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Compliance considerations for manufacturer prior authorization programs

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Patient access to many therapies is constrained by limitations on coverage imposed by third-party payers. Prior to receiving an expensive therapy, to achieve certainty as to coverage, a patient may choose, or be compelled, as a condition of coverage, to seek prior authorization from their payer. This process can be complicated, and patients and providers may be ill-equipped or disinclined to navigate it. Consequently, many device and pharmaceutical companies run prior authorization support programs designed to help navigate the prior authorization process. In connection with these programs, manufacturers seek patient and provider permission and cooperation to advocate on behalf of patients for coverage from payers.

Before coverage parameters are well established by a payer (e.g., through a coverage policy or practice), manufacturer involvement facilitates the provision of healthcare economic information to the payer about the product and serves as a mechanism to allow the manufacturer to advocate for favorable coverage in the particular and more generally. Once coverage is well established, these programs seek to remove barriers to access by employing knowledge about payer approaches to coverage and resources to navigate payer processes. In short, these manufacturer-sponsored prior authorization programs allow manufacturers to use their resources and expertise to advocate for competitive, consistent, and timely coverage of their products and are particularly important in establishing and maintaining access to broad coverage for innovative, expensive therapies with restrictive coverage policies.

Manufactures have an evident, legitimate self-interest in running prior authorization support programs. They are motivated by a proper purpose: to establish and assure continuing and competitive third-party payer coverage for their products. Indeed, Section 502(a) of the Federal Food, Drug, and Cosmetic Act[1] recognizes a manufacturer's role in providing to payers truthful and accurate healthcare economic information about their drugs to make coverage and reimbursement decisions, which the United States Food and Drug Administration also expands to devices.[2] Without competitive and predictable coverage, initial adoption by providers may be dissuaded. Providers may shy away from recommending products with unpredictable coverage, as well as from products with place-of-service restrictions or reimbursement rates that make them less attractive to use than existing therapies. Thus, manufacturers have a strong interest in being involved in establishing coverage and its parameters, and prior authorization programs give them an avenue to do so.

Manufacturers' interests in facilitating prior authorization may continue even after predictable coverage is achieved. The burden of seeking prior authorization may interfere with patient access to the product. This particularly is the case for products that require a great deal of effort in order to obtain prior authorization. For

some products, with some payers, it is not uncommon for the process to routinely involve not only seeking prior authorization, but also appealing a negative decision through the payer's appeals process. Providers and patients are unlikely to have the resources, expertise, or incentives to pursue these burdensome processes.

Facilitating coverage benefits manufacturers and patients by providing a clear path for patients to obtain access to new healthcare therapies. Without clear coverage, even new therapies that are more efficacious or efficient than the old may never be widely adopted. Providers, on the other hand, benefit from these programs only incidentally and incrementally. Providers may not profit from using any particular product and can often achieve the same financial result for themselves by substituting another item or service. As well, providers normally invest only limited resources in obtaining prior authorization, likely not materially different than those required of them to assist a manufacturer-sponsored prior authorization program. Accordingly, these programs may not, in fact, relieve providers of any costs they otherwise would be expected to incur.

In this article, we detail the key legal risks for manufacturers and providers posed by manufacturer-sponsored prior authorization programs and explore how these programs can be structured in a compliant manner.

Avoiding fraudulent misrepresentation

Through their prior authorization programs, manufacturers advocate to payers for coverage. This process necessarily involves giving information about medical necessity to the payer. When the prior authorization team, rather than the provider, is the source of that information, opportunities for obfuscation and misdirection occur, with the resultant possibility that those who engage or assist in misrepresentation may be liable for submitting or assisting in the submission of false claims. For example, the pharmaceutical company Insys recently entered into a settlement with the federal government with respect to its promotional practices related to its opioid, Subsys.[3] Part of the alleged scheme involved the Insys prior authorization program's efforts to obtain approval for coverage of the drug. These efforts allegedly involved a number of problematic behaviors, including presenting misleading information regarding the patient's diagnosis, obscuring the fact that it was Insys rather than the provider who was seeking prior authorization, and pressuring the prior authorization team to meet success targets for authorization.

In this regard, manufacturers should operate, and providers should participate, in prior authorization programs that are subject to the following guardrails:

- Information regarding the patient's condition should be supplied by providers, not the manufacturer. Any standardized suggestions for describing the patient's condition should be vetted by each of the participant's legal advisors to assure that they do not contain misrepresentations and are not misleading by dint of omission of material facts.
- The manufacturer's team should clearly identify who they are to payers. Taking this step may mean that the team will need to document to the payer that the manufacturer has been authorized by the provider and/or patient to represent them in this way. Accordingly, the manufacturer should confirm that it actually has consent from the patient or provider to advocate on their behalf.
- The team should not be pressured or incentivized to meet approval targets. Because an incentive to obtain approval is ultimately unavoidable, the manufacturer should audit the team's activities to ensure that they are compliant with any established guardrails.

