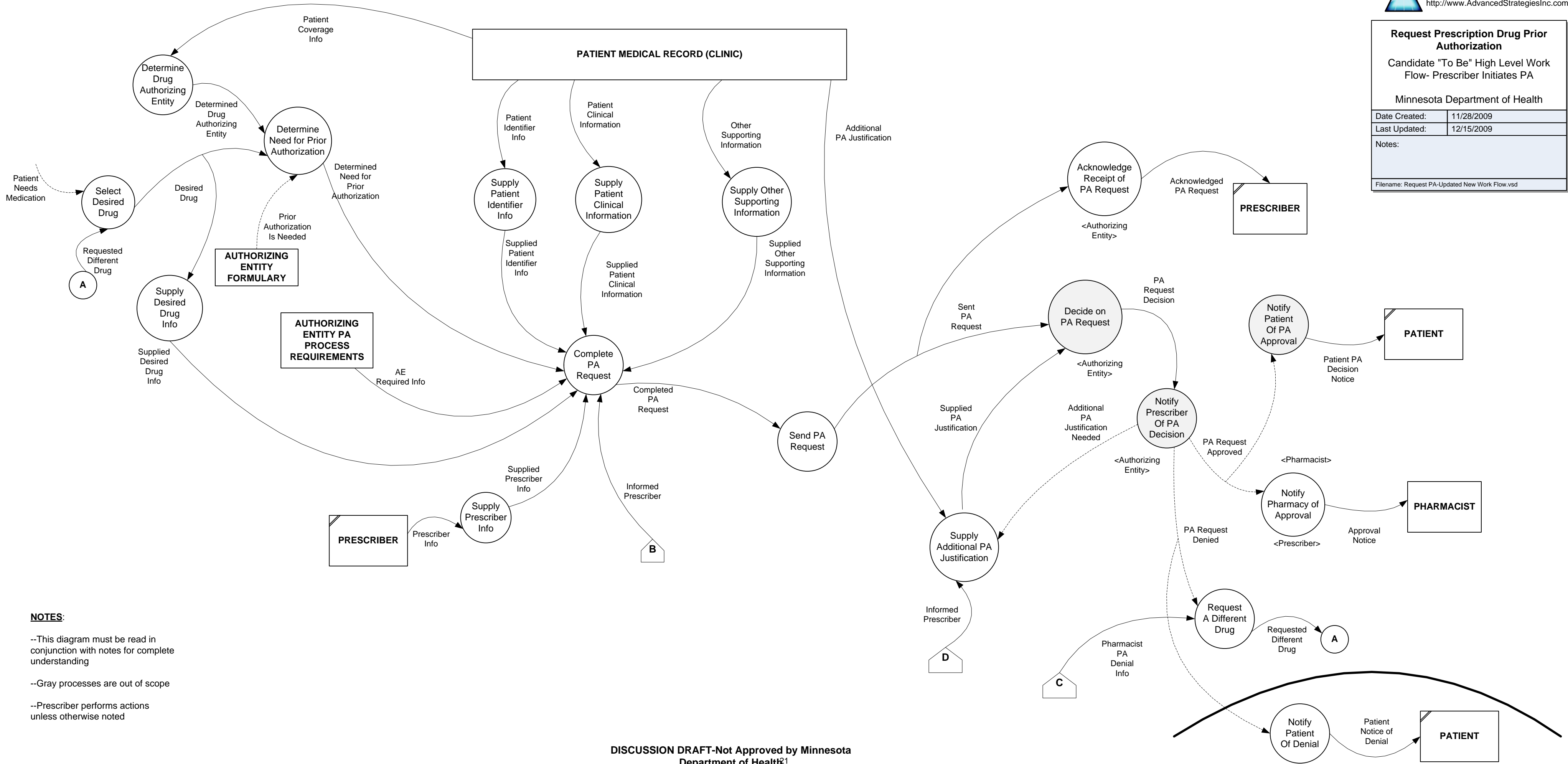
--Prescriber performs actions unless otherwise noted

