

Electronic Prior Authorization (ePA): Technology Advances and Emerging Legislative Requirements

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Activity Overview

Prior authorization (PA) is a requirement that affects 186 million prescriptions per year¹. The process was implemented to provide the most appropriate and cost-effective health care services. It is prominent in community, specialty, Long Term Care (LTC), mail order and hospital pharmacy settings. The traditional PA process is complex and burdensome to health care providers and can delay or prevent patients from getting the medications they need. The newly-adopted electronic prior authorization (ePA) standard reduces the burden of the traditional paper or phone-based PA process, improves first-fills, patient adherence and therapeutic outcomes, and prevents prescription abandonment. Electronic prior authorization can provide real-time submissions and determinations, dramatically improving patient access to needed medications.

Learning Objectives for Pharmacists and Pharmacy Technicians

Upon completion of this activity, the pharmacist should be able to:

- Describe the end-to end prior authorization workflow
- Explain the electronic process for medication prior authorization
- State current industry ePA standards
- Recall state legislation effecting prior authorization
- Explain the prior authorization workflow to patients or caregivers

Upon completion of this activity, the pharmacy technician should be able to:

- Describe the prior authorization workflow
- Explain the electronic process for medication prior authorization
- State current industry ePA standards
- Describe the role health care providers play in electronic prior authorization
- Recall state legislation effecting prior authorization
- Explain the pharmacist or pharmacy technician's role in the prior authorization process and communicate this to patients or caregivers

Intended Audience

Pharmacists and pharmacy technicians in all practice settings that handle prescription drug prior authorizations.

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The authors of this article are employed by CoverMyMeds, a company that provides electronic prior authorization solutions to pharmacies, physicians and payers.

Prior Authorization Overview

Prior authorization is the formulary management process of requiring pre-approval for certain medications. Pharmacy Benefits Managers (PBMs) typically enforce prior authorization rules through a claim rejection at the pharmacy. Until the PA process is completed, the patient's insurance will not cover the cost of prescribed medication. While a patient is able to pay out of pocket for the medication, that may be cost prohibitive depending on the therapy prescribed. The purpose for PA from an insurance plan or PBM perspective is to improve patient safety and contain costs. Prior authorization is generally utilized when the payer wishes to conduct a medical review to ensure the prescribed medication is appropriate and medically necessary.

The PA process normally begins in the pharmacy. When a rejected claim comes through, the pharmacist is alerted that a PA is needed and must notify the prescriber, typically via phone or fax. In many instances, the pharmacy can begin the PA by completing a form provided by the individual health plan and have the prescriber complete required clinical information. The physician and pharmacy is then notified of a determination after the health plan or PBM has made their clinical decision. After the determination has been made and a claim effectuated (in the case of an approval), the patient is able to receive their prescription with coverage from the insurance.

Health plans and PBMs implement PA for the following reasons:

- **Prior Authorization (PA).** The plan requires documentation of medical necessity before medication coverage. For a traditional PA, the plan has specific clinical criteria, which includes conditions under which the medication may be covered.
- **Quantity Limits (QL).** The plan provides coverage of a maximum dosage of medication per set period of time. Doses prescribed above this limit require documentation and rationale of medical necessity.
- **Step Therapy (ST).** The plan provides coverage of a medication only after receiving documentation that a patient has tried and failed one or more preferred alternative medications in a certain therapeutic class (or that those formulary alternatives are contraindicated or otherwise inappropriate for the patient).
- **Closed Formulary or Formulary Exception (FE).** The plan's benefit design does not provide certain medication coverage and requires the patient to obtain a prescription for a formulary alternative. FE requests can also apply to formulary medications where the prescriber feels that other utilization management criteria (such as PA, QL or ST) should not apply based on clinical documentation and rationale.² In contrast to a traditional PA, the plan may not have specific coverage criteria for the medication, but may still provide coverage after receiving documentation of medical necessity.
- **Copay or Tier Exceptions (TE).** The plan design may offer different levels or tiers of copayment or pricing for prescription drugs based on the cost of the medication. A tier exception request is when the provider or patient is requesting that a higher tier medication be charged at a lower tier price. Tier exceptions require documentation or rationale as to why preferred or lower tier products are not effective or are contraindicated.