Compliance with the Anti-Kickback Statute

Prior authorization programs also have the potential to implicate the federal Anti-Kickback Statute. Indeed, in

connection with the Insys indictment, the Department of Justice recently announced an indictment of a physician, alleging, in part, that Insys provided him improper inducements to prescribe Subsys by, among other things, hiring close personal affiliates of the doctor "to work as an Insys liaison to facilitate the approval of insurance forms for Subsys, including those submitted for Medicare patients."[4] Thus, the prior authorization program provided a close associate of the doctor with an opportunity to profit, presumably, for the purpose of currying favor with the prescribers. While not evidently a feature of the Insys case, it is possible that the provision of a prior authorization program—to the extent that it is seen as relieving providers from obligations they would otherwise have—could be seen as an improper inducement to patients or providers to purchase the subject product.

The three[5] Office of Inspector General (OIG) opinions[6] dealing with the question of whether prior authorization programs implicate the Anti-Kickback Statute all relate to imaging services.[7] Specifically, they focus on the question of whether a provider of imaging services, if it provides prior authorization services, by so doing is inducing referrals from the provider ordering the services from the imaging facility by assuming this obligation. These opinions generally conclude that the provision of these services could implicate the statute if they result in relieving the referring physician from an administrative burden the physician would otherwise incur. However, when certain features are in evidence, the OIG concludes that the arrangements present a low potential for abuse. These features include that the program is:

- Made available on an equal basis to all patients and physicians, without regard to any physician's overall volume or value of expected or past referrals, so that the program does not appear to be used to reward referrals;
- Not coupled with a guarantee to physicians or patients that its preauthorization service would result in preauthorization being approved, and thus does not encourage overuse;
- Operates transparently, in that the prior authorization personnel identify themselves to payers as representatives of their employer and disclose to payers the nature of the program; and,
- Pursuant to a legitimate business interest in offering uniform preauthorization services. In this regard, the OIG observes that: "Whereas insurers may place responsibility for preauthorization on imaging providers, referring physicians, or patients, *only Requestor's payments are at stake.* Requestor's financial interest in ensuring that preauthorization is diligently pursued provides a rationale for the Proposed Arrangement wholly distinct from a scheme to curry favor with referral sources" (emphasis added). (The OIG opinions addressing prior authorization programs also pointed out that the arrangement had no payments to, or ancillary agreements with, referral sources and that the requester would only submit documents provided by the physician or patient to payers. In addition, the OIG pointed out that requester would comply with all state and federal privacy laws in the conduct of its preauthorization services, and that requester would provide the physician with a copy of the information it submits to payers in connection with the preauthorization.)

To increase the defensibility of their prior authorization programs, manufacturers should integrate all of these features into their prior authorization programs, as well as avoid employing people close to providers (i.e., to provide prior authorization services, as Insys was alleged to have done).

It is important to note that, unlike the imaging provider–sponsored programs in the OIG opinion cited above, manufacturer-sponsored programs cannot claim to have the only financial interest in obtaining payment. With due regard to our observation that provider financial interests in obtaining coverage for any particular therapy may not be very strong, at least in general, providers can be seen as benefitting from positive coverage decisions

in that they will get paid as a consequence. This fact makes it critical that the programs be administered in a way that underscores their proper purpose and ensures that there is no indication that the program is being used as an improper inducement.

Specifically, for evident Anti-Kickback Statute compliance, we think that a manufacturer-sponsored prior authorization program should at least embody the following features.

A clear mission statement that is revaluated periodically

The mission of imaging providers—to get themselves paid—is self-evident, whereas the mission of the manufacturer is not as commonly understood. Given the central role that intent plays in Anti-Kickback cases, manufacturers should start with a mission statement that clearly articulates the purpose of the program. For new products, a manufacturer's interest would be to establish coverage of its product so as to facilitate patient access. A manufacturer's interest is most evident when coverage is not well established, and providers would not be expected to mount the type of effort that is required to establish routine, comprehensive coverage. Thus, the program should be tailored to support this goal and should be reevaluated once coverage is well established in order to determine whether the company maintains a bona fide independent interest in such a program.

