Electronic Prior Authorization and Its Potential Impact on Healthcare

HOW PAPER-BASED PRIOR AUTHORIZATION IMPEDES ELECTRONIC PRESCRIBING

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EXECUTIVE SUMMARY

“One cancer patient needed prior authorization for a cancer drug,” a pharmacist said. “The poor man died before he ever received prior authorization. It took weeks.” ¹

Prior authorization? How can a bureaucratic program keep a patient from receiving his cancer treatment? Unfortunately, it’s a scenario that plays out every day all across the country, from treatment of fibromyalgia to congestive heart failure to almost every medical condition. Several years ago, health plans came up with prior authorization as a cost-saving method for approving medications and diagnostic tests and procedures. Physicians must justify to health plans why the selected drug or procedure is medically necessary for the patient—a process which can take several days and, in the end, may be for nothing as the drug or procedure may be denied regardless of a physician’s request.

What’s the price tag to physicians for dealing with prior authorizations? An estimated $31 billion nationwide per year...or roughly $68,274 average per physician, per year.² And the cost doesn’t stop with physicians. Pharmacists spend an average of 5 hours per week handling prior authorization requests—time which is non-reimbursable and takes away from direct patient care.³ In terms of care, the patient is usually the loser, often waiting days to obtain a needed medication. A nationwide physician survey indicated that more than two-thirds (69%) of physicians typically wait several days to receive preauthorization from an insurer for drugs, while one in ten (10%) wait more than a week—a week in which the patient remains untreated.

Is there a solution to this problem? There’s certainly a way to make the process more efficient and significantly less time consuming, and that would be to transform the antiquated paper-based prior authorization process to an electronic process. While more than 52 percent of today’s office-based prescribers utilize electronic prescribing methods,⁵ most of these prescribers must continue to use the old-fashioned methods for obtaining prior authorization of medications from health plans, causing unnecessary delays for patients.

The current system requires a prescriber to fax or call a request to a health plan or PBM which then reviews the patient’s formulary and benefits, processes the prior authorization request, and faxes or calls a response back to the provider. A prior authorization request is often initiated from the pharmacy after a prescription has been received. In this case, the pharmacy must first contact the physician to start the process. This convoluted paper-based process can take days to complete, resulting in untreated and unhappy patients who sometimes leave the pharmacy and never obtain the medication which was prescribed for them. Additionally, it is particularly difficult for physicians who have migrated to a paper-less practice to keep up with a paper-based prior authorization.

When electronic prescribing first came on the scene, one of its main promising and overarching goals was to improve medical and pharmacy efficiencies. From a physician’s perspective, he or she should have all of the therapeutic options available to treat a particular patient, and the physician should know immediately whether those options are covered under the patient’s plan. Additionally, the physician should know at the point of care—while the patient is right there—if there are copays, and whether any prior authorizations are required.
In addition to improving patient safety, one of the goals of electronic prescribing was to transmit a “clean” prescription to the pharmacy of the patient’s choice—patient is covered, drug is covered and there are no surprises. In order to accomplish this goal, electronic prior authorization, with complete and accurate formulary and benefits information, must be part of the solution. Electronic prior authorization will empower physicians and patients to discuss appropriate treatment at the point of care, allowing the physician to select the medication best suited for treatment while at the same time considering the patient’s cost factors. Therefore, the formulary and benefits information provided by the health plans and PBMs must be patient-specific and must be provided regularly.

With patient-specific information at the point of care, a physician will be able to discuss treatment options with the patient; handle prior authorizations in real-time; and send a clean prescription to the pharmacy with no additional delays and no unknown, cost prohibitive factors for the patient—a scenario which will result in better patient care and better healthcare overall.

This analysis will discuss the issues surrounding e-prescribing and the process to create a workable electronic prior authorization program. As will be revealed in this analysis, public policy recommendations surrounding electronic prescribing and electronic prior authorization should be addressed at the state level either by statute or by regulation.

The Center for Health Transformation (CHT) collaborated with many leaders on this project including those listed on page 17 of this document. We would however like to specifically acknowledge the leadership role of the National Council for Prescription Drug Plans (NCPDP). NCPDP’s leadership in creating electronic solutions for pharmacy is extraordinary. From providing real time solutions which improve patient care to e-prescribing solutions which reduce medication errors, NCPDP has consistently advanced better care at lower costs. As such, CHT invited the President of NCPDP, Lee Ann Stember to author the foreword to this white paper.
FOREWORD

When faced with a barrier to providing needed healthcare for a loved one, the priorities of work, nuances of day-to-day life and the implications of global issues pale in comparison. For over 35 years, NCPDP has been the voice of all constituencies caught in the bureaucratic weeds and inefficiencies of our health care delivery system. From pharmacists to drug manufacturers, insurers, providers and patients—we have worked to streamline and automate costly, cumbersome and paper-based processes that prevent or cause delays in getting patients to treatment and on the road to recovery.

We are pleased to work with the Center for Health Transformation (CHT), an organization that has advocated for and catalyzed change to improve healthcare quality and lower costs. CHT’s collaborative approach and dedication to creating the 21st century intelligent health system align closely with NCPDP’s vision and goals.