Common examples/rationale for PA requirements:

- High-cost (often specialty) medications

- Medications which have less expensive, formulary alternatives, or when there are many comparable products on the market
- Off-label dosing and indications
- Brand name medications with generic equivalents
- Lifestyle medications (e.g., weight loss, cosmetic, erectile dysfunction)
- Ensure the correct insurance is being billed (e.g., Medicare Part B Vs D)

Traditional Prior Authorization Background and Process

Historically, the PA process has been a manual, non-standardized, and costly process for pharmacies and physicians. The annual cost of navigating the PA process for health care providers in the U.S. is estimated at \$31 billion.³ Most of the cost stems from system inefficiencies due to the fact that plans, prescribers and pharmacies must all communicate with each other, often via telephone or fax to resolve the PA. It has been reported that prescribers' offices spend an average of 20 hours per week working on PA activities, and pharmacists spend an average of five hours per week.¹ Patients are frequently left out of the process, unable to start their newly-prescribed medication and are vulnerable to prescription abandonment. Many plans have streamlined their PA processes with plan-specific web portals for submission, but this solution also has limitations. Each plan would have their own unique process, web portal, username and password which could cause significant inefficiencies or confusion for the provider.

Pharmacy PA Workflow

When a pharmacy receives a PA-related claim rejection, pharmacy staff typically notify the prescribing physician via fax or a phone call. If the physician believes the prescribed drug is the best option for the patient, their office will call the patient's health plan to request a PA via phone, or request that the correct PA form be sent to the office, which happens typically via fax for completion. Otherwise, a covered formulary alternative may be prescribed.

Prescriber PA Workflow

Delays in the PA process can begin even before the prescriber's office becomes involved: paperwork backlog, other administrative tasks and sporadic voicemail and fax machine review can slow the process. Once the prescriber's office receives a PA form from the plan, the office must manually complete and fax the form to the plan. Physician's offices often keep a collection of previously used prior authorization forms on hand to submit to the plan — this "recycling" method prevents an initial phone call, but can result in a PA denial or request for additional information if the form is outdated.

Plan PA Workflow

Once the prescriber faxes a PA request, the manual process continues at the health plan. Faxed forms must be manually entered into the plan's PA system. After data entry is complete, pharmacists, technicians and medical directors manually review the PA request to determine if a clinical determination can be made based on the information submitted. Incomplete or illegible forms often result in delays because the plan must contact the prescriber's office for more complete medical details.

In a national survey, over two-thirds of physicians had to wait several days to receive a PA determination from their patient's insurance company, while 10 percent waited more than a week.⁴ Interrupting or delaying the start of medication therapy can decrease patient adherence and lead to therapeutic abandonment, which negatively impacts a patient's overall health. An estimated 110 million prescriptions are abandoned at U.S. pharmacies annually, and on more than half of those occasions the patient did not fill an alternate prescription.⁵ Prior authorization is an important tool for managing prescription drug costs and patient safety; however, the administrative burden it places on health care providers has serious adverse effects. Streamlining the PA process is essential for improved health care quality and reduced system costs.

Consequences of medication abandonment can include:

- Disease progression
- Additional diagnoses
- Uncontrolled vital signs
- Abnormal laboratory values
- Reduced adherence to other medications
- Poor therapeutic outcomes
- Avoidable deterioration in health^{5,6}

Introducing Electronic Prior Authorization (ePA)

The National Council for Prescription Drug Programs (NCPDP) is a trade association responsible for the development and implementation of pharmacy transaction standards.⁷ Since 1977, NCPDP has set the industry standards that govern the electronic adjudication of prescription drug claims. In 2013, NCPDP released the SCRIPT Standard to include ePA to make the PA process more efficient. This new ePA standard helps streamline the PA workflow and is analogous to the electronic prescribing standard. It provides real-time PA submission, review, and approval, allowing health care providers to submit PA requests in a faster and simpler way.

Describing ePA requires some background on electronic prescribing (E-Prescribing), which allows electronic routing of the prescription to the pharmacy without use of email, phone or fax transmission. Electronic prescribing supports efforts to improve the standard of care, increase administrative efficiency and ensure the security of protected health information (PHI). Congress recently supported E-Prescribing by encouraging its use in two major laws:

- Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)
- Health Information Technology for Economic and Clinical Health (HITECH)

MIPPA offers an incentive program for eligible prescribers who are actively using E-Prescribing. Eligible professionals who did not become successful E-Prescribers by the end of 2012, or did not successfully submit at least 10 electronic prescriptions during the first six months of 2013, faced a two percent penalty for charges submitted in 2014 in the Medicare Part B Physician Fee Schedule.⁸