Even once coverage is well established, it would seem that a manufacturer could have a legitimate interest in running a prior authorization program for at least as long as prior authorization barriers are so burdensome that they operate to effectively prevent use even when therapy is indicated. For many products, in many situations, that may be as long as providers and patients would not be expected to overcome them in the normal course. That said, we think that for resource conservation, as well as risk mitigation, companies should revisit the need for their prior authorization programs on a regular basis.

Offer the program to patients not providers

The OIG's amenability to the imaging provider–run prior authorization programs seems to be predicated, at least in part, on the observation that providers are not obliged to seek prior authorization. (According to the OIG, "In the majority of cases—given the multitude of insurance plans and plan requirements—Requestor is unlikely to know a physician's obligations with respect to an order for a particular patient. Where Requestor may unwittingly relieve some physicians of their pre-authorization obligations, such relief would occur by chance, not design.") Nonetheless, manufacturers often position their programs as a service to providers, including by entering into business associate agreements with providers. Business associate agreements position the program as providing services *on behalf* of the provider, which is precisely the characterization the program should seek to avoid.

The program's mission should be to remove barriers to access to the manufacturer's product in the interest of increased patient access—while inducements to patients are also problematic, it is unlikely that a prior authorization program that is not advertised to patients, and is offered after the fact of a prescription for the precise product, would be seen as such. All program-related materials should make it clear that this, and not relieving providers of a burden, is the objective. So, for example, prior authorization programs should access private patient data by asking that patients sign a Health Insurance Portability and Accountability Act–compliant authorization to share their records with the manufacturer operating the program, rather than by entering into a business associate agreement with the provider. A patient authorization avoids the complication of that characterization as well as the need to assume the responsibilities of a business associate. This authorization can also encompass an appointment of the prior authorization service as the patient's advocate for the purpose of engaging with payers, which should address some payer concerns and requirements.

Avoid the assumption of provider duties

Relatedly, the program should be designed to avoid assuming traditional back-office provider functions. We recommend that, to the extent possible, any records production and, as much as practical, any paperwork-related obligations remain the responsibility of the providers. Doing this also serves the goal of ensuring that prior authorization staff are minimally involved in characterizing the patient's condition, and thus there is less of an opportunity for misrepresentation.

Make the program available to all

Also, to make it clear that the program is not being used as an inducement, it should be available to all patients without regard to the volume or value of business conducted by their provider and should not extend any guarantees of coverage.

Explicitly disclaim any guarantee of success

Guarantees of success can be seen as improper inducements in their own right. (For instance, the OIG pointed out in an advisory opinion that requester certified that it would make no assurances to physicians or patients that the preauthorization would be approved.) Also, to the extent that a patient or provider were to rely on a manufacturer's guarantees of success in obtaining coverage, the manufacturer may find itself with contractual liability to them.

Conclusion

While these general guardrails should go a long way to provide a defense for a prior authorization program, the specific implementation of each instance should be reviewed by counsel for any additional nuances that may inadvertently undermine an otherwise defensible program.

Takeaways

- Manufactures have a legitimate self-interest in running prior authorization support programs to establish and assure continuing and competitive third-party payer coverage for their products.
- If not carefully structured, programs otherwise meant for proper purposes could inadvertently encourage misrepresentation or be seen by the Office of Inspector General as implicating the federal Anti-Kickback Statute.
- Programs should be designed to minimize risk of misunderstanding and misrepresentation through transparency, solid record keeping, and not incentivizing approval targets.
- Risk can be further minimized by having a clear mission statement, a patient-centered focus, and broad availability, while avoiding assumption of provider duties and guarantees.
- Prior authorization programs should be reviewed on a case-by-case basis, as each program is unique to the product and the product's reimbursement scheme.

1 21 U.S.C. § 352.
2 U.S. Department of Health & Human Services, U.S. Food and Drug Administration, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers: Guidance for Industry and Review Staff," June 2018, https://bit.ly/3aejDQf.

3 U.S. Department of Justice, "Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations," news release, June 5, 2019, http://bit.ly/3b3tiIw.
4 U.S. Department of Justice, "Sarasota Pain Doctor And Former Insys Sales Representative Charged In Health Care Fraud Kickback Conspiracy," news release, September 16, 2020, http://bit.ly/3s03fJp.
5 U.S. Department of Health & Human Services, Office of Inspector General, "OIG Advisory Opinion No. 10-04," May 6, 2010, https://bit.ly/3qva9pm.
6 U.S. Department of Health & Human Services, Office of Inspector General, "OIG Advisory Opinion No. 10-20," September 28, 2010, https://bit.ly/3qDJAyg.
7 U.S. Department of Health & Human Services, Office of Inspector General, "OIG Advisory Opinion No. 12-10," August 23, 2012, https://bit.ly/2OAWsaF.