ELECTRONIC PRIOR AUTHORIZATION FOR MEDICATIONS:

THE TIME IS RIGHT FOR PLANS, PBMS AND OTHER PAYERS

Prior authorization (PA) is the process of obtaining preapproval from a payer for a prescribed therapy. For the payer, the goal from instituting a PA process is simple: to encourage appropriate clinical and cost-effective therapy. However, making the process work effectively is not simple. It is typically a timeconsuming, expensive and frustrating process to obtain approval or find a more appropriate, cost-effective therapy. At a minimum, it introduces delays in patient treatment; at worst, it creates obstacles that result in lack of treatment.

There is a better way, particularly as it applies to the significant and growing trend associated with PA for the 15% of health care that is medication therapy. This white paper focuses on the history of medication PA, the effect PA has had on the industry and its constituents and, most importantly, what payers, pharmacy

benefit managers (PBMs) and other participants can do to improve a necessary but cumbersome process through electronic work flow. It is time for the health care industry to embrace electronic prior authorization (ePA) of medications, a standardized electronic process in which real-time decisions on PA requests are provided at the point of prescribing. ePA represents:

"ePrescribing, for me and my patients, has been a tremendous success. Now, bring on electronic prior authorizations!"

> Dr. Jim Morrow Cumming, GA June 12, 2011

- The potential to dramatically improve efficiency by reducing labor costs for all stakeholders;
- An opportunity to improve the relationship between health plan and provider;
- A resource to encourage clinically appropriate prescribing and discourage overuse of particular drugs;
- A vehicle for delivering evidence-based information to clinicians; e.g., drug protocols for particular diseases;
- A platform for consistently capturing a comprehensive profile of clinical data necessary to accurately and promptly evaluate patients for drugs requiring authorization; and
- A means to prompt the clinician for information needed and a vehicle to reject incomplete PA requests.

Admittedly, PA has become commonplace within health care. That said, this white paper acknowledges the history behind ePA while focusing on its current state and why now is the time to develop and execute an effective strategy.



Today's Prior Authorization Landscape

Use of PA Is on the Rise. Use of PA is increasing, as shown in Table 1. In the past six years, the number of instances for which a formulary drug requires PA has doubled. While advances in medication therapy management, biotechnology, designer drugs and specialty pharmacy are drivers, cost containment appears to be the major cause.



Table 1. Medications on Formularies RequiringPrior Authorization by Insurer Type

Medicare Part D programs were early adopters of PA as it was among the strategies most frequently used by Medicare prescription drug plans to contain costs.¹ Similarly, commercial plans doubled the number of medications requiring PA between 2000 and 2006, and that figure nearly doubled again between 2006 and 2011, as shown in Table 1. Even among Medicaid programs, the number of medications requiring PA has increased, largely to contain costs.^{2,3}

The Current PA Process Is Burdensome and Expensive. Despite the benefits for payers, PA is time consuming and creates a burden on all stakeholders, not the least of which are physicians. The process is shown in Figure 1.

³ Tilly J, Elam L. Prior Authorization for Medicaid Prescription Drugs in Five States: Lessons for Policy Makers. Washington, DC, *Kaiser Commission on Medicaid and the Uninsured* Apr 2003.



¹ Brill JV. Trends in prescription drug plans delivery of the Medicare Part D prescription drug benefit. *Am J Health System Pharm.* 2007;64(15 suppl 10):S3-S6.

² Polinski JM, Wang PS, Fischer MA. Medicaid's prior authorization program and access to atypical antipsychotic medications. *Health Affairs* 2007;26(3):750-760.



Figure 1. Today's Paper-Based Prior Authorization Process

The process begins with the pharmacy notifying the physician that PA is required and then trying to determine the patient's benefit plan as well as identify its drug-specific PA form from among the thousands that are available both online and directly from the plan. 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. Upon receipt of a request for PA, the payer's PA staff reviews the information provided. More often than not, the information required to make a determination is missing or illegible. Therefore, clarifications often require further interaction between payer and prescriber.