The white paper, “Electronic Prior Authorization and Its Potential Impact on Healthcare,” presents a thoughtful and comprehensive view of the real world experience, challenges and need for a standardized electronic solution for prior authorizations, as well as state level policies required to support it. It is a compelling call to action for state legislators to mandate insurers to make formulary and benefit information available to physicians at the point of care to improve patient health outcomes by eliminating common barriers to compliance. Moreover, the white paper underscores the need for industry-wide standardization of electronic prior authorization using NCPDP standards.

The candid commentary by physicians and industry leaders that participated in the development of the white paper will resonate with clinicians, physician office staff, pharmacists and patients caught in the crossfire of a process that, once standardized and implemented — can have a profound and direct impact on improving patient health outcomes and at the same, lowering the cost of care.

Lee Ann Stember,
President, National Council for Prescription Drug Programs (NCPDP)
INTRODUCTION

The last few decades have seen the realization of stunning technological advances in the field of medicine. These advances have created opportunities for healthcare professionals to help patients better manage chronic diseases, live healthier, and improve their quality of life. Cardiovascular surgeons can use robotic arms to assist with heart surgery...patients can download an app and check their blood pressure, have it recorded in their own personal health record and e-mailed to their physician right from their smart phone...the STEM microscope, developed by UCLA physicists, can record neuron activity in real time. Medicine has been on the forefront of progress and change, evolving to better serve patients and healthcare providers.

Even the simple act of prescribing medications has evolved from the traditional pen and script pad to an electronic format where the physician enters the prescription into a tablet, laptop, smart phone, or desktop computer. The electronic health record (EHR) system or free standing e-prescribing program then transmits the prescription to the pharmacy of the patient’s choice...all in real time. A recent study indicates more than 90 percent of patients and providers are very satisfied with the use of electronic prescribing.

And yet, there’s a glitch in this technological procedure which can slow the entire process from real time to an unacceptable two, three or even four days. In some cases, that glitch causes patients to walk away untreated because obtaining the appropriate medication is just too much of a hassle. This glitch is the lack of an electronic prior authorization process. In its simplest form, a prior authorization program is used by a patient’s health plan and requires an additional step before the health plan or PBM will agree to pay for the medication.

Most prior authorization programs still rely on a paper request form sent via fax from the physician to the health plan. And, the process can take up to several days to complete. In instances where the prior authorization results in the health plan refusing to cover the requested drug or charging a copay which the patient cannot afford, the process must start over, with the physician selecting a different drug.

If physicians had immediate access to accurate, patient-specific formulary and benefits information and could prescribe a drug from an approved list, or could request and receive prior authorizations electronically in real time, then the wait for prior approval would be eliminated. Unfortunately, formulary and benefits information—much less patient-specific formulary and benefits information—isn’t always readily accessible and physicians must access a different web portal for each health plan—sometimes multiple portals for the same plan.

Prior authorization programs have been around for more than two decades. But these programs were conceived before e-prescribing and electronic health record (EHR) solutions were created to help decrease medical errors and improve efficiencies. The lack of an electronic solution for prior authorizations impedes the efficiency of the electronic prescribing system.

The Center for Health Transformation (CHT) held a series of stakeholder meetings to gain a better understanding of the prior authorization process and examine policy recommendations which would help the process become more effective in terms of cost and time for prescribers, pharmacists and patients, as well as the respective health plans. Participants in these meetings included local and national physician groups; local and national pharmacy groups; health plans and pharmacy benefit managers (PBMs); state officials; and drug manufacturers.
During those stakeholder meetings, participants discussed the inherent problems with the current paper-based prior authorization systems and brainstormed alternatives. Based on these discussions, this white paper presents the issues and provides several recommendations which sustain a patient-centered model of care focusing on improving patient outcomes without compromising healthcare costs.
ELECTRONIC PRESCRIBING

In 2006, the Institute of Medicine released a report entitled, *Preventing Medication Errors*, as part of its Quality Chasm Series. The report found staggering numbers of medication errors occurred annually in both ambulatory and non-ambulatory settings—1.5 million preventable adverse drug events—and called for changes in every facet of the healthcare delivery system. One such change was a recommendation for all prescribers and pharmacies to utilize electronic prescribing (e-prescribing) by 2010. In 2006, fewer than 10 percent of the nation's physicians used e-prescribing.

While that deadline was overly optimistic, as 2012 finds us still waiting for many prescribers and some pharmacies to embrace electronic platforms, significant progress has been made. According to Surescripts, which provides the nationwide infrastructure for e-prescribing, more than 52 percent of today's office-based prescribers utilize e-prescribing, and almost all pharmacies have the capability.

In terms of the number of prescriptions transmitted electronically, 25 percent of eligible prescriptions were sent electronically in 2010, compared to just 6.6 percent of the 1.57 billion eligible prescriptions in 2008.