Request Prescription Drug Prior Authorization

Current High Level Work Flow- Pharmacist Initiates PA

Minnesota Department of Health

Date Created:	11/28/2009
Last Updated:	12/15/2009
Notes:	

Filename: Request PA-Updated New Work Flow.vsd

PATIENT PRESCRIPTION HISTORY

Patient Coverage Info

Submit Claim

Submitted Rx

Submitted Claim

Submit Rx

<Patient>

Rx

PRESCRIBER

AUTHORIZING ENTITY

Prior Authorization Is Needed

B

Informed Prescriber

Inform Prescriber

Info Is Needed From Prescriber

Review Patient Rx History

Patient Rx History

PATIENT PRESCRIPTION HISTORY

Pharmacist Has Needed Info

Complete PA Request

Supplied Pharmacist Info

Supply Pharmacist Info

Pharmacist Info

PHARMACIST

Completed PA Request

D

Informed Prescriber

Notify Prescriber Additional PA Info Needed

Additional PA Information Needed

Notify Pharmacy Additional PA Info Needed

<Authorizing Entity>

Additional Information Needed

Decide on PA Request

<Authorizing Entity>

C

Pharmacist PA Denial Info

Notify Prescriber of Denial

Authorizing Entity PA Denial Info

Notify Pharmacy of PA Denial

PA Request Denied

PA Request Approved

Approval Notice

Notify Pharmacy of Approval

<Authorizing Entity>

Readjudicate Claim

Filled Prescription

PATIENT

NOTES:

--This diagram must be read in conjunction with notes for complete understanding

--Gray processes are out of scope

--Pharmacist performs actions unless otherwise noted

Appendix B

Website security considerations and best practices

Web Application Security – Recommendations from
national organizations for discussion

Background

The Minnesota Department of Health (MDH) is outlining a set of high level specifications for direct data entry (DDE) web portals to be implemented and maintained by group purchasers (payers) to facilitate a more standard prescription drug prior authorization (PA) transaction process, pursuant to MN Statutes § 62J.497.

Below is a brief compilation of some recommendations regarding Web Application Security from several relevant national organizations' websites. The compilation is intended to facilitate discussion regarding possible security features of web portals to facilitate prescription drug PAs.

Elements of Security

Web application security is based on several important concepts, including:

- **Identification and Authentication:** Verify the identity of a user before allowing access to information system.
  - Login pages should be encrypted - Credentials should only traverse encrypted links.
  - Connect from a secured network
  - Don't share login credentials or use default accounts.
  - Maintain a secure workstation - Apply all operating system, software, and browser patches.
  - Require strong passwords – Make sure passwords have a character, number, and special character. Make sure passwords are at least 8 characters in length (longer passwords are better). It is better to have more complex passwords and of longer length than to change often. Changing passwords often forces users to write passwords down. Lock passwords after 3 failed logon attempts for 30 minutes.
  - Prefer key-based authentication over password authentication – "Typical two factor solutions involve registering a hardware device such as a token, phone or biometric device on top of the "something you know". In all cases, the two factors should be used together for best results (OWASP)."
  - Training – Provide training materials or in person training.

- **Authorization.** Permission is granted to web application by system owner.
  - A process must be defined to ask for and grant user access - business owner should define roles. Where will authorization requests be submitted? Who will determine access rights?
  - User privileges should be limited to the greatest degree possible – users should be assigned roles
  - Documentation as to who has been granted access and to what level
  - Make sure audit tracking has been turned on. Determine what level of auditing will be needed. How long should the audit logs be kept?