Frequently, the provider will be contacted again for clinical information. Despite directions on payer Web sites, many doctors frequently have no idea what information payers need or really want. In addition to the hassle factor, there are huge administrative costs associated with manually obtaining the patient information, photocopying it and then mailing or faxing it to the payer. This process can take several iterations — including numerous phone calls and additional rounds of faxes — before the PA request is approved or denied.

Once sufficient information is obtained by the payer, requests are often triaged with simple cases evaluated by nonclinical staff while more complex cases may be brought to a clinician or, in some instances, a committee. Once a determination has been made, the payer typically communicates the determination to the pharmacy and/or physician via fax. If approved, the PA drug will be covered; the pharmacy claim will be processed successfully and the prescription will be filled.



At the heart of the problem are the wide variations among payer PA processes. Additionally, today's PA processes are largely manual and fax driven, often requiring a lengthy and iterative dialogue among physician, pharmacy and payer. Turnaround time can be hours or even days, depending on the payer, the complexity of the patient's condition and staffing in the physician's office, pharmacy and payer. Incomplete information and PA requests containing errors, both of which are common, further extend the time to a decision.

Because of the time and work flow issues created, many physicians avoid the PA process by prescribing an alternative therapy that does not require PA, even though it may not be optimal for the patient, increasing the potential for adverse events or other complications. Finally, the complexity and inconvenience of the PA process means that many prescriptions are never followed up on or filled, even for a less expensive alternative therapy, raising serious patient safety and quality-of-care issues. "Whether it stops inappropriate utilization or provides the right drug for the right patient at the right time in the right setting, the current PA process results in too many abandoned prescriptions. It has been estimated that as many as 30-40% of PA requests result in a patient not getting a prescription."

> CoverMyMeds – an ePA solution provider

Electronic PA Emerges as a Way to Solve a Problem and Create Value

In the current electronic age, there should be no need to rely on telephones and fax machines for data exchange and time lags should be minimal.

There is an obvious alternative: electronic prior authorization (ePA), a standardized process in which a real-time decision on a PA request is provided at the point of prescribing. In a health care world with dramatic levels of electronic medical record and ePrescribing adoption, it is self-evident that ePA is long overdue. It creates a streamlined process for communicating the need for PA directly to the prescriber and allows the prescriber to respond directly and instantly with the needed information during the prescribing process. ePA also offers the provider near real-time response concerning approval or denial at the point of care. A thoughtful, standardized ePA process would eliminate several administrative steps, reduce the "hassle factor" of the paper system for physicians and pharmacies, and help patients receive their medications faster and more conveniently.

While widespread adoption of ePA is admittedly several years away, recent innovations and solutions have been introduced that change the landscape, so now is the time to determine and execute - a strategy that offers a competitive advantage and opportunity to shape the evolution of ePA.



Some market leaders have already recognized the opportunity, having developed solutions and piloting programs. These solutions provide the beginning of a bridge to a more efficient and standardized process that will likely help define the ePA solutions of the future.

ePA Today. Today's emerging ePA solutions use portal architectures to partially automate today's paper process, but do not yet represent a true end-to-end solution that can be easily integrated with ePrescribing systems or electronic health records.

There are generally three types of portal-based PA solutions available today: prescriberinitiated, prescriber-initiated augmented by automatic decision making and pharmacyinitiated, all of which are interim solutions and a migration path solution based on the National Council for Prescription Drug Programs (NCPDP) standard outlined previously. In addition to portal solutions, a number of entities utilize call centers to help patients and prescribers navigate the PA process.

