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Specialty Carve-Outs: What Are the Implications for Patients and Practices?

FROM THE EDITOR

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Self-insured employers, perhaps even yours, are being presented with programs called “specialty carve-outs” as an opportunity for saving significant money on the drug portion of their employee benefits. Unfortunately, they are being told that there are “specialty funding” and “lower cost drug options” without being told the full story. As a result, these programs are exposing companies, employees, and patients to significant risks.

Tempting Programs for Self-Insured Employers

The sales pitch from specialty carve-out brokers is very tempting. Specialty drugs comprise almost 50% of a health plan’s total drug spend, and the pipeline is growing. The National Alliance for Healthcare Purchaser Coalitions (NAHPC) reports that while 1.2% of all health plan members are high-cost claimants, they make up one-third of total healthcare spending. Michael Thompson, NAHPC’s President and Chief Executive Officer, notes that “high-cost claims are the biggest threat to employer-sponsored healthcare coverage today. Only through collective employer action can these risks be mitigated.”[1]

How Does a Specialty Carve-Out Program Work?

Each year, self-insured employers work with their third-party administrators, brokers, and other agents to review previous and projected healthcare expenditures, and then they look for opportunities to mitigate their projected expenditures. The specialty carve-out solutions (also known as alternative funding programs) presented to these concerned employers simply eliminate coverage for specific, or in some cases all, specialty drugs. The third-party vendors promote the availability of specialty drug funding and lower cost options to the employer. Then, when an employee discovers that that they are not insured for the treatment they need, they are referred to the contracted specialty carve-out program, which seeks alternative methods to obtain the necessary drugs at little to no cost to the employer (and usually waives any costs to the employee). These alternative methods include searching for funding and medications from patient assistance programs (PAPs) and foundations, as well as sourcing prescriptions from countries other than the United States.

The employer is persuaded to exclude some or all specialty drugs from the employee benefit plan formulary and allow those claims to be administered by a third-party vendor that is often separate from the commercial plan's medical or pharmacy benefit manager. These vendors collect income and other demographics from the now "uninsured" employee and present the situation to

PAPs. If they are successful, the drugs are provided through the manufacturer's charitable program or funded through a charitable foundation, at no cost to the employer or employee. The third-party vendor then collects a fee ranging from 20% to 30% of the drug's full list price, or a fixed per-employee, per-month amount for "saving" the employer on its specialty drug obligations.

How These Programs Affect Employees and Providers

Employees are told that signing up with these "preferred" vendors may be mandatory. Marketing materials and benefit letters tout the possibility of obtaining expensive drugs at a sharply reduced cost or no cost at all. However, if employees do not use the program to obtain these drugs, they will be held liable for up to the full amount of the drug manufacturer's PAP limits, meaning they could be expected to pay as much as $20,000 or $30,000 per month. These penalty payments would not be applied to their insurance deductibles or co-insurance requirements.

If employees *do* enroll and use a third-party vendor, they will be expected to receive the drugs either through direct shipment (both brown-bagging [home] and white-bagging [physician's office]) or from whichever source the vendor chooses, such as an unknown distributor or even an imported drug from outside

of the country. Delivery times may range from a few days to 5 to 7 weeks, depending on the source. To make matters worse, refrigerated product delivery is complicated and not easily controlled.

When patients are told that they must participate in these types of third-party programs, the provider is also affected. The drug may be brown-bag shipped to the patient or white-bag shipped to the provider. If the provider chooses not to use a drug shipped from an unknown source or country, the patient is forced to choose to either decline participation in the program (with the financial penalties discussed earlier) or find an alternate provider who will accept the conditions of the program. In the fine print of the client documents for some of these vendors, there is added language specifying that patients must contact their physician if they have any unexpected side effects from medications ordered through that vendor, which would be a source not known to (or trusted by) the physician, and possibly imported wholesale against current US law.

Several providers have already reported to me their serious concerns regarding the health and safety of their patients because of these programs. These include the following:

- Patients are being told that they are not actually insured

- Patients and providers must wait for the vendor to go through their internal enrollment and implementation process
- Patients are experiencing significant stress after being told they may not receive the treatment that their physician recommends, from a source that their physician trusts
- Patients and providers are facing the financial consequences of not using the third-party vendors
- Providers are experiencing uncertainty regarding patients' benefits coverage when it was assumed that they were fully insured under their employer's benefit plan.

Egregious Aspects of Specialty Carve-Out Programs

Essential Health Benefits Are Being Denied

The Patient Protection and Affordable Care Act (ACA) requires individual and small group markets to cover 10 essential health benefits, including ambulatory patient services, prescription drugs, and preventative and wellness services and chronic disease management.[2]

Specialty carve-out vendors improperly designate one or more specialty prescription drugs as a "nonessential" health benefit and therefore not subject to the ACA's essential health benefit limits on the consumer's annual out-of-pocket costs. The vendors then declare that they are able to charge patients penalties for nonparticipation in their programs equal to the full amount of patient assistance available through the drug manufacturer's PAP and refuse to count those penalty copays towards the consumer's annual deductible and out-of-pocket costs.

