Medication Prior Authorization from the Providers Perspective: A Prospective Observational Study

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Abstract

Background: The prior authorization (PA) process for medications used by community providers requires modernization. Therefore, a deeper understanding of current state of PA from the community provider perspective is imperative to inform and modernize this managed care tool.

Objectives: Objectives of this study were to identify, analyze and categorize the issues associated with the medication PA process from provider practice perspective.

Methods: A prospective non-experimental, cross sectional, observational study was performed using semi-structured interviews and direct observation at a convenience sample of eight primary care and medicine subspecialty group practices in XX, Arizona, USA. Participating practices were required to have an established medication PA process. The participant feedback from each site was analyzed using the Richards qualitative coding technique that includes descriptive coding, topic coding, and analytical coding.

Results: Data were obtained from eight unique community provider offices (8 sites) at which 29 prescribers practice. The pain points identified represented five main categories: 1) information transfer gaps; 2) format disparities; 3) outdated technologies; 4) care consequences; and 5) workarounds. Prescribers and their staff suggested improvements that included real time eligibility and formulary alerts regarding PA during the e-prescribing process, accurate, up-to-date formulary data with easy-to-access alternatives, and embedded PA that is integrated with electronic medical record data. Three sites used medication PA portals such as CoverMyMeds® for information gathering, but at the time of data collection, no sites used these PA portals for prospective electronic prior authorization (ePA) or the electronic process of requesting authorization from health plan payers for coverage.

Conclusion: The PA process for medication used by community providers is in urgent need of

modernization. Pain points identified in this study could be alleviated by implementing medication ePA solutions. However, providers and their staff are largely unaware that ePA exists. Additional research in this area is needed.

Key words: prior authorization process; qualitative analysis; primary care

INTRODUCTION

The prior authorization (PA) process requires that a provider obtain health plan approval before certain treatments, procedures or medications are covered by a health insurer. PA serves a dual purpose in managed care, functioning as a cost control mechanism and a patient safety tool. Many aspects of PA workflow still rely on the resource-intense use of paper forms, telephone calls, facsimile communications and portal access. PA for medications involves patients, pharmacists, PBMs, health plans and prescribers, for whom the process is particularly burdensome.[1] This article provides a prescriber-centric view of the current state of PA with a focus on specific issues necessary to modernize this managed care tool.

The requirement for medication PA is often discovered at the pharmacy during the electronic claims adjudication process. While individual pharmacy practices vary, in response to a denial, pharmacy staff may call the patient's pharmacy benefit manager (PBM) or health plan to request a denial override. More often, however, pharmacy staff inform the patient and notify the prescriber of the denial, which in turn, activates the provider's PA process.

The provider PA process commences with prescriber staff seeking the specific PBM requirements and mandatory forms. When required data is extracted and supporting medical documentation located, the patient information is scanned or submitted by facsimile to the PBM. Phone calls regarding status and disposition from the patient and must be addressed. Additional information may be requested prior to a coverage determination. Notification of approval or denial from the PBM follows, generally in response to a provider query. The prescriber office then notifies the pharmacy. Claim re-adjudication, prescription fulfillment and patient notification then follows. Medications that are denied follow a similar path culminating in substitution, appeal or abandonment.

This multi-step process of medication PA is time consuming and places a significant, uncompensated burden on prescribers.[2-8] A recent survey of US providers noted that over half of the responding practices spend up to 20 hours per week on PAs.[2] The Biomedical Central Health Services Research reported that traditional paper-based PAs consume $23 to $31 billion dollars (2006 US dollars) each year.[2] A study determined that the average time spent on a traditional paper-based PA was twenty minutes.[3] One of nation's largest pharmacy benefit management firms (Express Scripts) reported that while specialty medications accounted for about 1% of total prescriptions, nearly half of prescription drug expenses in 2016 were for specialty medications.[9] With the increasing cost of prescriptions, particularly specialty medications, and the steady flow of new FDA approvals, more and more drugs are requiring PA.[9]