Further, a new 2012 study shows that e-prescribing significantly increases the odds of a patient actually picking up a medication at the pharmacy—a consistent 10 percent increase in patient first-fill medication adherence (i.e., new prescriptions that were picked up by the patient) among physicians who adopted e-prescribing technology when compared with physicians who did not use e-prescribing. The savings associated with increased patient adherence was an astonishing $140-$240 billion over ten years.

The federal government also made accelerating e-prescribing a focus over the past few years. In 2003, the Medicare Modernization Act (MMA) required health plans to support e-prescribing in order to participate in the Medicare Part D prescription benefit. And more recently, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

MIPPA provides a Medicare e-prescribing incentive program for physicians, clinics, and hospitals using the advanced technology tool. The HITECH Act designates e-prescribing as an essential requirement for meaningful use under the electronic health record (EHR) incentive programs.

NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS (NCPDP)

The National Council for Prescription Drug Programs (NCPDP) is the national standards setting organization for virtually every sector of the pharmacy services industry. NCPDP was founded in 1977 as the extension of a Drug Ad Hoc Committee that made recommendations for the US National Drug Code (NDC). NCPDP is a not-for-profit, ANSI-accredited, standards development organization with over 1700 members. The diverse membership provides leadership and healthcare business solutions through education and standards, created using a consensus-building process. NCPDP has been named in US
federal legislation and regulation, including Health Insurance Portability and Accountability Act (HIPAA), the Medicare Prescription Drug, Improvement, and Modernization Act, and HITECH.

NCPDP has been involved with the development of standards in the pharmacy benefit arena for several decades and has been instrumental in the transition of manual, paper processes to more efficient electronic transactions from start to finish in the life of a prescription. These efforts also include the organization’s focus on electronic prescribing for the past 15 years. NCPDP’s visionary leadership on e-prescribing cannot and should not be understated. Without NCPDP, there would be no electronic prescribing.

THE ORIGIN OF THE FORMULARY

Health plans have long used formularies as a cost containment mechanism and as a way to enhance revenues through prescription drug rebates from manufacturers. Sometimes formularies are called preferred drug lists. Typically, there are three types of formularies: “open” where most all medications are covered; “incented” where patients pay lower copayments for preferred products; and “closed” which have limited medications within each therapeutic class.

Most health plans have moved away from both the open and closed formulary models and are using the incented model which deploys multiple tiers. Each tier typically represents an increase in the patient’s out of pocket expense or copayment. For example, under a three-tiered copayment incented formulary, generic drugs would have a relatively low monthly copayment (e.g. $10). A preferred brand name product would carry a moderate copayment (e.g. $25) while a non-preferred brand name drug would carry the highest copayment (e.g. $50-$100). In addition to multiple tiers, health plans also require prior authorization of certain medications.

There are hundreds, if not thousands, of formularies which health plans administer on behalf of plan sponsors (usually employers). It’s virtually impossible for physicians to know which medications are covered by all of the various plans accepted by their practices.

WHAT IS PRIOR AUTHORIZATION?

While the progress in e-prescribing is good, a number of challenges have surfaced, one of which is the lack of electronic means to process prior authorizations (PA), which can negate the benefits of e-prescribing entirely.

Prior authorization is the process by which a health plan restricts the availability of certain medications by plan members or patients. The process is purported to reduce costs and ensure the medical necessity of certain selected prescription medications. Health plans usually have formularies and any medication not on the formulary may be denied or require PA from the health plan. Sometimes, the approval may come in the form of steps. For example, health plans may require physicians and patients to try a less
expensive drug first, and if it proves to be ineffective or is not tolerated well by the patient then switch to the originally requested drug. In some instances, the prior authorization may be clinically based, but more often the process is used as a cost containment method.

Health plans implement prior authorizations for a variety of reasons, including:

- Brand name medicines with generic equivalents.
- Expensive medicines, including specialty medications.
- Medicines with age limits, e.g. Retin-A®. Acne is considered to be a condition of children and young adults.
- Drugs used for cosmetic reasons. For example, Propecia®, which is prescribed to re-grow hair or to prevent hair loss.
- Lifestyle drugs e.g. Viagra® and Cialis®.
- Drugs not usually covered by the health plan or PBM, but said to be medically necessary by the doctor. Many different drugs can be used to treat the same condition.
- Drugs that are covered by the health plan or PBM but are being prescribed in higher than "normal" dose.
- Off-label usage.

Almost all prior authorization programs are paper-based. Often, physicians have no idea if a medication is on the preferred drug list or requires PA because physicians usually don’t have access to a patient’s formulary. And, to further complicate matters, each health plan may have its own set of PA criteria which can vary by drug, indication, gender and other factors.

While healthcare as a whole is migrating toward the use of technology, paper-based prior authorization programs can make all of the technological efficiencies evaporate. Delays in starting necessary medication therapy caused by slow, non-integrated, 20th century paper-based prior authorization programs do not advance better patient care.

**HOW PRIOR AUTHORIZATIONS HAPPEN**

In the traditional paper-based medical practice, physicians actually still “write” prescriptions for their patients. Patients then take the written prescription to the pharmacy, where medications which are either not covered or those requiring a prior authorization are often discovered.