- **Integrity.** The user of the data must have confidence that the data has not been altered in an unauthorized manner while in storage, during processing, or in transit.
  - Manage your Web site via encrypted connections
  - Use strong, cross-platform compatible encryption – "Proprietary encryption algorithms are not to be trusted as they typically rely on 'security through obscurity' and not sound mathematics.
    - Symmetric:
      - Key sizes of 128 bits (standard for SSL) are sufficient for most applications
      - Consider 168 or 256 bits for secure systems such as large financial transactions
    - Asymmetric:
      - Key sizes of 1280 bits are sufficient for most personal applications
      - 1536 bits should be acceptable today for most secure applications
      - 2048 bits should be considered for highly protected applications
    - Hashes:
      - Hash sizes of 128 bits (standard for SSL) are sufficient for most applications
      - Consider 168 or 256 bits for secure systems, as many hash functions are currently being revised (see above).
      - NIST and other standards bodies will provide up to date guidance on suggested key sizes (OWASP)".
  - Make sure you implement strong security measures that apply to all systems – not just those specific to Web security
  - Use redundancy to protect the Web site
  - Use firewalls to protect access from data

- **Non-repudiation.** Assurance that the sender of information is provided with proof of delivery and the recipient is provided with proof of the sender's identity, so neither can later deny having processed the information.
  - Applications should be scan and tested for common security vulnerabilities. Applications should be tested against standards such as Open Web Application Security Project (OWASP) to prevent against known application security attacks (including SQL injection, parameter manipulation, buffer overflows, cross-site scripting, and so on)
  - Security audits of web server environment
  - Documentation
  - Defined security policies

- **Confidentiality.** Authorized restrictions must be in place on information access and disclosure, including means for protecting personal privacy and proprietary information.
  - Data validation should be done server-side

- **Integrity checks**. Ensure that the data has not been tampered with and is the same as before

- **Validation**. Ensure that the data is strongly typed, correct syntax, within length boundaries, contains only permitted characters, or that numbers are correctly signed and within range boundaries

- **Business rules**. Ensure that data is not only validated, but business rule correct. For example, interest rates fall within permitted boundaries. (OWASP)"

Privacy. Restricting access to subscriber or relying party information in accordance with Minnesota law, Federal law and organization policy.

- Make sure to follow standards such as HIPAA, the Payment Card Industry (PCI), etc.
- Data loss reporting policy

References

National Institute of Standards and Technology (NIST) Computer Security Division (CSD). (n.d.). CSRC Home. Retrieved December 11, 2009, from http://csrc.nist.gov/index.html

Open Web Application Security Project (OWASP). (n.d.). Main Page. Retrieved December 11, 2009, from http://www.owasp.org/index.php/Main_Page

PCI Compliance Guide. (n.d.). PCI Compliance Guide Home Page. Retrieved December 11, 2009, from http://www.pcicomplianceguide.org/pcifaqs.php

U.S. Department of Health & Human Services. (n.d.). Health Information Privacy. Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Retrieved December 11, 2009, from http://www.hhs.gov/ocr/privacy/

Appendix C

Minnesota Administrative Uniformity Committee (AUC) position statement and recommendations

January 21, 2010

Dear Mr. Haugen,

As the Chair and Co-Chair of the Administrative Uniformity Committee (AUC) and on behalf of all of our members, we wish to express our concerns and provide input as the Minnesota Department of Health (MDH) finalizes their report for the Standardized Prescription Drug Prior Authorization Project.

We strongly support the goals of reducing administrative costs and burdens through greater standardization of health care administrative transactions, and to increase the electronic exchange of administrative data. We understand that the goal of Minn. Stat. 62J.497, Subd. 5 is to remove the burden of obtaining paper forms that are not form-fillable (must be hand-written) for submitting prior authorization (PA) requests. The AUC supports the goal to create a simple, standard, and efficient process for PA requests between prescribers and payers. However, we have serious concerns with the draft report and the statute as follows:

1. **Makes poor use of limited financial resources**: The draft report focuses on requiring payers to build web portals. Such a requirement would be a bad investment because the nation is moving towards national standards that will eventually make web portals unnecessary.
2. **Still does not reduce the administrative burden or cost**: Web portals do not use the data in the electronic medical record (EMR), and still require administrative processes and human intervention (rekeying data). Thus, they do not achieve administrative simplification or cost reduction.
3. **Lacks standards for other processes associated with this transaction**: Under this law there is no standard for the response, so the provider would have to administer multiple processes to communicate with each and every Pharmacy Benefit Management company (PBM)/health plan. In addition, there is no requirement for standardization in the questions contained in the prior authorization request.

