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On Healthcare

HEALTHCARE

THE IMPACT OF MANUFACTURER-SPONSORED PATIENT SERVICE PROGRAMS

Announcer: Welcome to Navigant On Healthcare, offering insights for healthcare leaders striving for success in an evolving industry.

Host: Welcome to Navigant On Healthcare. I am your host, Alven Weil, and today we will discuss the impact of patient assistance programs and related hub services, which have come under some scrutiny recently. Joining us today are Casey Horton and Dana Edwards. Casey is Navigant's life sciences director of governance, risk management and compliance. He leads numerous risks, compliance and operational improvement projects in the U.S., and more than 60 other countries. Casey brings deep experience and knowledge of compliance program development, corporate integrity agreements, execution of compliance and enterprise risk assessments, global monitoring initiatives and third-party, due diligence review programs. Casey also leads some of Navigant's efforts around setting up compliance patient assistance programs.

Dana is Navigant's life sciences director of programs and services, leading Navigant's service line for patient services including patient assistant programs and hub services. She brings more than 20 years of experience in administration and oversight of these types of programs. Casey and Dana, welcome.

Patient assistance programs and hub services have come under some scrutiny recently. As a brief introduction to our listeners, can you provide an overview of how patient assistance programs are designed to work, as well as some of the recent changes, specifically enforcement and the new corporate integrity grievance?

Casey Horton: Sure. Well, thanks, Alven. With medicines getting more and more specialized and the costs increasing, the method of delivery of these products is becoming much more complicated than just popping a pill. There's injections and infusions, pens, and the like, and patients need a lot more assistance in using those, as well as paying for them. So, to assist with these challenges, manufacturers have been developing programs to assist both patients and the healthcare professionals that

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About Navigant

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prescribe the products. Some of these programs can include a variety of different activities, such as reimbursement support or fast start programs — also some education programs, both in person for the patient and the healthcare professional, or over the phone, just to name a few of the of these activities.

As you may have heard, there has recently been some enforcement related to manufacturers' relationships with charitable co-pay foundations. These foundations, which are supported by the manufacturers, have been put into place to help uninsured and under insured patients pay for these expensive medications, which in itself sounds like a good thing. But, while companies may donate to independent nonprofits who provide co-pay assistance, in these settlements, the government is alleging that the manufacturers used these arrangements with the charities as conduits to pay for patient co-pays. And drug manufacturers are prohibited from subsidizing co-payments to patients that are involved in federal healthcare programs such as Medicare. That's why these have become an issue.

Host: From an operational perspective, what are some specific elements that a company should think about when setting up a patient hub?

Dana Edwards: So, at a high level, the three areas of focus that companies should consider when setting up these services are one: the type of product, that's whether it's a medical benefit or pharmacy benefit, route of administration, or other product nuances. They should also take into account a patient's journey with consideration to the five dimensions of adherence, including disease state, how the therapy fits into the overall regimen, how system factors, as well as patient and socioeconomic factors. Finally, the third area are the provider/stakeholders. Thinking about the specialty and the level of education, or support required, as they introduce their brand.

Then, at a more tactical level, companies need to think through customer access, or how customers will initiate those services and that includes things like provider portals, websites, phone numbers, fax numbers, programs set up to support compliant operations. And that includes things like establishing standard operating procedures, setting up your database, or CRM, to support execution of services, as well as reporting. And then, staff training including both clinical and operational training. And then, from a communication and marketing planning, you should be thinking about education for your field team as well as promotion to your customers.

Host: So, the industry has seen both patient assistance programs and patient support programs. Can you explain the difference between these two?

Casey: Well, as I always tell my clients in this space, definitions are important. Out of all the clients that I've worked with and the companies that I've worked with, I've never seen two companies group the same activities under the same heading. But, in general, patient assistance programs refer to activities that assist the patient in getting the product. Patient support programs are generally programs that help to educate the patient and in some case the providers on the product and the overall disease state. Some of those examples are dosing and delivery of the product and information on managing an overall disease state. Diabetes is one in the U.S. that's a really good example of a more complicated product that is starting to be more widely used around the country.

Host: So, Casey, how do hub services fit in then?

Casey: Many manufacturers have set up patient hubs where all of the patient-focused activities within the company are managed. Then, in some cases, some of those activities companies have chosen to outsource to third party vendors who may be able to execute those more efficiently on the manufacturer's behalf.

Host: Now, what services are available to patients through these types of programs?

Dana: These programs typically provide a range of services that support patient access to therapy, and that includes reimbursement support to help the patients navigate their insurance coverage to get on therapy and could include services like benefit investigation to research a patient's policy for coverage, prior authorization to support appropriate authorization for coverage or appeal support to help when things are denied. And they can also include a fast start or bridge program. And those programs are designed to help patients initiate therapy quickly while working through access challenges. Patient assistance, and that could be in the form of free products for uninsured patients, or in the form of financial assistance, or co-pay assistance for under insured patients, as well as adherence support. And that's really to help the patients initiate and stay on therapy. And that could include things like welcome calls, educational calls, or other touch points through the duration of therapy to help patients remain on therapy.

Host: Now, how do you determine that hub services vendors are following your policies?

Casey: One of the keys to making sure that these vendors are acting in a compliant manner is to first make sure that they're adequately trained on the manufacturer's procedures and policies. Additionally, I always recommend that the manufacturer perform an assessment or an audit of the vendor that's providing these services. These reviews should include following a case all the way through the process, from the time it goes into the hub until it's ultimately processed or paid. As well as listening to the taped recording of vendor personnel interacting with both the patient and the providers, as well as with the insurance coverage.

Host: Casey and Dana, any other information you would like to add to this discussion?

Casey: Well, just one with respect to the charitable relationships we discussed earlier, I want to be clear that these types of relationships are definitely not prohibited, but they do need to be independent in nature and that includes removing any of the decision-making responsibility relating to how a manufacturer is going to support these charitable co-pay foundations from the commercial arm of the business. These donations should not be used for commercial purpose, but rather for the broader good of the patient.

Host: Great information, Dana, Casey. Thanks so much for joining us today and sharing your expertise.

Casey: Thanks for having us.

Dana: Yes, thank you.

Announcer: That concludes today's episode. Be sure to check in with us for future installments on the Navigant On Healthcare podcast series on navigant.com/healthcarepodcast. Navigant On Healthcare is a podcast series produced by Navigant's healthcare practice. If you enjoyed this episode, please share it with friends and colleagues on social media. Learn more at navigant.com.