If the medication is not covered or requires a prior authorization, the pharmacist must contact the physician who then selects a different therapy or contacts the health plan to begin the prior authorization process. In most cases, the physician completes and faxes a form to the health plan. Once the health plan receives the form, its PA staff must sort through the information provided. More often than not, important or mandatory information is omitted. Other times, information provided must be clarified. One plan estimates that 80 percent of prior authorization requests require follow up. While the process is time consuming, a more serious concern is the delay inherent in the PA program, which results in prescriptions being abandoned nearly 40 percent of the time.
Prescribing systems use the NCPDP Formulary and Benefit Standard to obtain files from health plans and PBMs with benefit and formulary information. EHRs check the F&B files for medications that require PA. Most EHR systems use a “warning” mechanism embedded within the EHR’s e-prescribing program for medications which require a PA or are in an upper copayment tier for the health plan. For example, Allscripts, a large EHR vendor, issues a mobile e-prescribing application for subscribing physicians for use on their smart phone. This mobile app uses colors and faces to help physicians with prescribing options. In this example, a medication with a low copayment would be represented by a green smiling face while a red frowning face may represent medications which were either not covered, required a prior authorization or had higher copayment ($50-$100). There is a degree of subjectivity as to how EHR vendors represent medications which may or may not require additional consideration by physicians and their patients.

Some health plans use a generic prior authorization request form, which usually requires basic information, i.e., demographics, diagnosis, medical history—information which is readily available from the electronic health record and can auto-populate the request form. These generic forms do not share any criteria or specific drug information with relation to the patient’s formulary and benefits and often result in additional communication between the physician, health plan, pharmacy and patient.

Other health plans utilize prior authorization request forms that are specific to the medication or drug class and are organized by therapeutic area. These forms may require information relating to lab values, medical history, and other relevant criteria. These forms may include guidelines for approval of a medication.

There is no standard among health plans for creating prior authorization guidelines or criteria, and the information is usually not apparent to the prescriber. However, several states have proposed legislation to assist in the prior authorization process, and the State of California enacted legislation which creates a standardized prior authorization form for health plans operating in that state.

**ISSUES WITH THE PAPER-BASED SYSTEM**

The number of prior authorizations has increased nearly six-fold from 2005 to 2011, which can be attributed to a variety of factors, including advances in medication therapy management, biotechnology, designer drugs, specialty pharmacy, and the cost of pharmacy benefit management. If the prior authorization for a requested medication is denied, the patient has additional options:

1. Pay for the medication out of pocket.
2. Appeal the denial.
3. Abandon the medication.

Pharmacists spend an average of five hours per week dealing with prior authorization requests.
None of these options provide the best healthcare for the patient. For many patients, paying for the medication out of pocket or with a higher copayment is often an impossible alternative. And while most health plans have an appeal mechanism, the process is often cumbersome and results in yet more delays for treatment of the patient. A popular alternative among patients is simply to walk away untreated. For various reasons, including time, transportation and cost, the abandonment rate for medications requiring prior authorization is reported to be nearly 40 percent.\(^\text{20}\)

Not only are patients sorely affected by the current PA process, but also pharmacists and physicians, who front the cost of staff to administer the program. The impact on pharmacists is severe: a recent *Drug Topics* survey showed that on average, pharmacists spend almost five hours a week dealing with prior authorization requests.\(^\text{21}\) Nearly four out of five pharmacists surveyed said that prior authorization requests are consuming more and more of their time—time which could otherwise be spent providing direct patient care. For pharmacists and physicians, the time is non-reimbursable—meaning that, although they must pay staff to handle the PA requests, there is no option to bill the health plan for this time.

A particularly disturbing finding of the *Drug Topics* survey was that nearly three of five responding pharmacists (61 percent) knew of an incident when the requirement for prior authorization adversely affected patient care. “One cancer patient needed prior authorization for a cancer drug,” a respondent said. “The poor man died before he ever received prior authorization. It took weeks.”

Another respondent said, “It [PA] adds unwanted and unneeded stress to people who are being released from the hospital after life-altering procedures, such as a patient whose medications are not covered after a kidney transplant, or a heart attack patient who requires injectable anti-thrombotic medicine.”

Further, the process alienates patients and causes tension between patients and pharmacy staff. More than half of the survey respondents said that several times a day they have patients who become upset due to prior authorization-related delays.\(^\text{22}\)

Physicians are also frustrated with the current lack of standardization of electronic prior authorizations, and with the prior authorization process as a whole. James R. Morrow, M.D., a family practice physician in Cumming, Georgia, has first-hand knowledge of an instance in which the prior authorization process adversely affected one of his patients. “I saw a patient a few weeks ago and prescribed Provigil\textsuperscript{®} for excessive daytime sleepiness, sort of like shift-fatigue from a shift worker. The patient had a severe problem, going to sleep driving, etc. I transmitted the script and did not know until several weeks later that the patient never got the medication. He came in for an unrelated issue and mentioned that he couldn’t get it because the insurance company would not cover it. The patient didn’t pursue it and had been having a lot of trouble. He could kill himself or someone else driving sleepy.”
Dr. Morrow operates his practice on the cutting edge of technology, utilizing electronic prescribing 99 percent of the time. He says if the ability to circumvent the paper process were available, he would be able to provide better and more efficient care to his patients. “If there is ever a medication I know of that is cheaper and easier and will do the same thing, I will use it. I just need to know and I need to know while the patient is here (in my office) so I can discuss it with them.”