As the volume and number of medication PAs increase, provider frustration is palpable.[10] In addition to care disruption, PAs have been burdening provider offices and clinics with increased financial and administrative costs.[11] Electronic Health Record (EHR) adoption, e-prescribing and PA portals have had little impact on reducing PA burden. Primary literature evaluating the overall PA process is scant. Current literature justifies PA for specific medications and supports PA generally, citing benefits such as reducing waste, reducing costs, proper utilization, and improving patient outcomes.[8,12-28] However, despite the integral role of the provider in PA, few studies have analyzed the PA process from the provider's perspective.[2,3,29] Therefore, a deeper understanding of current state of PA from the community provider perspective is imperative to inform and modernize this managed care tool. The objectives of this study were to identify, analyze and categorize the perceived issues associated with the medication PA process from the perspective of the provider.

METHODS

Study design

A prospective, non-experimental, cross sectional, qualitative, observational study was performed using semi-structured interviews and direct observation utilizing a convenience sample of eight physician group practices in XX, Arizona, USA. For inclusion, the participating medical practice settings were required to perform medication PAs at least weekly. The medication-intensive specialties of internal medicine, family practice and sub-specialties of rheumatology, pulmonology and endocrinology, were targeted. Surgeons were excluded due to their limited, analgesic-focused prescribing practices. One investigator (XX) generated a list of practice sites where personnel, including providers and supporting staff, performed PAs on a routine basis by coordinating an email outreach with the three largest medical associations in XX, Arizona, USA. Prospective participants were then personally contacted by an email and/or telephone call that explained the aims of the study and participant responsibilities. Participant providers agreed to be shadowed by data collectors and to be available for semi-structured interviews (see Appendix for interview questions and process). Investigators contacted interested provider sites and provided detailed study information by phone and email. Participation in this study was voluntary and anonymity of the participating sites was assured. The University of XX Institutional Review Board approved this study.

Data Collection

Data were obtained by direct observation of individuals involved in the PA process at each practice site and by semi-structured interviews of providers and staff. Data collectors included eight groups of five University of XX students pursuing a master's in business administration (MBA) who used the Toyota Production Systems A3 Process[30] to collect data at each practice site. The student observers were trained to collect the data for this study by

attending a standardized training session that included a Health Insurance Portability and Accountability Act (HIPAA) privacy module; a general introduction to managed care, PBMs, the prescribing process, and the traditional PA medication process. The data were recorded via written notes only.

Data collection tools were structured to include a detailed process map for the PA process; identification of barriers and personnel supporting and/or performing PA; and root cause analysis using the A3 Process[30], a course requirement. Each team (n=8) performed a root cause analysis. The content validity of the semi-structured interview and observation questions was achieved by a thorough literature review. The most commonly reported problems with the PA process included patient dissatisfaction with the process and delay in medication receipt; inefficiencies resulting from communication issues between the pharmacy benefit manager, provider, pharmacy and patient increased provider workload and costs. The face validity of the semi-structured and direct observation questionnaires was assessed by the physician author (XX).

Data were collected over a 2-week period (April 13, 2015 to April 24, 2015) during mutually agreeable times between student observers and provider office managers. A field observation protocol (see Appendix A) was developed and used to standardize the data collection process. The student observers shadowed the PA coordinators at each site for an average of 4 hours, focusing on the PA process as executed by the site prescribers and PA coordinators. As per the field observation protocol, students initiated the observation process by introducing themselves, obtaining informed consent and explaining the aims and procedures of the study. The direct observation questionnaire was used to guide and document the PA process at each site. The semi-structured interview questionnaire was completed based on the availability and

willingness of the participants to reflect on the issues associated with the current PA process. The field observation protocol (including informed consent, direct observation questionnaire and semi-structured interview questionnaire) is provided in Appendix A.

Data Analysis

The participant feedback from each site was analyzed using the Richards qualitative coding technique that includes descriptive coding, topic coding, and analytical coding.[31] The technique provided a framework to prepare data sets for further analysis by providing themes throughout the coding process. Descriptive coding is common in qualitative studies and is used to describe the attributes of a case. In this study descriptive coding was used to code practice setting characteristics. Topic coding is helpful in allocating passages to topics. This type (topic) of coding is used to put the data "where they belong." This study used topic coding to label the responses according to subject (general classification of categories was followed by iterative recoding with subcategory expansion). Analytical coding refers to the form of coding that involves interpretation and reflection on meaning. Analytic coding involves a few logical steps such as selecting a passage that is interesting, followed by examining why this passage seems to be interesting. The next step in analytical coding is generate a category and name it carefully. In this study we followed these steps to generate issue themes. Qualitative analyses were conducted using Atlas TI Version 1.0.31 (117) by two researchers. Discrepancies were addressed by discussion to reach consensus between the two researchers.