The HITECH Act is part of the American Recovery and Reinvestment Act of 2009 (ARRA). It was part of the economic stimulus bill that pushed for the adoption of electronic health records (EHR) and addresses the privacy and security concerns associated with electronic transmission of health information.⁹

An ePA uses a similar electronic route as described in E-Prescribing with the addition of an implemented decision tree that can generate an immediate determination for medications. The NCPDP has worked to create an ePA standard which meets the requirements of the Health Insurance Portability Accountability Act (HIPAA) protecting the privacy of individually identifiable health information. These HIPAA standards regulate the electronic transmission of specific health care transactions, including eligibility, claim status, referrals, claims, and a remittance to ensure patient information is protected.

NCPDP ePA Standard Process

The NCPDP ePA SCRIPT standard is a four-part transaction specific to a particular patient, plan, and drug (see diagram 1). The PBM provides the criteria repository that is appropriate to the ePA based on the patient benefit plan and medication.

Part 1: The first part of the four-part transaction is the completion of patient and medication information, which is then submitted to the insurance plan.

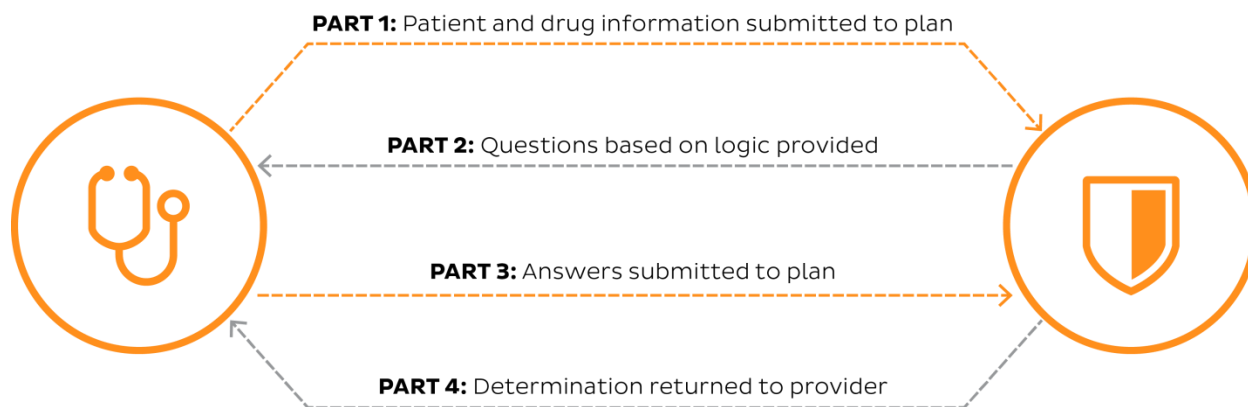
Part 2: Based upon detailed logic the plan dictates, a patient and drug-specific question set is provided to the physician for completion.

Part 3: The returned questions are submitted electronically back to the plan from the physician.

Part 4: A coverage decision is electronically returned to the physician from the plan.

Through a claims adjudication system, the ePA may result in a real-time coverage decision response. If the provider has met the coverage criteria, the plan can approve the PA instantly based upon specific information provided. The utilization of ePA also helps improve the transparency of the PA process. Since each request is specific to the patient and drug, it is easier to see the information required on the authorization, as well as ensure that the request is being completed for the correct plan or PBM. There is no confusion regarding correct requests because the question set is unique for the patient and medication, and is delivered appropriately after the plan or PBM performs eligibility verification.

Diagram 1- ePA NCPDP standard



The Electronic Prior Authorization Workflow

There are two possible workflows for the ePA process: Prospective and Retrospective. Prospective ePA occurs most often by the physician at the point of prescribing, whereas retrospective occurs after the claim rejection and is initiated either by the pharmacy or by the prescriber after they are notified of the rejection.

Prospective ePA Workflow

In a prospective ePA workflow, the prescriber begins the process by submitting an ePA request transaction to the plan, often during the E-Prescribing process. Once this transaction is reviewed by the plan, a response is sent back to the prescriber. With real-time PA adjudication, the prescriber is then aware of the decision of the ePA request

before the patient leaves the office. The patient can then fill the prescription at the pharmacy without delay. In this prospective ePA workflow, the prior authorization is undetectable to the pharmacy, as the claim would not receive an authorization rejection, and does not disturb workflow.

