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More Than Just Paperwork: Prior Authorizations, the Latest Enforcement Risk



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Introduction

Prior authorizations for medical products and services are an increasingly common feature of health-care payer/provider relationships. Government health-care programs and private insurers rely on prior authorizations (PAs) to hold down the cost of drugs, devices, and services for their members, while providers and patients chafe at the second-guessing and administrative burdens that come with PAs. Some manufacturers have recently taken extraordinary steps to evade PA requirements, attracting the attention of the Department of Justice. PAs will remain an important component of the health-care landscape for years to come, and manufacturers, providers, and their counsel must pay attention to potential enforcement risk they face if they manipulate PAs.

PAs mark the intersection of powerful, competing forces in health care. Manufacturers sink millions of dollars in research and development into products, and they face intense pressure to generate a return on that investment. The physicians who order these products expect that their prescriptions will be filled as ordered—not second-guessed by an insurance company. Yet the cost of prescription drugs and other health-care services can be astronomical, and government and private insurers face pressure of their own to hold down costs for their members. Thus, payers are increasingly requiring physicians to submit PAs before approving medical products and services. While many companies have offered appropriate assistance to providers to help navigate the PA process, some companies have gone further, manipulating and falsifying PAs to secure reimbursement for drugs and products that would otherwise not be covered.

Not surprisingly, this misconduct has attracted the attention of the government. On September 6, 2017, Senator Claire McCaskill (D-Mo.) released a report entitled "Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization" ("McCaskill Report"). The McCaskill Report came on the heels of a December 2016 federal indictment of six executives and managers from Insys Therapeutics Inc. ("Insys") for health-care

fraud, related, in part, to the manipulation of PAs ("Insys indictment"). The Insys indictment is just the latest example of DOJ enforcement activity related to PA abuse. Drug and device manufacturers and health-care providers face a challenging environment as they struggle to obtain coverage for their products while navigating this new compliance regime.

I. Background

Health-care payers, including private insurance companies and government insurers (including Medicare, Medicaid, and TRICARE), utilize PAs to hold down the costs of pharmaceuticals, devices, and other medical services. For example, insurers often maintain a formulary identifying all drugs that are covered for beneficiaries on a particular health insurance plan. A typical formulary is arranged by tiers: the lowest tier is occupied by inexpensive generic medications, followed by preferred, brand-name medications, nonpreferred branded medications, and then specialty medications. If a physician prescribes a medication in a higher tier, the plan may either require the member to first try a medication in a lower tier ("step therapy"). If the more inexpensive medication does not work, many plans will approve medications on higher tiers, or noncovered medication but only after the member's physician submits a PA. In the PA, the physician must provide a medical justification for the more expensive medication, and many plans require physicians to certify in the PA that members have tried medications on lower tiers without success. Some manufacturers negotiate discounts and rebates with plans to secure favorable formulary access.

Government and private insurers view PAs as a critical cost-savings measure. Insurers utilize PAs to avoid paying for expensive drugs and services which, in their view, do not tangibly improve the treatment that their beneficiaries receive. While insurers will frequently cover innovative—and expensive—drugs that provide unique therapy for their patients, they balk at later-generation medications that do not provide tangible, additional benefits yet can be more expensive, in orders of magnitude, than generic equivalents.

However, insurers have received considerable criticism from physicians, patients, and manufacturers for requiring PAs. Clinicians' criticism is, at its core, rooted in the reality that the PA concept necessarily questions the clinical judgment of prescribing practitioners, who would prefer to see their patients receive exactly the medication that the practitioner ordered without outside interference. Many practitioners also complain that the process of obtaining a PA for a patient is a long, administratively complex and inefficient process that prevents them from treating patients. Patients share many of these concerns. Many patients associate PA with administrative complexity, having experienced frustration related to PA first-hand. Patients tend to trust the judgment of their medical advisors, and, all things being equal, would prefer for their prescriptions to be filled as ordered.