Michael E. Greene, M.D., family practitioner in Macon, Georgia, says he won’t use the health plans’ web portals. “I don’t prescribe medications or treat patients based on what an insurance company says they need.” Dr. Greene believes prior authorizations should be eliminated altogether; barring that scenario, at the very least, health plans should be transparent with patients and explain why a drug is being denied and whether the denial is based on price rather than the best interests of the patient’s health.

When discussing electronic prior authorization, Daniel A. Wujek, M.D., of Litchfield Family Practice Center in Litchfield, Illinois, says the current paper-based method is a major drain on their resources. “We currently have one full time staff member whose sole responsibility is to manage getting prior authorizations. The ability to quickly obtain an authorization while a patient was in the office would be outstanding. We frequently run into this road block when trying to prescribe a drug or to schedule procedures or diagnostic tests, such as CT scans or MRIs. I believe that more patients would keep their appointments for these procedures if we were able to manage prior authorizations in an efficient method during their office visit. With electronic authorizations, we would also run into less of the invariable problems related to human error. It is not infrequent to have our staff call for a PA, get this cleared, then get a call back later that a procedure wasn’t covered because no PA could be found.”

The time spent on dealing with paper-based prior authorization programs seems to be one of the biggest frustrations for physicians’ offices. Matthew C. Winkleman, M.D., a family practice physician in Harrisburg, Illinois, says he has a staff member who spends 2-3 hours every day just working on prior authorizations. “She tries to do this primarily in the early morning hours to avoid times when phone traffic is high volume. One of her biggest frustrations is the time involved in waiting to speak to someone and then the time often waiting for the appropriate forms to be sent as well as to hear a decision—often at the same time dealing with a patient who is frustrated with the delay and directing that blame on our office.”

**A BETTER WAY**

While some health plans do post formulary and benefits information on their websites, medical office workflow issues present a whole host of other considerations for physicians working on electronic platforms with either an electronic health record (EHR) system or free standing electronic prescribing (e-prescribing) program. Physician practices need access to health plan and patient-specific formulary and benefits information just like every pharmacy currently does...at the point of care where the physician and the patient make prescribing decisions—without having to navigate through multiple platforms. Should the physician select a medication clearly marked as requiring prior approval, the physician would be able to click a few buttons to delineate why that particular drug was requested and receive immediate feedback...
from the health plan. The physician could then have a discussion with the patient regarding copay or cost of the medication, thus preempting possible medication abandonment and saving time for the physician’s staff, pharmacy staff and the patient.

Electronic prior authorization solutions are already in place in several state Medicaid plans. Kansas implemented an electronic prior authorization program for its Medicaid program and estimates are that savings will reach $1.5 million in its first year of operation.23

NCPDP has developed a draft standard for electronic prior authorization (ePA) which is currently being utilized and tested in several national pilot projects. One consideration of the task group is the flow of data from provider to health plan and embracing clinical workflow by having PA criteria automated to prevent duplicative entry. NCPDP is continuing to revise the standard through a working task group and anticipates completion by then end of 2012.

“We need a standard that covers all the gaps,” said John S. Klimek, R.Ph., NCPDP Senior Vice President, Industry Information Technology. “We need to be able to process electronic prior authorizations at the physician level and the pharmacy level. A national standard is needed to ensure there are not multiple methods of processing prior authorizations, a situation which would only increase the level of frustration among physicians and pharmacists.”

And, Mr. Klimek cautions, even if standards are finalized and adopted by the end of 2012, it will take another 12-18 months for full implementation due to all the necessary steps involved in the process.

Meanwhile, other entities are also making efforts to streamline the prior authorization process. CVS Caremark is launching a pilot program of a real-time, integrated electronic prior authorization capability, a step in the direction of helping develop a technical standard for industry use.

The CVS Caremark ePA pilot aims to enable prescribers that use a variety of available e-prescribing and EHR tools to coordinate a real-time ePA request when initiating a prescription for a patient. Prescribers will also have the option to access the process through a client portal. The prescriber will be able to send an ePA request detailing the coverage criteria related to a prior authorization request and receive a real-time status update regarding an approval for the medication. Requests that are denied will be communicated following manual review by clinical staff.24

“CVS Caremark understands the opportunities that innovations such as electronic prior authorization provide to prescribers and patients looking to embrace a more efficient and effective way to share critical prescribing information,” said Troyen A. Brennan, M.D., M.P.H., chief medical officer of CVS Caremark. “The prior authorization process is currently evolving to keep pace as prescribers transition toward electronic prescribing and electronic patient records to better manage their patients’ pharmacy care. This pilot is an important step toward demonstrating how the industry can integrate ePA with e-prescribing to streamline and speed up processing of prior authorizations to ensure that members have quick access to care that is medically appropriate and cost-effective.”