Many efforts are in place to move the prior authorization process to the point of care in the prospective ePA workflow. The goal is implementation within electronic health record (EHR) vendors to have the prior authorization occur before the patient leaves the physician's office. In the optimal environment, the EHR vendor's E-Prescribing system would contain the plan's formulary and criteria set to have visibility as to whether a PA is needed. This is a scenario the market is working toward. Data has indicated that in 2014, 71 percent of PA requests were initiated at the pharmacy, whereas only 29 percent were prospectively initiated by a prescriber.¹

Retrospective ePA Workflow

A retrospective PA occurs when a claim rejects at the pharmacy. There are a variety of reject codes to alert a pharmacy of the need for a PA. Reject codes commonly seen by a pharmacy include 70, 75, 76, or 78 (table 1), which typically require a PA to be submitted.

Table 1¹⁰

Reject Code	Description
70	Product/Service Not Covered – Plan/Benefit Exclusion
75	Prior Authorization Required
76	Plan Limitations Exceeded
78	Cost Exceeds Maximum
A5	Not Cover Under Part D Law
A6	This Product/Service May Be Covered Under Part B
MR	Product Not On Formulary
9G	Quantity Dispensed Exceeds Maximum Allowed
608	Step Therapy, Alternate Drug Therapy Required

When the pharmacy receives a rejection for a claim that requires a PA, they can contact the prescriber via fax, phone or electronically within a pharmacy software vendor, through a claims switch, or via web portal. The pharmacy will forward the patient and insurance information to the prescriber, then transmit the claim to initiate an ePA. The prescriber submits an ePA request transaction to the plan for review, following the process described in the prospective ePA explanation above.

Pharmacy Application of ePA

There are several ways a pharmacy can start an ePA and send to the prescriber for completion. These methods include internet sites, the pharmacy's claims adjudication provider, or through a pharmacy software vendor. These electronic methods give the pharmacy direct access to a real-time response once the ePA is submitted by the

prescriber and the payer has made a determination. Allowing the patient to get the medication they need when they need it can reduce or prevent prescription abandonment, increase patient adherence, improve therapeutic outcomes, and increase patient satisfaction.

Pharmacy Advantages via ePA includes:

- A consistent process for submitting PA requests to plans
- Decrease time spent on PAs
- Drug-specific and patient-benefit specific questions to reduce plan requests for additional information
- Faster turnaround time due to real-time approvals and reduced administrative (data entry) time for payer
- Improved patient access to prescribed medications
- Decrease in prescription abandonment
- Increased patient adherence
- Improved therapeutic outcomes^{1,5,6}

Efficiencies for the Pharmacy

The average pharmacy spends 4.6 hours per week managing PAs — these hours are non-reimbursable and take time from patient treatment. The delays caused by a disjointed workflow result in prescription abandonment 40 percent of the time.^{1,11} Abandoned prescriptions cost pharmacies more than half a billion dollars annually in the United States.¹

Electronic prior authorization has reduced pharmacist time significantly when utilized within their existing pharmacy system. Data has revealed that the electronic solution gets patients on therapy 50 percent faster, decreasing the odds of abandonment.¹² The use of ePA can improve efficiency for physicians as well. A faxed or phoned PA request is estimated to cost the physician 10.78 dollars compared to the cost of an ePA, which is estimated at 2.07 dollars.¹³

Electronic Prior Authorization Legislation

With the creation of the NCPDP named ePA standard, the SCRIPT Standard, and the increase in prescription drug authorizations, PA legislation initiatives have become more prevalent at the state level. At present, 25 states have implemented legislation relating to the PA process. These laws range from the use of standardized forms for submission to mandating the use of the NCPDP SCRIPT ePA standard transactions. Additionally, many PA laws also mandate specific timeframes for payers to provide a determination for both standard and urgent or expedited requests. Since PA legislation is currently only regulated at the state-level, there is a large amount of variability between states. Not only is the variability related to ePA or PA forms, some of the legislation is becoming more granular, focusing on certain drug types such as chronic disease state medications and opioids. Given the issues the U.S. faces regarding medication abuse, proposed legislation around the opioid epidemic is not surprising. Of the remaining states that do not currently have legislation regarding PA, some currently have pending bills, including: Missouri, New Jersey, New York and Ohio.¹

Referencing the National Adoption Scorecard for ePA, below is an excerpt of passed or pending legislation as of April 2016. These are subject to change as mandates continue to progress or be proposed.