Pharmaceutical manufacturers also have criticized PA requirements. Inclusion on plan formularies is essential for pharmaceutical companies to be profitable. PAs present substantial obstacles for pharmaceutical companies. When a clinician has a prescription denied through PA, the clinician may turn to an alternative medication that enjoys broader coverage. Over time, if the clinician repeatedly has prescriptions for a certain drug rejected, he or she may begin prescribing the alternative simply to avoid the administrative difficulty associated with PA rejections, even if he or she believes that their first choice is clinically superior, adversely affecting brand loyalty. Similarly, if a patient with a minor ailment learns that a prescription was rejected due to PA requirements, the patient may decide that it is not worth the trouble to fill the prescription—a phenomenon known as "prescription abandonment." In short, PA requirements pose a serious threat to drug and device manufacturers' bottom lines.

II. Government Enforcement Efforts to Address PA Manipulation

PA requirements have figured prominently into a number of recent DOJ enforcement actions.

A. Insys

Insys, a pharmaceutical company based in Chandler, Ariz., manufactures Subsys, a fentanyl-based spray medication. Fentanyl is an extremely powerful, rapid-onset opioid that produces effects similar to morphine and heroin. Insys secured FDA approval for Subsys to treat cancer patients experiencing breakthrough pain. According to the Insys indictment and the McCaskill Report, Insys marketed Subsys beyond this limited indication, including to physicians who did not treat cancer patients, such as physicians treating pain. Many of these physicians prescribed Insys, but insurance companies frequently did not approve the orders. A typical Subsys prescription could cost thousands of dollars each month. Many insurance plans and pharmacy benefit managers (PBMs) imposed restrictions on branded fentanyl medications. For instance, most insurers and PBMs required physicians to submit PAs for Subsys, describing the patient's diagnosis and medical history, prior to approval.

The government alleges that Insys created a "reimbursement unit" to circumvent Subsys PA restrictions. According to the indictment, Insys executives and managers trained reimbursement unit employees to mislead insurers in order to secure approved PAs. This unit allegedly contacted insurers directly (after receiving "opt in" forms from physicians) and attempted to push through Subsys PAs. The misleading tactics allegedly included (a) concealing that the employees were calling from Insys, and instead stating that they were calling from the doctor's office; (b) stating that the doctor was treating the patient for "on label" breakthrough cancer pain, which was often not the case; (c) incorrectly stating that the patient suffered from dysphagia (difficulty swallowing), which often led insurers to approve a nonformulary drug; and (d) misstating that the patient had tried another drug in the class already, without success, satisfying step therapy requirements. Insys executives also allegedly imposed a compensation structure rewarding those reimbursement unit employees who obtained the most PAs. According to the indictment, Insys's efforts through the reimbursement unit resulted in an increase in Subsys PA approvals from 30 percent to 85 percent.

The Insys executives' trial is scheduled for October 2018. One likely trial witness is Elizabeth Gurrieri, a former manager from the Insys reimbursement unit, who recently pleaded guilty to wire fraud. At her plea hearing, Ms. Gurrieri admitted that she "specifically directed employees to lie using a number of different methods used to mislead insurers." According to a criminal complaint, Ms. Gurrieri and others taught reimbursement unit employees "how to mislead and deceive insurers regarding their employment, patient diagnoses, and tried and failed medications …. In this environment, corruption became endemic within the Reimbursement Unit."

B. Warner Chilcott

Warner Chilcott (WC) was a New Jersey-based pharmaceutical company that manufactured a number of products, including Atelvia, a drug designed to treat osteoporosis. When WC introduced Atelvia, the market for osteoporosis medication was crowded and included a generic alternative, which cost only $10 per dose, while Atelvia could cost up to $140 per dose. Given the price disparity, many insurers and PBMs excluded Atelvia from their formularies, only paying for Atelvia if physicians submitted a PA explaining the medical rationale for the branded drug.