Prescriber-initiated Portals – Many payers are developing Web sites that contain forms, requirements and other information needed to process a PA request. In some situations, the portal provides Web screens on which the prescriber or office staff may answer questions. The health plan/pharmacy benefit manager primarily benefits from this approach because the PA process is more automated and streamlined. However, single-payer portals have considerable disadvantages for prescribers as they are required to log onto different Web sites for each payer and must complete forms without the benefit of prepopulated patient information.

ePA: a decade of interest

- **1996** Standards established by Health Insurance Portability and Accountability Act (HIPAA) for health transactions including prior authorization.
- **2003** The Medicare Modernization Act included provisions for the evaluation of ePrescribing standards, including electronic prior authorization.
- 2004 A multistakeholder workgroup under the NCPDP was created. This workgroup had three primary objectives:
 - Promote standardized automated PA adjudication;
 - Coordinate the further development and alignment of standards; and
 - Identify additional needed standards.
- 2006 Federal pilots were conducted that determined the PA standard as designated in HIPAA was inadequate for medications, largely because it was designed for medical services and not prior authorization of medications; the two processes have similarities and differences.

Other pilots determined that no single ePA standard could be effectively utilized. Workarounds were possible, but not ideal because standardized transaction fields would be used for purposes other than their original intent. Because of this problem and others, use of several standards in concert with the HIPAA standard was evaluated. Testing found it too cumbersome and required redundant input of information. An additional concern was the burden placed on companies to have expertise in and sometimes participation in two standards development organizations (SDOs). As a result, a single new standard for medication prior authorization was recommended for development in 2007.

- 2008 Federal government produces ePA value model.
- 2009 NCPDP drafted standards for ePA messaging and real-time eligibility. Because these draft standards have not yet been tested in pilots, approved by NCPDP or approved by any other SDO, there has not been much uptake. Minnesota passed legislation requiring ePA as part of ePrescribing.
- **2011** Renewed interest, new pilot activity, additional states considering requiring electronic PA.



Prescriber-initiated Portals with Automated Decision-making – This model is simply a more advanced version of the version above. It addresses the initial request process with the prescriber, but also automates much of the decision-making process that occurs once the PA is received by the health plan. While more attractive to health plans, the single-payer access and lack of integration with prescriber work flow limits the appeal to prescribers. Agadia and Ibeza are companies providing solutions in this category.

Prescriber-initiated & Pharmacy-initiated Portals – As expected, this model extends the functionality to allow pharmacies to initiate a request to an intermediary following a pharmacy claim rejection due to PA requirement triggers. The intermediary uses the information from the rejected claim to identify the patient, drug prescriber and plan. Based on this information, the intermediary then sends the appropriate planspecific PA form to the prescriber either via fax or

a portal; in some cases, the form may be sent directly to the prescriber's ePrescribing application for placement in the work queue. This solution has considerable appeal because most PAs are currently initiated by the pharmacist rather than the prescriber, and this solution lessens the inconvenience of PA on both because it works for almost any drug and any payer. The solution fits into the work flow of both the pharmacist and prescriber, and when integrated with in-house computer systems can provide transaction flows where available formulary and benefit information fall short. Two of the more prominent players in this space are CoverMyMeds, which covers all medications and all payers, and Armada, which until recently focused only on high-cost/specialty medications.

PA Call Centers – In response to difficulties in gathering information and submitting PA requests (especially for specialty medications), PA call centers have become increasingly common. This service is usually sponsored by a pharmaceutical manufacturer to help patients and prescribers work through the PA process and is subcontracted to a third party. The Lash Group and McKesson are two examples.



<u>Agadia</u> – Provides a Web-based solution for drugs and medical services to physician offices that includes initiation, transmission and real-time resolution of PA requests by using fully integrated portals and solutions; currently only available for certain plans.

<u>Armada</u> – Provides a solution based on pharmacy claim rejection. Pharmacies notify prescribers, who download PA request forms and submit a single portal.

CoverMyMeds – Provides a one-stop shop for delivery of PA requests to plans, with the process being initiated by a pharmacy claim rejection or the prescriber who knows PA is going to be required. Service includes all payers and drugs.

Ibeza - A recent entrant to the ePA space that provides an automated rules engine for determination of drug and medical PAs.

Most of today's PA requests are initiated when a pharmacy claim is rejected because PA is required, the drug is not covered, or a plan limit is exceeded. As a result,

- 1/3 receive the initial drug;
- 1/3 receive a different drug; and
- 1/3 abandon therapy.