Surescripts is participating in the CVS Caremark-led ePA pilot to monitor and understand how what is learned can be applied to the industry. NaviNet, through its NaviNet Mobile Connect platform, will be participating in the ePA pilot as well as Allscripts, whose client base includes all former users of CVS Caremark’s proprietary iScribe e-prescribing tool, which was transitioned to the Allscripts ePrescribe solution in 2010. MedPlus has indicated its intent to deliver ePA functionality in a future release of their
tool. Additional vendors have expressed their intent to deliver ePA functionality in future product releases upon the successful completion of this pilot.

CVS Caremark believes the ePA pilot transactions will help assist in the development of standards that will be able to be used by any e-prescribing vendor. The company intends to share both the transactions and the results from the implementation with the market and the appropriate ANSI-accredited standards organizations to help drive the adoption of ePA standards by payer and provider systems.

**STATE-BASED POLICY SOLUTIONS**

While NCPDP has established a national mechanism to address e-prescribing, patient eligibility, formulary and benefits information and e-prior authorization through the adoption of standards, states are the most logical public policy route. Since state governments regulate insurance products including health insurers, health plans and PBMs, and since states also license and regulate physicians, pharmacists and hospitals, it seems most appropriate for states to address the broad public policy issues of formulary transparency and electronic prior authorization.

For example, while it is not an electronic solution, the State of California passed legislation in 2011 mandating that health plans and PBMs use a standardized prior authorization “form.”25 The State of North Dakota passed legislation requiring health plans and PBMs to create electronic solutions for prior authorization by August 1, 2013.26

It should be noted that if and when state legislatures or insurance departments address formulary transparency and electronic prior authorization, most states actually cite the NCPDP e-prior authorization standard.27,28 From a rational public policy perspective, states should specifically require compliance with the most current national standard adopted by NCPDP.

In most states, the Office of Insurance Commissioner regulates health insurance, benefits and coverage, plan administration and other state mandated provisions.29 Since health plans and PBMs are often licensed by and subject to the Insurance Commissioner, state legislatures would need to direct the Insurance Commissioner to require health plans to be transparent in providing their prescription drug formulary and benefits for e-prescribing by physicians and other clinicians. Such transparency would empower the clinician with the knowledge about formulary and benefits issues like prior authorization and co-payment issues. Finally, state lawmakers would need to require compliance with the battle-tested, market-ready NCPDP standard for electronic prior authorization.

Using this analysis and other available resources, the Center for Health Transformation makes the following policy recommendations and urges their adoption.
Formulary and Benefits Transparency

There are two separate and distinct policy considerations. The first focuses on formulary and benefits accuracy and transparency. There is little doubt that patient-specific formulary and benefits information should be available to physicians at the point of care. It is in the best interests of all concerned—the patient, the physician (or other prescriber), the pharmacy and pharmacist and the health plan (or PBM)—when patient-specific, accurate formulary and benefits information is readily accessible and embedded in the electronic health record (EHR) system. Having that information better positions the physician to have a conversation with the patient about various therapeutic options.

Having access to patient-specific formularies at the point of care also helps health plans drive clinical and cost effectiveness information to the prescribing practitioner. Formulary and benefits compliance is a huge consideration for health plans as utilization is often determined by the size of the rebate which the plan sponsor, health plan or PBM garners from pharmaceutical manufacturers. Decisions regarding concerns about prior authorization requests or tiered copayments should occur at the point of care.

More formulary and benefits information at the point of care is better than less formulary information. More conversations about prescription drug therapy options are better than fewer conversations. Having access to patient-specific formulary information helps clinicians make better prescribing decisions which in turn leads to better patient outcomes.

The recommendation from CHT is that health plans and PBMs should publish and make available patient-specific formularies to EHR vendors for integration with practitioners' electronic systems. However, getting health plans and PBMs to provide patient-specific formulary information is only part of the solution. To ensure compliance, EHR vendors must routinely push patient-specific formulary information to physicians via their EHR solution.

Such a policy would ensure that physicians and other prescribers were making informed decisions about the most appropriate prescription drug therapy. Since NCPDP’s nationally-adopted Formulary and Benefit (F&B) standard is readily available and in widespread use, health plans can easily provide patient-specific formulary information to physicians at the point of care.

Electronic Prior Authorization

The second policy recommendation focuses around creating electronic solutions for prior authorization requests. While prior authorization programs for prescription medications are not new or novel, they were conceived and deployed when physicians actually wrote a prescription drug order on a piece of paper. Electronic prescribing has changed everything. Workflow patterns have changed. The way in which physicians document a patient’s symptoms and keep track of treatment therapy choices has been transformed away from paper and into an electronic platform.
Creating an electronic solution for prescription drug prior authorization for those physicians using e-prescribing for their patients is the best solution. Such solutions could take many forms:

- **Integrated model**: An integrated model would embed all e-prescribing technology, including an electronic prior authorization process, into the EHR and e-prescribing systems. The prior authorization request would self-populate with patient-specific, clinical data directly from the EHR. The request and approval would be documented in the EHR, all in real time. Physicians would know at the point of care whether a drug was covered, the copayment levels and if a prior authorization was required. A “clean” prescription would be transmitted at the point of care with the patient better informed about their therapy including any out-of-pocket costs for the patient.