RESULTS

Each team visited their assigned practice site to observe the medication PA process and to obtain staff feedback according to the protocol. Data were obtained from eight provider practice sites at which 29 prescribers practice. See Table 1 for details on practice type and provider

specialty. Seven sites (87.5%) had designated staff to handle the most medication PA tasks on behalf of prescribers. One office, part of a multi-site practice, used dedicated, centralized staff to handle the PAs for all providers in the group. Most provider offices relied on a manual process, however three practices employed web-based online PA portals (e.g., CoverMymeds®). The pain points in the medication PA process identified by the observers were classified according to five major themes: 1) information transfer gaps; 2) format disparities; 3) outdated technologies; 4) unintended workarounds and 5) care consequences. Each theme is described below and summarized in Table 2.

Information transfer gaps were the most commonly identified pain point. Accessing outdated or incorrect PA documents and "lost paperwork" referring to faxed information that does not reached the desired recipient were the scenarios most often cited by staff. PA questionnaires and PBMs criteria were usually stored in paper files at the practice. These forms were often incomplete or outdated, owing to frequent changes in formularies, modifications in PA requirements and ineffective dissemination of this information by PBMs and plans. Providers noted that notification of outcome (i.e., approval, denial or "need more information") was not uniformly or proactively communicated. Providers also emphasized the need for accurate formulary information at the time of prescribing and the accessibility of PA requirements during the prescribing process. Finally, prescribers expressed a strong desire to initiate the PA process proactively, at the time of prescribing, rather than by retrospectively responding to a pharmacy-initiated PA request. According to prescribers, a proactive PA process will reduce patient wait time for medications, minimize the time spent fielding phone calls from patients and pharmacies regarding status, and reduce the number of steps needed to complete the PA requirements for a given medication.

Format disparity refers to the lack of standardization of the forms, formats, and processes amongst and between PBMs and plans. Respondents indicated that patient demographics, past medical history, laboratory and procedure details are required fields, yet the order and layout of such information on an individual PA form varies widely. There is also wide variation in the document completion and submission processes. For example, required paper forms may need to be faxed, scanned and/or emailed; they may also require a staff-initiated telephone call or verbal explanation directly from the prescriber.

Outdated or poorly implemented technology was exemplified by the heavy reliance on facsimile transmission, lack of electronic health record integration, and the inability to electronically monitor and respond to PA status changes. Three offices reported varying levels of success using the medication PA portal *CoverMymeds*® to locate PA forms and requirements for specific PBMS and plans. Such PA portals aid provider offices by providing links to current PA forms and by automating review and tracking of PA submissions. The remaining practices called the PBM for the appropriate form to be transmitted by facsimile or email. These forms were then printed, completed and faxed back to the PBM for processing.

Workarounds to accommodate the PA burden were described by all practices. The most common approach was adding dedicated staff to PA or designating time for existing staff to focus on the PA process. One large multi-site group practice resources a centralized PA office. Provider staff also maintain paper files of PA sheets and criteria as well as "cheat sheets" listing key phrases associated with prior PA success for specific drugs. However, despite such shortcuts, participants reported during interviews that total PA form completion time from start to submission ranged from 10 minutes to 48 minutes per form. Participants noted that actual prescriber time was 2 to 3 minutes per PA, with staff minimizing the provider involvement to

review and signature, though some PAs required prescribers to call the PBM and talk with a PBM nurse reviewer or medical director as part of the process.