CoverMyMeds – an ePA solution provider

Developing an ePA Standard Will Take Time

The ePA standard is currently being developed by the National Council for Prescription Drug Programs (NCPDP). One of health care's leading standards development organizations (SDO), the NCPDP is American National Standards Institute (ANSI) accredited and best known for pharmacy claims (telecommunications) and electronic prescription (SCRIPT) standards. ANSI accreditation means that the NCPDP has been certified with policies and processes that lead to consensus. While not guaranteeing complete stakeholder agreement, it ensures that multiple perspectives are considered and major objections addressed. That translates, understandably, into a rigorous but time-consuming process. Other factors, however contribute to the lengthy process, as well, including the NCPDP's reliance upon volunteers, a limited number of meetings and venues per year, and delays typical of any consensus-based decision process.

The development of a standard conceived of and facilitated by NCPDP can take from 3 to 4 years, with additional time required for adoption. This is because most steps involved in the development of a standard typically takes one to three months, with consensus necessary before moving on to the next step. The piloting or retesting step can take up to 12 months for each. A typical process would be:

- 1. Work group within SDO identifies a problem;
- 2. Volunteer task group within the work group is formed;
- 3. Plan established and sub-task groups are formed;
- 4. Task group comes to consensus and provides recommendation to work group;
- 5. Standard is proposed by work group;
- 6. Standard is pilot tested;
- 7. Standard is modified based on test;
- 8. Standard is retested, if needed;
- 9. Standard is balloted at SDO and voted on;
- 10. Standard is released to industry.

In short, the development and ratification process for any industry standard, let alone one for an industry as complex and multifaceted as health care, is complex and time consuming. Fortunately for ePA, there are other more immediate options worth considering.



"We are not aware of a widely adopted, common industry transaction standard that has been demonstrated to support real-time ePA, nor are we aware of a common or universal electronic format that has been demonstrated to facilitate distribution of prior authorization forms. We are aware of work that has been done by NCPDP to create an XML-based ePA messaging standard and a real-time eligibility check messaging standard. We understand that these are draft standards that have not yet been pilot tested and have not been fully 'balloted' (voted on) through NCPDP's process."

> Dr. Doug Fridsma Director, Office of Standards and Interoperability Office of the National Coordinator of Health Information Technology

Moving Forward With New Requirements and Pilot Programs

Another important factor at play is the considerable interest by federal and state governments and the industry to move ePA standards and automation forward. North Dakota and Minnesota, for example, have both passed legislation mandating ePA by 2013 and 2015, respectively, and similar bills are circulating in numerous other state legislatures. Payers with a presence in these states will need to keep apprised of this legislation and have a strategy to act.

There also has been renewed interest in pilot testing a new ePA standard. That standard, developed in 2009 by a NCPDP task group, was needed because the current Health Insurance Portability and Accountability Act (HIPAA) transaction standard for PA focuses on claims for medical care and services and is not adequate for medications. This new standard has served to add momentum to the ePA bandwagon.

At the April 2011 NCPDP work group meetings, CVS Caremark announced the beginning of a pilot project that didn't use the standard because of observed deficiencies. As summer progressed, information about other pilots started to emerge. NCPDP organized a focus group for the sharing of ePA information in October, which stimulated even more interest in testing and modifying the ePA standard created in 2009.

Four different projects were discussed at that meeting, all of which seek to provide an electronic solution to PA. Some adhere to the NCPDP standards while others do not. Three are integrating ePA into electronic health records (EHRs). These initiatives are described below:

- CVS Caremark announced an ePA pilot in April 2011, using an opensource ePA process and standard. Scheduled for January 2012, the pilot would integrate the PA request process within ePrescribing and EHR applications with a limited number of ePrescribing vendors, health plans and medications. Results of the pilot are expected to be available toward the end of 2012, and Caremark has committed to take the lessons learned and the transactions themselves to NCPDP. Companies participating in the pilot include Allscripts, Navinet (formerly Prematics) and MedPlus.
- Humana has announced an ePA pilot using the standard created by the 2009 NCPDP task group. Working with Agadia, the Humana pilot is similar to the CVS Caremark pilot, with launch anticipated by the end of 2011. So far, no participating ePrescribing software vendor(s) has been named. Humana has also offered to share findings and lessons learned with the NCPDP task group.