- **Payer Specific Portal model**: This model would have each health plan or PBM create its own electronic solution for the prior authorization process. Several electronic prior authorization programs are operational using a plan/PBM-specific web-based portal.

- **Multi-Payer Portal model**: This model would create a central clearinghouse for the electronic processing of prior authorization requests from multiple payers. Several large health plans would participate using the same or virtually the same clinical criteria.

- **Third Party Administered model**: This model uses a so-called “trusted” third party administered prior authorization program. Several of the current third party models in the market do not provide processing in real time, a significant disadvantage in an electronic world.

Regardless of the model utilized, standardization is the key to effectiveness. NCPDP, the recognized leader in standardization for the pharmacy services industry, is working to create a set of standards for electronic prior authorization that will facilitate the process efficiently from a time and cost perspective. To eliminate confusion and reduce complications in the prior authorization process, CHT recommends that any electronic solution incorporate the finalized version of NCPDP standards. The standards should automate the functions related to completing and transmitting the prior authorization and should support and promote clinical workflow and not create unnecessary barriers.

**CONCLUSION**

When e-prescribing was originally formed as a concept, physicians would theoretically transmit “clean” prescriptions to the pharmacy—meaning the patient’s eligibility was confirmed, the coverage for the drug and dose were confirmed, and any copayment or prior authorization issues were resolved. Unfortunately, the lack of formulary transparency and the lack of a standardized electronic solution for prior authorizations has made the transmission of a clean prescription an impossibility much of the time, which reduces the effectiveness and efficiencies of an e-prescribing system.

Combining formulary transparency and an efficient, standardized solution for prior authorizations will improve communications between doctor and patient; will increase time efficiency in both the physician’s office and the pharmacy; will drastically decrease the number of abandoned prescriptions; will assist health plans in formulary management—and by accomplishing all of these goals, will consequently result in improved healthcare overall.
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ADDENDUM A

A Perspective of the Stakeholders

Physicians: For those medical practices which have implemented health information technology programs including e-prescribing, physicians are frustrated by the lack of formulary information in their electronic health record systems. Additionally, physicians who use EHRs or free-standing e-prescribing programs do not understand why there are not appropriate electronic solutions for prior authorization of prescription medications.

Currently, there are very few electronic prior authorization programs. Physicians and medical practices must invest heavily in terms of staff time and effort. Medical practices must needlessly employ multiple full-time employees to file, process and document the paper-based prior authorization process. As such, physicians—particularly those utilizing electronic platforms—would support solutions which focus on increasing patient-specific formulary transparency and creating electronic prior authorization solutions which integrate the clinical workflow process.

Pharmacists: Community pharmacies have long relied on computers and electronic systems to improve efficiencies, reduce medication errors, advance patient care and facilitate patient counseling by pharmacists. Traditionally, pharmacists have shouldered the administrative burden of formulary compliance. Whether it is calling a physician to change a prescription because the prescribed drug was not covered by a health plan or notifying a physician of the requirement of a prior authorization, pharmacies are the place where the prescribing process grinds to a halt. Electronic prescribing offered the hope of “clean” prescriptions. However, because of the lack of transparency of formulary information and the proliferation of the use of prior authorization, pharmacists have become increasingly frustrated with the process. Additionally, while pharmacy reimbursement rates continue to decrease, the administrative burden on pharmacies and pharmacists has increased to an average of five hours per week. Therefore, pharmacists would support solutions which allow physicians to see formulary issues at the point of care and create electronic prior authorization solutions.

Patients: Patients have become increasingly frustrated with perceived administrative hassles which result in the delay of therapy. Most patients do not even know of the existence of formularies until the prescription is presented or transmitted to the pharmacy. Many patients and most physicians wonder why health plans and PBMs still utilize prior authorization programs when well over 90% of all prior authorization requests are granted. However, patients and caregivers are more concerned about starting the most appropriate, most effective prescription drug therapy in a timely manner. Delays in starting prescription drug therapy are costly and can result in higher healthcare costs. Creating electronic solutions for prior authorizations for physicians utilizing EHR systems would ease many of patients’ frustrations.

NCPDP: The National Council of Prescription Drug Programs (NCPDP) is the national standards setting organization for the pharmacy services industry. NCPDP was founded in 1977 as the extension of a Drug Ad Hoc Committee that made recommendations for the US National Drug Code (NDC). NCPDP is a not-for-profit, ANSI-accredited, standards development organization with over 1500 members representing virtually every sector of the pharmacy services industry. The diverse membership provides leadership and healthcare business solutions through education and standards, created using a consensus-building process. NCPDP has been named in US federal legislation and regulation, including Health Insurance Portability and Accountability Act (HIPAA) and the Medicare Prescription Drug, Improvement, and Modernization Act. NCPDP members have created standards such as the Telecommunication Standard
and Batch Standard for the processing of pharmacy claims electronically, the SCRIPT Standard for e-prescribing, and the Manufacturers’ Rebate Standard. It is important to note that NCPDP and its members have already adopted a national standard for electronic prior authorization. That standard is currently being utilized, deployed and tested in several national pilot projects which were just launched in January 2012. NCPDP supports the creation of electronic prior authorization when physicians use e-prescribing technology solutions.