Care consequences, specifically those with direct impact on patient care and safety, were ubiquitous. Participants noted that when PA is required, fulfilment delay ranges from 48 hours to 14 days. According to prescribers and staff, such delays, even a few days, often result in medication abandonment, though quantification was not available. Participants shared illustrative anecdotes in expressing frustration with the waste and inefficiency of the medication PA process and its negative impact on patient care. Such anecdotes included patients making multiple trips to the pharmacy and/or provider's office to have prescriptions filled or changed when a medication is dropped from a PBM formulary, removed from the preferred list, or the patient changes health plans.

DISCUSSION

From the provider perspective, the workflow referred to as the "medication PA process" is more accurately characterized as a hodgepodge of uncompensated tasks that provide little if any benefit to patients and may result in harm to some patients. Providers have consistently expressed the need to eliminate or at least modernize PA.[32] The dearth of observational, qualitative literature substantiating provider PA "pain points" has contributed to the improvement lag. This study identifies key opportunities to improve PA in five specific areas: 1) information transfer gaps; 2) format disparity; 3) outdated technology; 4) workarounds and 5) care consequences.

According to providers and staff, the direct and indirect impact on patients, identified as "care consequences," should be the key driver for PA reform. Prescribers note that patients who have been stabilized on a medication suffer consequences when a medication is suddenly

dropped from a PBM formulary, removed from the preferred list, or changes health care plans. Patients with disabilities or lower socio-economic status may be disproportionally impacted by PA delays due to pre-existing transportation barriers. Decompensation or destabilization of an individual's health condition, additional provider visits and pharmacy trips to re-establish the regimen or initiate a new, preferred medication are among previously reported consequences.[33]

Community practices care for patients covered by a multitude of plans with corresponding PBMs with unique formularies and PA requirements. Prescribers are generally unaware of medication cost, formulary tier, need for PA, stepped care or other restrictions and requirements for each patient. The literature indicates that providers will often change to a preferred medication if they have information demonstrating lower out-of-pocket costs for their patient or personal avoidance of the PA process.[34] To effect such changes, prescribers need online, accurate, up-to-date benefit and formulary information for every patient accessible during the e-prescribing process.[33]

Participants also identified information transfer gaps, format disparity, outdated technology and the need to create workarounds as "pain points." We believe these are the foci for improvement. Re-engineering the medication PA process from the electronic prescription by integrating real-time plan eligibility and formulary information, alerts and incorporating decision support to streamline PA submission or suggest formulary alternatives is highly desired. If PA is required, the prescriber can access real time, accurate information and engage in electronic communication with PBM software resulting in automated approval before transmitting the prescription to the pharmacy. Readers may recognize that these features are currently available as proprietary software solutions referred to as prospective "electronic prior authorization (ePA)"

for medication with varying availability from EHR vendors.[35] However, many PBM and health plan system infrastructures are currently not prepared to accept or administer ePA transactions.[35]

Allscripts, CVS Caremark, Navinent/CoverMyMeds® and Surescripts completed successful ePA pilot tests [36] and Suresripts collaborated with DrFirst to embed prospective ePA capabilities into their mainstream e-prescribing technologies enabling low complexity PA to be approved electronically before the patient leaves the providers' office[35]. Though clinical reviews may still be needed, providers applaud the concept of having some prescriptions approved in the office, avoiding wasted patient trips to the pharmacy, extra communications and treatment delays.[35] PA requiring clinical review can, in ideal circumstances, be completed in one business day, including prescriber notification.[37]

The overall goal of prospective ePA is to reduce administrative burden and increase workflow efficiency. For providers and patients to realize the benefits of ePA, adoption and uniform implementation of the National Council on Prescription Drug Plans (NCPDP) SCRIPT ePA standards must be coordinated amongst key stakeholders, namely PBMs, insurers, pharmacy retailers, and EHR and e-prescribing vendors. Fortunately, there is growing support for national implementation of ePA. Last year, the American Medical Association, with 16 other organizations representing physicians, medical groups, hospitals, pharmacists and patients, released a comprehensive set of 21 principles to guide PA process updates.[32] According to the most recent CoverMymeds® ePA National Adoption Scorecard, twenty-eight states had laws pertaining to PAs, and 9 states requiring the use of NCPDP SCRIPT Standard for ePA.[38]

Despite the promise of ePA, evidence gathered during this study suggests that providers and staff are often aware of electronic tools that may alleviate some of the "pain points" of PA.