Pending Legislation:**Connecticut**

SB 34: Relates to prescribed drugs for chronic disease — calls for the health carrier to issue an “electronic authorization” to a covered persons pharmacy for the dispensing of the temporary supply of a drug, other than CII or CIII, sufficient for the duration of the time to complete a prospective review.

New Jersey

AB 1906: Repeating bill — would require the Commissioner of Banking and Insurance to develop a standard PA form for prescription drugs for use by network providers. Must be available in paper and electronic form.

Ohio

SB 129: Would require use of a standard PA form or ePA via NCPDP SCRIPT. Once PA is approved, plan cannot come back and deny for payment. Also sets parameters on response times for urgent and non-urgent PA submissions.

Missouri

HB 2186: Will require a pilot committee to recommend rules for the implementation of the NCPDP SCRIPT Standard once the standard is adopted.

New Hampshire

HB 1608: This bill requires all health insurers, health maintenance organizations (HMOs), health services corporations, medical services corporations, and preferred provider organizations (PPOs) use and accept only the uniform PA forms developed by the commissioner of insurance pursuant to rules adopted pursuant to RSA 541-A. But does not preclude internet, web-based or other e-connectivity usage.

New York

SB 4721: Indicates standards will be developed for PA requests considering the NCPDP SCRIPT Standard.

West Virginia

SB 273: Would permit the electronic submission of PA requests using methods and systems that are interoperable with E-Prescribing systems, EHR, and Health Information Exchange (HIE) platforms. Permitted electronic submission formats shall conform to the NCPDP SCRIPT Standard.

Passed Legislation:**Florida**

SB 423: Passed April 2016 — requires the use of a uniform PA form for medications, as created by the Financial Services Commission and the Agency for Health Care Admin or by the plan, if the plan does not already have a form. If the plan is using an electronic PA methodology, the Financial Services Commission and the Agency for Health Care Admin form data elements would be expected to be required

Minnesota

Passed a bill mandating ePA in 2009. The law mandates that by Jan. 1, 2016, drug PA requests must be accessible and submitted by health care providers, and accepted and processed by plans and PBMs, electronically through secure electronic transmissions.

North Dakota

This bill requires that electronic authorization be available to providers and that payers must accept ePA transactions.¹⁴

California

SB 282 — Requires use of a state-developed universal form or NCPDP ePA standard transactions beginning Jan. 1, 2013. Only these 2 methods of submission can be accepted by health plans or PBMs regulated in CA. This legislation applies to health plans that are regulated by either the CA Department of Managed Healthcare or CA Department of Insurance.¹⁵

Texas

Legislation requires use of a universal form by Sept. 1, 2015 and ePA being required 24 months after a national named standard.¹⁶

Colorado

Beginning Jan.1, 2015, a uniform process must be utilized. This legislation also contains language around how quickly a plan must reach out for additional information as well as for making a final determination.¹⁷

States such as California and Colorado have implemented rules to define how quickly payers must return a determination. For example, CA SB 282 indicates that if a plan does not respond within 72 hours for a non-urgent request or 24 hours for an urgent request, the authorization is automatically deemed approved.¹⁵

Pharmacists and other health care providers should reach out to their state's pharmacist or medical association for information relating to recent legislative developments related to legislation or can search for information online, such as the ePA National Adoption Scorecard or state legislative websites to determine current laws regulating PA.¹

Industry Support

The American Pharmacists Association (APhA), which works with organizations to improve the production of handling prescriptions and improving the design of the PA, is an avid supporter of improving the PA process. The American Medical Association (AMA) is another supporter of ePA, and according to their study, 75 percent of physicians reported an automated PA system would help them manage patients more proficiently.^{18,19} The Academy of Managed Care Pharmacy (AMCP) also supports the use and adoption of the NCPDP SCRIPT ePA Standard. In 2013, AMCP sent a letter to industry stakeholders urging them to support the adoption of ePA and to ensure state legislation included language in support of the NCPDP SCRIPT Standard.²⁰ Electronic prior authorization can improve outcomes for patients by providing them faster access to needed medications and initiate therapy in a more timely manner.⁷

Benefits of ePA Adoption

There are three key areas that ePA will benefit pharmacies:

- **Improving Patient Care** – Getting patients on the medications that they need as quickly as possible.
- **Enhancing Productivity** – Automating the PA process inside the pharmacy dispensing/claim system to streamline pharmacy workflow.
- **Increasing Revenue** – Capturing lost prescriptions that could be abandoned prescriptions after the initial claim rejection.