**Health Plans and PBMs:** Health plans and pharmacy benefit managers (PBMs) have historically used formularies as a cost containment mechanism and to drive formulary compliance. Additionally, health plans use prior authorization programs to help increase revenues from pharmaceutical manufacturer rebate programs. There is a place for prior authorization programs in ensuring medical appropriateness and clinical efficacy. However, paper-based prior authorization programs are expensive to manage and operate. Medco, CVS-Caremark, and Humana are all participating in pilot programs which feature electronic prior authorization solutions. NCPDP has led a national effort which resulted in the adoption of a national standard which creates an electronic process for prior authorization programs. Health plans and PBMs are not opposed to electronic prior authorization programs, but rather they are dealing with a whole series of other priorities including administering and implementing federal health reform. Crafted correctly, electronic prior authorization programs would be a windfall for health plans and PBMs.

**Electronic Health Record (EHR) Vendors:** The EHR vendor community strongly supports the migration of physicians and other healthcare providers to electronic platforms. Barriers, including traditional, paper-based prior authorization programs, make it more difficult for physicians and other clinicians to effectively and efficiently utilize advanced technology solutions. Physicians and health systems spend tens of thousands of dollars with EHR vendors each year on new installations and maintenance fees. Electronic prior authorization solutions should be developed which utilize data interchange captured from the patient’s electronic health record. Therefore, EHR vendors should support measures such as the creation of electronic prior authorization programs for pharmacy and medical services aimed at making electronic health record systems operate appropriately.

**Pharmaceutical Manufacturers:** Pharmaceutical manufacturers have historically supported physicians who utilize EHR and e-prescribing systems. These systems have helped physicians better manage their practices, improved patient safety, increased patient adherence and created mechanisms to track healthcare quality metrics. However, manufacturers have opposed prior authorization programs, largely because of the perception that such programs are based exclusively on the cost of the medication. As indicated earlier, pharmaceutical manufacturers understand that there may be a place for prior authorization programs in ensuring clinical appropriateness. The pharmaceutical industry would support improving the prior authorization process by creating electronic solutions for physicians and other prescribers.
ADDENDUM B

Definitions of Key Terms and Concepts

FORMULARY: A preferred list of drug products that typically limits the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement. A government body, third-party insurer or health plan, or an institution may compile a formulary. Some institutions or health plans develop closed (i.e. restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have no restrictions (open formulary) or may have certain restrictions such as higher patient cost-sharing requirements for off-formulary drugs.

POINT OF CARE: Patient is in physician’s office and physician has opportunity to discuss treatment options with patient.

POINT OF SALE: Prescription is being processed in the pharmacy.

PHYSICIAN: In this white paper, we use the term “physician” to describe the healthcare professional who is authorized to prescribe medication for patients.

ELECTRONIC HEALTH RECORD: An electronic health record is a long-term aggregate of a patient’s health information and may be a record of a variety of providers and types of medical care. This record is sometimes confused with an electronic medical record, which is a record of a patient’s health maintained by a physician as a record primarily of the physician’s care of the patient.

ELECTRONIC MEDICAL RECORD: An electronic medical record is a record of patient health maintained by the patient’s physician as a record of that physician’s care of the patient. This record is often confused with an electronic health record, which is a more comprehensive, long-term aggregate of a patient’s health information and may be a record of a variety of providers and types of medical care.

ELECTRONIC PRIOR AUTHORIZATION: ePA or EPA. Electronic means of requesting approval from a health plan for a medication that is designated as requiring prior authorization before it will be covered by the health plan.

E-PRESCRIBING: electronic means to generate prescriptions through an automated data-entry process utilizing e-prescribing software and a transmission network which links to participating pharmacies.

ERISA (EMPLOYEE RETIREMENT INCOME SECURITY ACT): The Employee Retirement Income Security Act is a Federal law that sets minimum standards for pension plans and self-insured health plans in private industry.

PHARMACY BENEFIT MANAGER (PBM): An organization that provides administrative services in processing and analyzing prescription claims for pharmacy benefit and coverage programs. PBM services can include contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. PBMs are expected to play a key role in managing pharmacy benefit plans in the Medicare drug program.
END NOTE CITATIONS

1 “Survey shows, on average, 4.6 hours per week are spent channeling the approval process,” August 11, 2008. Martin Sipkoff. http://bit.ly/z6Fug0


3 “Survey shows, on average, 4.6 hours per week are spent channeling the approval process,” August 11, 2008. Martin Sipkoff. http://bit.ly/z6Fug0


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