WC executives informed the sales force that pushing through Atelvia PAs had to be a "core competency" that was "part of the job." Executives and managers shared with sales personnel medical justifications that would likely result in a successful PA. Many WC sales representatives coached physicians and staff on the language to use in an Atelvia PA. Sales representatives also wined and dined physicians and their staff who handled PAs, providing them with free food and beverages and "speaker" payments, as inducements not only to prescribe Atelvia, but also to push through Atelvia PAs. And dozens of WC sales representatives simply filled out Atelvia PAs themselves, using "canned" medical justifications without knowing whether they applied to the patient. Some WC sales representatives hand-wrote PAs in physicians' offices; others called in PAs to insurance companies, falsely stating that they were employed by the physician. And many sales representatives used an online PA clearinghouse website to submit PAs to insurers and PBMs, creating accounts in the name of physicians and staff.

In October 2015, WC pleaded guilty to conspiracy to commit health-care fraud—a scheme which included PA manipulation. In addition, in 2016, three former WC managers pleaded guilty to directing their employees to manipulate Atelvia PAs.

C. Shire Pharmaceuticals

In September 2014, Shire Pharmaceuticals LLC agreed to pay $56.5 million to resolve a DOJ investigation alleging that the company violated the False Claims Act in connection with its promotion of several drugs. One of the areas covered by the settlement agreement was Shire's alleged manipulation of PAs. The investigation was initiated by whistleblower lawsuits in the Eastern District of Pennsylvania and the Northern District of Illinois. According to the lawsuits, Shire manipulated the PA process related to Vyvanse and Daytrana, medications designed to treat Attention Deficit Hyperactivity Disorder. The government alleged that Shire sales representatives and other agents misrepresented the features of Vyvanse to Medicaid formulary committees in order to gain acceptance on state formularies and avoid PA requirements. The government alleged that Shire also manipulated the PA process by (1) making telephone calls to Medicaid attempting to secure coverage for the drugs, failing to disclose that they were Shire representatives, as opposed to members of physicians' staffs; and (2) drafting letters for physicians to assist in gaining coverage for Vyvanse and Daytrana.

D. CareMed Pharmacy

In October 2014, Sorkin's RX Ltd. D/B/A CareMed Pharmaceutical Services (“CareMed”) agreed to pay $10 million to resolve a False Claims Act investigation by the U.S. Attorney's Office for the Southern District of New York. According to the government's complaint, CareMed, a New York pharmacy that sold specialty drugs, made false statements to insurance companies in connection with obtaining prior authorizations to fill prescriptions. Like the WC and Insys sales representatives, the government alleged that, when certain CareMed representatives contacted insurance companies, they falsely stated that they were calling from physicians’ offices, rather than the pharmacy. In addition, some CareMed employees allegedly falsified patients ’ medical information in order to obtain PAs.

E. CareCore

Finally, a recent settlement demonstrates the challenges that payers face when they establish PA requirements. In May 2017, CareCore National LLC (“ CareCore”), a benefits management company, agreed to pay $54 million to resolve a False Claims Act investigation with the U.S. Attorney's Office for the Southern District of New York. CareCore reviewed PAs for diagnostic procedures for a number of insurers, including Medicare and Medicaid's managed care programs. CareCore was contractually obligated to process PA requests in a timely fashion. The government alleged that, due to a large number of PA requests, CareCore improperly approved between 200,000 and 300,000 PAs without having appropriate medical personnel review and authorize the requests.

III. Government Regulatory Efforts to Address PA Manipulation

While the DOJ brought enforcement actions to address PA manipulation, the HHS has attempted to address the problem of overutilization by imposing PA requirements in health-care sectors that are vulnerable to abuse. For instance, in 2012, responding to concerns about overutilization of power mobility devices, the CMS launched a PA program for devices in seven states. The government reported that, as a result of this measure, federal expenditures for power mobility devices decreased. In the wake of that success, the CMS launched several more PA demonstration projects for other designated health services.