Therefore, the AUC recommends an *interim* solution where a form-fillable standardized form with common data elements could be created for the initial request and response (that can be sent via fax or a secure electronic method). The standardized form could utilize the data elements identified in the Minnesota Uniform Formulary Exception form and the data elements identified by the MDH Standardized Prescription Drug Prior Authorization work group. MDH could create and publish the standardized Prescription Drug Prior Authorization form that payers and providers could adopt as the standard.

We have learned that some large providers still want the flexibility to fax a form-fillable form while the industry standards are being developed. Therefore, to accommodate the needs of the provider community, we recommend the language in Minn. Stat. 62J.497, Subd. 5 (b) be changed either to delay the effective date of January 1, 2011, or to delete the sentence that states "Facsimile shall not be considered electronic transmission."

The AUC remains committed to developing standards for data content for the PA request and response. The AUC will also evaluate the National Council for Prescription Drug Programs (NCPDP) standard to support the data content and Electronic Data Interchange (EDI) efforts for the PA request and response with the goal of implementing a national standard. In addition, the AUC will volunteer to continue investigating any other uses of EDI models for PA request and response (meaning no web or faxing).

We appreciate the opportunity to provide these comments and request they be reflected in the final report. Please feel free to contact either of us if you have questions.

Sincerely,

Erika Greenlee   Paige Hinz
2010 AUC Chair   2010 AUC Co-Chair

Endnotes and References

[1] National Committee on Vital and Health Statistics (NCVHS) letter to Tommy Thompson, Secretary, US Department of Health and Human Services, Sept. 2, 2004. Accessed at: http://www.ncvhs.hhs.gov/040902lt2.htm. The letter reported that "It is estimated that 2 percent of prescriptions now require prior authorization."

[2] Wegner, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. American Journal of Managed Care. 2009;15(12):e115-e122). Accessed at http://www.ajmc.com/articles/managed-care/2009/2009-12-vol15-n12/AJMC_decWegnerWbX_e115finl.

[3] Source: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008. Tony Schueth, Task Group Leader, NCPDPD (Multi-SDO) Prior Authorization Workflow-to-Transactions Task Group, CEO & Managing Partner, Point-of-Care Partners, LLC and Jon White, M.D., Director of Health Information Technology, AHRQ Center for Primary Care, Prevention, and Clinical Partnerships. (Presentation slides, accessed at: http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textonly/slide9.html. Slide 9 states that: "Findings from 2004 PDR online survey (n=3,529):63% of prescribers write some Rxs that require PA")

[4] Source: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008. (Presentation slides, accessed at http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textonly/slide8.html. See slide 8.)

[5] See for example: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA) (cited above, see slides 9-12). See also: Balkrishnan, R., et al. Prior Authorization of Newer Insomnia Medications in Managed Care: Is It Cost Saving?".J Clin Sleep Med. 2007 June 15; 3(4) 393-398. Accessed at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1978307/. See also Wegner, SE, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. The American Journal of Managed Care. Volume 15, Number 12, December 2009. e115-3-121. Accessed online 1/29/10 at: http://www.ajmc.com/articles/managed-care/2009/2009-12-vol15-n12/AJMC_decWegnerWbX_e115finl

[6] Wegner, SE, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. The American Journal of Managed Care. Volume 15, Number 12, December 2009. e115-3-121. Accessed online 1/29/10 at: http://www.ajmc.com/articles/managed-care/2009/2009-12-vol15-n12/AJMC_decWegnerWbX_e115finl. See also Balkrishnan, R., et al. Prior Authorization of Newer Insomnia Medications in Managed Care: Is It Cost Saving?". J Clin Sleep Med. 2007 June 15; 3(4) 393-398.