Additional communication and research is needed to understand limitations and increase provider awareness and improve systems availability.

This study has several limitations. The sample size is relatively small and the data were collected via a convenience sampling in XX, Arizona. Therefore, the extent to which results are representative is unclear. Finally, with its focus on providers, perspectives of the other key stakeholders (pharmacy personnel, health plans, PBMs or patients) are not represented. Additional research in this area is needed to address these limitations.

CONCLUSION

Modernization of medication PA is imperative. The identified provider "pain points" discussed in this study, specifically, patient care consequences, information transfer gaps, format disparity, reliance on outdated technology and workarounds could be alleviated by universal implementation of prospective ePA as a fully integrated clinical decision support feature of all certified electronic health records. Patient-specific, accurate, real-time formulary information with intelligent, automated on-demand PA embedded within the e-prescribing workflow is on the horizon. While we can speculate that prospective ePA solutions will increase efficiency while improving care, additional research in this area that encompasses all stakeholder perspectives is needed for confirmation. Future research should also be directed towards developing and evaluating mutually feasible alternatives to PA. Until then, increasing provider awareness of existing ePA solutions and engaging stakeholders to facilitate implementation is the next step in our journey towards improving patient care.

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Table 1: Participating site practice specialty and health care provider mix

Practice Specialty (n=8 sites)	**N (%)**
Family Medicine	3 (37.5)
Internal Medicine	2 (25)
Rheumatology	1 (12.5)
Pulmonology	1 (12.5)
Endocrinology	1 (12.5)
Provider Type (n=29 providers)	
Medical Doctor	20 (68.97)
Nurse Practitioner	7 (24.14)
Physician Assistant	2 (6.89)