Illegal Wholesale Importation of Drugs into the United States

The US Food & Drug Administration (FDA) guidance on importation of drugs into the United States asserts that in most circumstances, it is illegal for individuals to import drugs into the country for personal use.[3] "The Federal Food, Drug and Cosmetic Act prohibits the interstate shipment of "unapproved drugs," which includes the importation of unapproved drugs from outside of the United States. Unapproved drugs include those not manufactured according to FDA standards."[4-6]

If a drug has not been FDA-approved for use in the United States, even if it has been approved in another country, it is illegal to import because the FDA cannot ensure its safety and efficacy.[3] However, the FDA does not typically object to the

personal importation of drugs—even those that it has not approved—in the following specific scenarios.[3]

- The drug is being used for a serious condition for which effective treatment is not available in the United States
- There is no commercialization or promotion of the drug to US residents
- The drug is considered to not represent an unreasonable risk
- The individual importing the drug verifies in writing that it is for his or her own use, and provides contact information for the physician providing treatment or shows the product is for the continuation of treatment initiated in another country
- Generally, not more than a 3-month supply of the drug is imported.

However, specialty carve-out vendors are engaging in wholesale importation of massive quantities of prescription drugs—without reference to pedigree or sourcing—from countries such as Canada, India, and Australia. One justification that I have personally heard from a vendor is that, yes, it is technically illegal, but "a blind eye is turned on the practice because drugs in the United States are too costly, and the importation is justified because of the savings on drug costs to employers and employees."

Employers and employees are made aware of potential cost-savings, but not the significant medical risks associated with turning to illegally imported drugs. Physicians cannot accept the risk of administering prescription drugs to vulnerable patients without knowing and trusting that those drugs have been legally and ethically sourced with a responsible pedigree.

Draining Already Limited Support for Needy Patients

When specialty carve-out programs deliberately block employed patients from coverage for a specific drug or illness, they are also targeting other vulnerable patients. PAPs and foundation programs set aside limited funds for needy patients. By draining PAPs and foundation support for their customers, these vendors are putting the PAP and foundation programs themselves at risk for no longer being able to help those for whom they were established to serve.

"Bait and Switch" Insurance Health Coverage

When a self-insured employer allows a third-party vendor to determine that specific prescription drugs are not covered, there is usually no advance notification given to the employee, who will be directly affected. Employees usually discover that the drugs they need will not be covered when they receive a "no coverage" notice upon their diagnosis and planned treatment. Then, they are

told to enroll in the third-party vendor program and provide detailed financial and personal information so that the vendor can pursue alternative funding. Promises are made that the treatment may become available at minimal or no cost to the employee. However, if the third-party vendor is unsuccessful in obtaining alternative funding or the necessary drug, the employee is frequently suddenly returned to the regular insurance health benefit and given the coverage that they thought they had all along before being deemed "uncovered." This "bait and switch" is very concerning to employers, employees, state insurance regulators, and consumer advocacy groups.

Who Are the Third-Party Vendors?

Unfortunately, this is a growing business niche with a compelling story of cost-savings if one does not look too deeply into the details (which many employers and employees have not done). It may be difficult to detect the presence of third-party vendors because most providers are not accustomed to employed and insured patients receiving wholesale denials from their employers. Furthermore, foundations and PAPs are not accustomed to questioning whether a statement of a patient being uninsured for a drug is driven by actually having no insurance at all, or if it is an employed patient who may now be uninsured for a targeted drug. If you are a self-insured employer, your broker may already have made one of these programs part of your own insurance plan.

Some of these companies include ImpaxRx, PaydHealth, PayerMatrix, RxFree4me, SHARx, SavOnSP, ScriptSourcing, and at least a dozen more. Their public websites tout the potential savings but are fairly sparse on the details of how the process works or where the savings and drugs come from. I was able to dig deep into the Internet and find YouTube marketing segments, as well as actual contracts with clients, which reveal the flaws in these programs.

What Are the Next Steps?

We need to protect our patients. These programs offer a compelling message about savings but fail to present the dark side, namely, the potential for patient harm, confusion, and coercion; unnecessary treatment delays; the legal and ethical challenges of drug importation; bait and switch insurance coverage games; and the danger of draining funds from PAPs and foundations. I have already heard from foundations and manufacturers that are seeing dramatic increases in the demands for their limited patient support. At least one manufacturer has recently posted changes to its PAPs that limit coverage to unemployed patients.

We can take the following steps to protect our patients:

- Become aware of the existence of these programs and track their impact in our own practices

- Document diseases, drugs, employers, unions, and clients affected by these vendors
- Document adverse consequences for patients as they are forced through the process, rates of substitution, medication sources, frequency of recoverage for patients
- Track white-bagging and brown-bagging program demands and related communications to physicians and patients under these programs
- Align with state oncology societies, the National Oncology State Network, and other organizations to address these talking points and issues.

If you see something, say something. I welcome your comments and can be reached at **dawnho@aol.com**. I am actively working with several organizations and partners to challenge these programs, and would appreciate observations from affected practices, foundations, manufacturers, and patients.

Sources for drug funding are limited and exist for patients who are truly in need. The business model of these specialty carve-out vendors is to bill employers for "savings generated" by selectively uninsuring treatments for specific diseases, orphan diseases and cancer for otherwise-insured employed patients, and grabbing monies set aside for charitable purposes or importing lower cost drugs illegally from outside the United States in the name of saving employers money on their drug spend. This violates the intent of Essential Health Benefit

designation, drains limited funds away from more needy ill patients, and targets people at their most vulnerable. It is my hope that useful feedback and guidance may help to mitigate the impact of these vendors and help employers understand the risks and adverse consequences of these programs.

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