A. Nonemergent Ambulance Services

Encouraged by the apparent success of the power mobility device PA program, the CMS once again turned to PAs in December 2014 to attempt to contain costs associated with overutilization of nonemergent ambulance transportation services. “Phase I” of the program applied in three states. “ Phase II” of the program involved an expansion to six additional states under Section 515 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The demonstration requires all repetitive scheduled nonemergent ambulance transports to complete a PA, or claims will be stopped for pre-payment review. After imposing this requirement, the CMS reported that spending on scheduled ambulance trips dropped from $18.9 million in 2014 to $5.4 million in 2015.

B. Home Health

More recently, in 2016, the CMS introduced the Pre-Claim Review Demonstration for Home Health Services, citing, among other things, a 59 percent error rate among home health claims. Under this demonstration, home health agencies (HHAs) submit their documentation for pre-claim review, and the CMS responds with a coverage decision within 10 days. Through this process, the CMS hoped to “educate HHAs on what documentation is required and encourage them to submit the correct documentation …” The CMS has stated that, unlike a true PA program, the pre-claim submission process in the HHA program does not stop care from being provided, but rather merely reviews the services provided after the fact. This program has had mixed success. In 2017, the CMS halted the program's expansion, after providers complained about a range of issues involving the program's administration, including a lack of organization and consistency from the CMS, and the administrative burden involved with submission of pre-claim documentation.

IV. Lessons Learned

Government and private insurers clearly believe that PA requirements have yielded substantial savings and reduced expenditures. Moreover, in the wake of the opioid crisis, government and private insurers have announced new PA requirements prior to approving opioid prescriptions. Thus, providers and patients will continue to be frustrated by the administrative complexities involved with getting prescriptions approved. Indeed, the paperwork burden

on providers to get PAs approved has been a common thread through the DOJ enforcement actions described above: pharmaceutical representatives, under pressure to get sales, tell physicians that if they simply prescribe the drug, the representative will "take care" of the PA.

It is apparent from the recent and widespread enforcement activity in this space—spanning companies doing business in Arizona, New Jersey, Philadelphia, Chicago, and Long Island—that this is a high risk area for manufacturers and providers. "Assisting" a clinician with a PA—beyond, say, simply furnishing a PA form and explaining the process, exposes a manufacturer to potential false claims, HIPAA violations, and fraud enforcement. Similarly, from the provider's perspective, while it may seem innocuous to allow an industry representative to assist with the PA process, red flags should go up any time an arrangement is suggested that would cause protected health information to leave a medical office. Moreover, providers should always confirm that any PA, letter or certificate of medical necessity, or any other document bearing his or her signature, contains truthful information concerning the patient's condition and medical history.

Finally, some health-care companies in recent years have reassessed traditional compensation models to de-emphasize incentive-based payments. Indeed, the DOJ has insisted in some recent plea and settlement agreements that companies abandon incentive-based compensation to varying degrees. More broadly, the American health-care industry is undergoing a dramatic shift from the volume-based, fee for service payment methodology that has been in place for decades to a value-based paradigm in which clinicians are compensated based in part upon the quality of their patients' health-care outcomes. Many physicians and other practitioners are successfully navigating the gradual shift from volume to value as managed care, through vehicles such as accountable care organizations continues to become more prevalent. Aligning the goals of sales representatives with their physician and patient customers could fundamentally change the way that pharmaceutical sales staff approach their work, and reduce the temptation to fraudulently produce higher sales numbers—including by falsifying PAs.

Conclusion

There is little doubt that PAs are here to stay. Health-care providers, medical device manufacturers, pharmaceutical companies and their counsel should be aware of this trend, as well as any plan-specific PA requirements. Moreover, through a number of high-profile enforcement actions and policy initiatives, the federal government has demonstrated that PAs will be a prominent feature of the health-care landscape for the foreseeable future, and abuse will not be tolerated. Manufacturers and providers should stress-test their compliance programs to ensure that their employees are aware of PA requirements and not improperly accessing confidential patient information and/or making misrepresentations to the government or private insurers in connection with PA submissions.