- RelayHealth and CoverMyMeds announced an ePA initiative at the point of care. Unlike other projects, this pilot also looks to address PA requests that occur after a claim rejection, given the assumption claims will still be rejected for some time. This all-payer, all-drug solution should be universally accessible because it relies on the NCPDP ePA standard for content and physician connectivity and the HIPPA-named NCPDP Telecommunications D.0 standard for transport.
- Medco is introducing a slightly different ePA approach whereby an ePA is initiated within the pharmacy after receiving a prescription that requires PA. Using the RxChange and RxStatus functions of the NCPDP SCRIPT standard, the pharmacy would notify the prescriber, who would then need to follow a secure link to a portal where, without having to log in, he or she would answer drug- and patient-specific PA questions. These questions would be sent to Medco, who would provide an immediate response. This model is supported by physician focus groups and allows the company to learn about PA using existing capabilities before building new ones, according to a Medco executive.

Much work remains to be done before we get to an integrated, standards-based ePA process. Pilot tests need to be completed and learnings incorporated into vendor solutions and work flows for pharmacies, providers and payers. An ePA standard needs to be finalized and approved by NCPDP and then adopted by the federal government through the HIPAA process. Until then, the above initiatives and vendor solutions, along with others yet to emerge, promise to be effective interim solutions for alleviating the administrative burden the manual PA process inflicts on plans, providers, pharmacies and patients.

Looking to the Future

While widespread use of standardized ePA at the point of care is still a few years away, there is an immediate need for simplification and standardization of the preauthorization process for physicians and patients. Immediate steps that payers and others should consider to jump-start the process and incorporate improvements from the beginning include:

- Approve and adopt a standard for PA of medications;
- Apply results of pilots to improve both the processes and standards;
- Ensure the PA process can be programmed into the applicable payer, provider and pharmacy systems and work flow;
- Develop technologies that will integrate medical data with transactions to seamlessly and securely transmit patient information and plan criteria more cleanly;



- Develop consistent PA requirements based on nationally recognized health care standard transactions; and
- Standardize the process across payers to ensure that application is consistent across health care.

Longer term, ePA systems will need to link to clinical and demographic data from a prescriber's EHR to eliminate duplicate entry and enable relevant information to be sent electronically for review. Logic based on plan-specific criteria could then be applied to deliver a response to the provider immediately.

Our vision for a long term ePA solution is one that:

- Minimizes the administrative burden on prescribers, pharmacies, plans and patients;
- Integrates with prescribers EHRs and seamlessly abstracts relevant information;
- Ensures that patients get the most appropriate therapy;
- Occurs in real-time to avoid therapy delay or walk away altogether; and
- Works for all medications and all plans.

Conclusion

The current PA process has remained stubbornly fixed over the years. Clearly, PA requirements are increasing and will likely continue to do so, and the burdens that accompany this antiquated process will increase in lockstep with them. In an era of rapid technological change, PA continues to rely on telephones and faxes. With more than 50% of all ambulatory prescribers now prescribing electronically, it is time to address this unique but increasingly important piece of the health care system.

The PA process is ripe for its own evolution. The recent innovations and pilot programs highlighted here indicate that momentum, savings and competitive advantage are to be gained now. Equally important, the efforts invested today can deliver immediate and substantial benefits for all stakeholders while providing a migration path to more integrated, automated and comprehensive solutions that take greater advantage of evolving industry standards.

In short, health plans and PBMs should be seriously considering their ePA strategies and putting those strategies into the market. The benefits to be gained through better member care and satisfaction, increased goodwill with providers and operational efficiency combine to build a business case that dovetails with the industry's increasing willingness to adopt a better solution. That time is now.