412

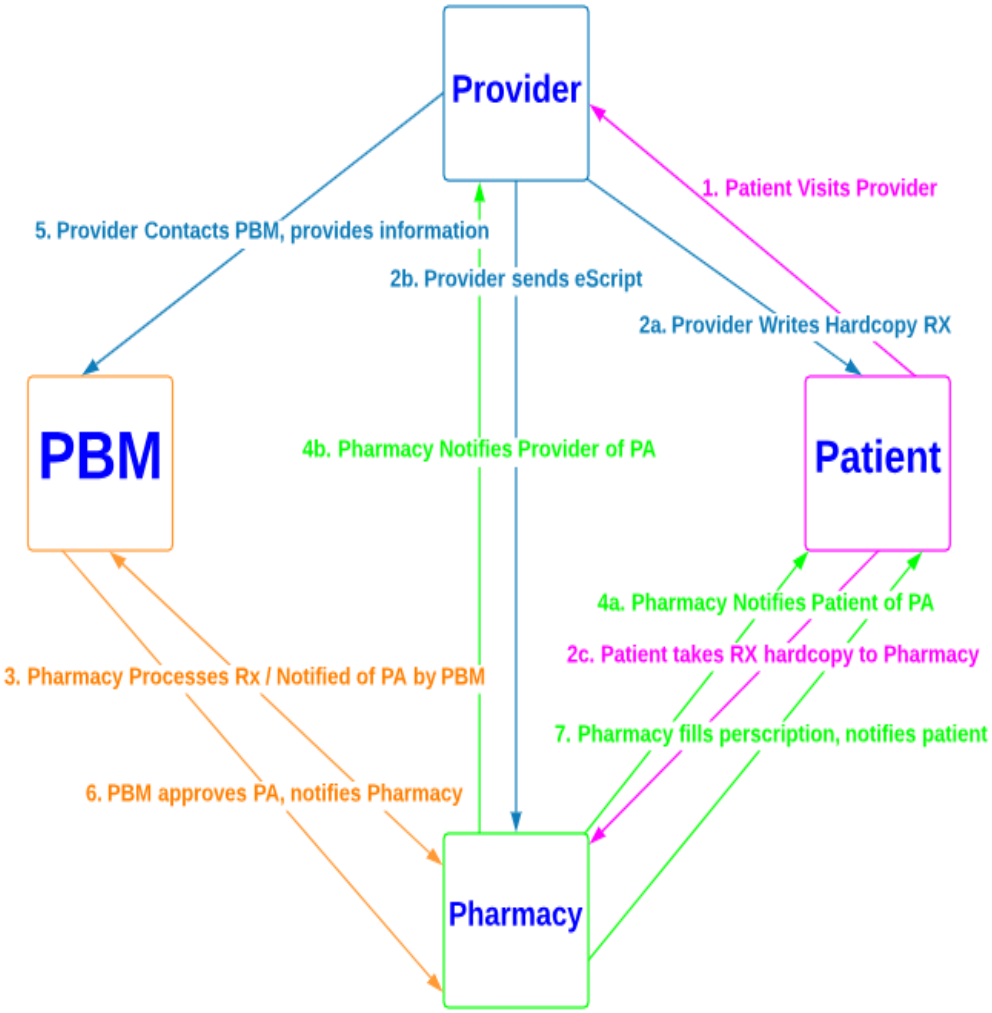
Table 2: Medication Prior Authorization (PA) Issue Themes from Prescriber and Staff Interviews			
Issue	**Groups Involved or Stakeholders**	**Details Provided by Interviewees**	**Examples of Interviewee Suggestions for Improvement**
Information Transfer Gaps	Pharmacy Benefit Manager (PBM) to Provider	Provider unaware that PA required	"An electronic (e)PA process integrated into the Electronic Health Record (EHR) should be widely implemented. This will enable providers to identify which medications require a PA for each patient before the patient leaves the office."
	PBM to Pharmacy	Pharmacy unaware PA needed until electronic claims adjudication	"With an ePA process the PBM would not need to be responsible for PA status."
	Pharmacy to Provider	Pharmacy did not notify provider about PA in a timely manner	"If there was ePA, the pharmacy would not need to be responsible for this communication."
Format Disparities	Every PBM has a unique process	Provider staff must accommodate a multitude of PA forms and instructions	"The ePA process integrated into the EHR would allow PBM requirements for each medication to be conveyed to the provider at the time of prescribing."
Outdated Technologies	Stand-alone portals, e.g. *covermymeds*® used in 3 sites Facsimile communication used in other sites	Portal does not always provide correct form. Providers must interface with multiple PBMs, each with unique formulary, PA forms and formats. Formularies, forms and PA requirements change frequently. Staff are unable to keep pace with requirements.	ePA technology embedded into e-prescribing software permits PA using an on-line process. Automated, up to date formularies needed.

		Facsimiles do not "go through"	
Workarounds	Staff may resort to any means necessary: "Tell the insurance companies whatever the heck they want to hear."	Some sites process up to Because of the volume of PAs (interviewees reported processing 16 PAs per day – especially specialists seeing patients who may have failed responses to several medications) and the long time for processing each request (interviewees reported spending from 10-15 minutes on average on the PA process for one patient; usual range is 10-48 minutes with outliers up to 14 days. (See Figure 1)), office staff reported feeling pressured find work arounds that would allow them to get their work completed. For example, they reported being willing to tell the insurance companies whatever they wanted to hear to get the PA processed even if the information was not completely accurate.	"Develop a standardized industry-wide PA process including standardized forms. Providers could use the formulary and benefit functionality of their EHR to identify which medications need PA for a specific patient."
Care Consequences	Patient forgoes medication	Denials are common, while window for appeal is short (30-60 days) and requires additional input from provider, medical assistant, pharmacist, and often, the patient. Annual re-authorization often needed for chronic medications	ePA can automate the approval process and speed the time spent on PAs. AMA workforce recommends that PA be valid for entire life of a

			prescription.[32]

Reference: 32: O'Reilly KB. American Medical Association. 21 principles to reform prior-authorization requirements. 2017; https://wire.ama-assn.org/ama-news/21-principles-reform-prior-authorization-requirements. Accessed April 25, 2017.