[7] Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA), February 5, 2008 at http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textonly/slide4.html, slide 4.

[8] See footnote 1, National Committee on Vital and Health Statistics (NCVHS) letter to Tommy Thompson, Secretary, US Department of Health and Human Services, Sept. 2, 2004. Accessed at: http://www.ncvhs.hhs.gov/040902lt2.htm

[9] Wegner, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. American Journal of Managed Care. 2009;15(12):e115-e122).

[10] Balkrishnan, R., et al. Prior Authorization of Newer Insomnia Medications in Managed Care: Is It Cost Saving?". J Clin Sleep Med. 2007 June 15; 3(4) 393-398.

[11] Source: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008 (Presentation slides, accessed at: http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textonly/slide9.html. Slide 9.)

[12] Source: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008. (Presentation slides, accessed at: http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textonly/slide8.html, slide 8).

[13] See sources as for footnote 5 above: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA) (cited above, see slides 9-12). See also: Balkrishnan, R., et al. Prior Authorization of Newer Insomnia Medications in Managed Care: Is It Cost Saving?". J Clin Sleep Med. 2007 June 15; 3(4) 393-398. Accessed at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1978307/. See also Wegner, SE, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. The American Journal of Managed Care. Volume 15, Number 12, December 2009. e115-3-121. Accessed online 1/29/10 at: http://www.ajmc.com/articles/managed-care/2009/2009-12-vol15-n12/AJMC_decWegnerWbX_e115finl.

[14] Wegner, SE, et. al. A Physician-Friendly Alternative to Prior Authorization for Prescription Drugs. The American Journal of Managed Care. Volume 15, Number 12, December 2009. e115-3-121. Accessed online 1/29/10 at: http://www.ajmc.com/articles/managed-care/2009/2009-12-vol15-n12/AJMC_decWegnerWbX_e115finl.

[15] Source: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008. (Presentation slides, accessed at: http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textmostly/slide5.html and http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textmostly/slide6.html. See slides 5-6).

[16] See for example: Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA) (cited above); Balkrishnan, R., et al. Prior Authorization of Newer Insomnia Medications in Managed Care: Is It Cost Saving?". J Clin Sleep Med. 2007 June 15; 3(4) 393-398.

[17] Letter to Tommy Thompson, Secretary, US Department of Health and Human Services, from the National Committee on Vital and Health Statistics (NCVHS), September 2, 2004. Accessed at http://www.ncvhs.hhs.gov/040902lt2.htm. The letter states: "The ASC X12N 278 [Health Care Services Review Standard Version 004010X094A1] is a HIPAA standard that provides for prior authorization inquiry and response in general. It provides very limited support for prior authorization of drugs and is not widely used." See also slide 35 of Current State of E-Prescribing Standards: Electronic Prior Authorization (ePA). February 5, 2008. (Presentation slides, accessed at: http://healthit.ahrq.gov/images/erx_meeting_20080218/attachment4/attachment4_files/textmostly/slide35.html.)

[18] 45 CFR § 162.1302 specifies that the current standard for retail pharmacy drug referral and certification and authorization The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in §162.920).

[19] Announcement by National Council of Prescription Drug Plans (NCPDP) in "NCPDP Now" electronic newsletter, Nov. 20, 2009. Article entitled: "**INDUSTRY PRIOR AUTHORIZATION PILOT.** NCPDP's WG11 Prior Authorization Workflow-to-Transactions Task Group has created an XML transaction for the exchange of prior authorization information between prescribers and payers. The download includes a presentation on the historical work, the XML files, and flow diagrams supported."

[20] Information provided to MDH by participants as part of working meetings in November - December, 2009.

[21] Information provided to MDH by participants as part of working meetings November – December, 2009. See also: "Off and Running: Current Efforts to Standardize Electronic Prior Authorization", *AMCP 2006 Educational Conference,* October 5, 2006. Presentation slides accessed at: http://www.pocp.com/Documents/ePriorAuth-AMCP-Final.pdf. See slide 18.