Below is an example of a clinical application of ePA:

Scenario 1

Patient XYZ is prescribed an extremely expensive oral cancer medication. The pharmacy staff adjudicates the claim, which is rejected by the plan due to a PA requirement. An ePA is started at the pharmacy through the pharmacy's dispensing system integration with an ePA vendor and sent electronically to the prescriber. The prescriber then receives the ePA with specific information already completed from the pharmacy claim, such as the patient, medication, and patient's plan. The prescriber's office submits the PA electronically to the plan with the designation of "urgent" because it is critical that the patient begin therapy. Within 24 hours, the pharmacy and prescriber's office receive notification that the medication has been approved. The patient is able to fill and start taking their medication within 24 hours. Using a traditional fax PA process, it may take 24 hours before the prescriber even begins the submission process.

Pharmacist Role and Communication to Patients

When a patient arrives at the pharmacy with a prescription that requires a PA, it is ideal if the patient can be informed about what to expect from the PA process and how they can be kept informed of the progress of their prescription, their options of either continuing with a PA or paying out of pocket for the prescribed medication, and when they can return to pick up the medication. With the migration to E-Prescribing, where the prescriber sends the prescription electronically to the pharmacy, the first time the patient is in the pharmacy in person is when they are there to pick up the medication. If possible, the pharmacy could call the patient to inform them that there is a PA required and explain the ePA process or option for paying out of pocket prior to having the patient in the pharmacy for pickup.

ePA Talking Points:

- The prescription submitted by their provider requires a review to determine if the plan will cover the medication.
- With ePA, the pharmacy, provider and health plan are all able to be linked electronically to provide the prescription and other medical details to the plan for their review and determination.
- Once the plan has either decided to approve or deny the request, the provider and pharmacy will be informed of the outcome and will follow up on the details of the decision and next steps.

Pharmacists can work with their pharmacy dispensing system vendor, or corporate office, to determine if they are currently integrated with a solution to initiate PAs electronically. Automatic selection of the appropriate form and being able to systematically populate the prescription information saves time for both the pharmacy staff and the physician who will be completing the request. From a PA legislation perspective, pharmacists and pharmacy staff can familiarize themselves with applicable state laws and updates to state laws through their state pharmacy associations, vendors or through online resources.

Pharmacists can also assist in the PA process by following up with providers if they haven't heard back on a plan determination within 3 to 5 business days. With ePA integrations, pharmacies are able to remain informed of the outcome of the requests through electronic portal messaging or approval files sent on a scheduled basis to inform the pharmacist of claims that can be re-adjudicated for payment. Pharmacists are also in a great position to reach out to prescribers via phone and discuss alternative therapeutic options or the status of the PA request if they haven't heard

back on a determination in a timely manner to ensure that the patient begins therapy or to verify that the prescriber has taken action on the authorization request.

Pharmacy Actions for a Streamlined ePA Approach

In creating a process for implementing or utilizing ePA solutions, here are a few items the pharmacist or pharmacy manager will need to consider:

- Establishment of a training strategy for the pharmacy staff and ongoing for new staff
- Development of materials or speaking points for discussing PA with patients and options for their prescription
- Determination of how and when to outreach to prescribers who are resistant to completing PAs and are not providing alternative medications for dispensing
- Time needed for development and implementation of ePA pharmacy technology if dispensing system is not currently live with ePA integration

Conclusion

Prescription drug spending is increasing in the U.S. and a factor contributing to that growth is larger adoption and approval of specialty medications. As medication costs continue to climb, both private and government health plans need to implement programs to help control cost and ensure appropriate prescribing. One such managed care tool is PA. The NCPDP ePA standard can dramatically improve the PA process for pharmacies, physician's offices, health plans and patients. It standardizes a fragmented and manual process, allowing the submission of PA requests for any plan with one electronic transaction, and greatly simplifies the complex process of navigating PA forms and plans for health care providers. Under the ePA standard, pharmacists and physicians can reduce time spent on paperwork, and increase time spent caring for patients, who can now access medications quickly, improving adherence, time to therapy, and preventing prescription abandonment. Technology is changing health care, and with ePA, all stakeholders in the PA process will benefit from these new innovations.

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