421 **Figure 1: Medication Prior Authorization (PA) Process from provider's perspective**



422

Key: **Flow Chart Depicting the Current Prior Authorization (PA) Process**
Diagram is labeled in sequential order starting with patient and provider interaction. **Solid lines** are mandatory steps in the process Pink refers to Patient initiated activity; Green refers to Pharmacy initiated activity; Blue refers to Provider initiated activity; Orange refers to PBM initiated activity
Abbreviations: PBM - Pharmacy Benefit Manager; Rx- Prescription for medication ; eScript- Electronic Prescription; PA - Prior-Authorization
The PA process begins when the patient visits the provider and the provider writes a hardcopy prescription or sends an e-prescription to the pharmacy. The pharmacy processes the prescription and an electronic claim is sent for real time online claims adjudication to the PBM. When replying, the PBM notifies the pharmacy that a PA is required. The pharmacy notifies the patient and provider that PA is required. The PBM requires additional information from the provider to approve the PA. The provider communicates the additional information or his/her staff via fax or

telephone. Once the provider has met the requirements, the PBM decides if the PA will be approved. If the PA is approved, the pharmacy adjudicates the claim and the prescription is processed and provided to the patient.

APPENDIX A: FIELD OBSERVATION PROTOCOL AND SEMI-STRUCTRED INTERVIEW QUESTIONS

During all field observations, students will observe and record how providers and PA Coordinators navigate the medication prior authorization process. Investigators will **shadow each participant for a 4-hour time period** in participants' own clinical practice settings. Specifically, observers will: (a) note how participants interact with the process; and (b) schedule brief interviews with participants.

NOTE: Items in *italics* is to be spoken to participants.

1. Introduction

Thank you for allowing us to observe. My name is (_____). I am a student with the University of XX XX College of Management. As you may be aware, we are conducting a study in coordination with the University of XX College of Pharmacy, to evaluate the medication prior authorization process. We appreciate your willingness to be observed, possibly interviewed, as you complete the prior authorization process.

Informed Consent Procedures

a. Potential participant is eligible and willing to participate
    1) Provide copy of consent form to potential participant.
    2) Provide verbal description of research study.
    3) Answer all questions participant may have.
    4) Obtain informed consent.

2. Introduction To Project Aims and Procedures [5 minutes]

The prior authorization is a time consuming and expensive process for all parties involved. We would like your help in evaluating the current process and how it may be improved. We will map the process, identify the problems or disadvantages of the process.

Please go about your normal workday and try to imagine that I'm not here. Please notify me when you become aware that a prior authorization has been required. I will observe the process and take notes. I may then schedule a short interview and have a few short questions to ask you. Do you have any questions? [Pause for questions and comments.] *Good, then I'll now begin observing.*

3. Procedures

Observe the prior authorization process and answer the questions:

1) *Who notified the office of the Prior Authorization?*
2) *What is the medication requiring the Prior Authorization?*
3) *Why is the medication requiring a Prior Authorization?*
4) *Was the Insurance Company called, if so what information was given?*
5) *What information was required in order for the PA to be approved? How was the information communicated?*
6) *Was the office staff able to complete the prior authorization process and have the medication approved?*
7) *How long did the process take and/or how long do you think it will take to complete?*

8) *How can the process be improved?*

If there is an abundance of time during a break, or if the participant wants to talk more after the observation period, consider asking the following:

1) *How do you feel the process can be improved?*
2) *What are the current problems with the process?*
3) *What do you spend the most time on during the process?*

4. Observation Duration

Approximately 4 hour time periods are required for each participant to consent and be observed.

5. Conclusion

As we now conclude this observation, what else would you like to say about this topic that you have not had a chance to say already? Do you have any concerns, challenges, or questions we have not discussed? [Pause for questions and comments.] *Thank you very much for your participation today. Your views and experiences you've shared with us will be a great help as we work to improve the current prior authorization process. We very much appreciate your time.*

[Shake Hands], ask for contact information.

Data Collection Questionnaire:

Date:

Office Staff:

Insurance Company:

1. Who notified the office of the Prior Authorization?

2. What is the medication requiring the Prior Authorization?

3. Why is the medication requiring a Prior Authorization?

4. Was the Insurance Company called, if so what information was given?

5. What information was required in order for the PA to be approved? How was the information communicated?

6. Was the office staff able to complete the prior authorization process and have the medication approved?

7. How long did the process take and/or how long do you think it will take to complete?

8. How can the process be improved?