When Is a Brand a Generic? In a Contract With a PBM

When a health plan contracts with a PBM, it should insist on strict definitions of brand drug and generic drug, an experienced negotiator advises

By Linda J. Cahn

Samuel Goldwyn famously quipped: "A verbal contract isn't worth the paper it's written on." Well sometimes PBM/client contracts aren't worth the paper they are written on. And that's no joke.

We can show this by looking at contract definitions of two terms — brand drug and generic drug. For, unbeknownst to most pharmacy benefit manager clients, many PBMs are manipulating these two contract definitions and thereby eviscerating the contract's utility for their clients.

Fortunately, it's not that difficult to understand what PBMs are doing, or how to draft airtight definitions of "brand drug" and "generic drug" to prevent PBMs from manipulating the contract. Nor is it particularly hard to require PBMs to accept airtight contract definitions, if the clients use their RFP (request for proposals) leverage to do so.

In this article, we use the term "PBM clients" to identify any entities that arrange prescription drug coverage through PBMs, including health plans, employers, unions, and government entities.

Ambiguous definitions

Nearly all PBM contracts begin with a definition section.

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Sometimes it contains no definitions whatsoever for "brand drug" or "generic drug." When there are no definitions, PBMs are free to interpret both terms in any way they choose.

Typically, the definition section defines one or both terms, but a PBM drafts the definitions to enable it to classify many drugs in any manner it chooses.

Here are two typical definitions found in many PBM contracts:

> **Brand drug:** The term "brand drug" shall mean any covered product that is not a generic drug.
> **Generic drug:** The term "generic drug" shall mean a multisource drug set forth in First DataBank's National Drug Data File, or some other nationally recognized source, as reasonably determined by the PBM, that is available in sufficient supply from multiple FDA-approved generic manufacturers of such drugs.

Under these definitions, a PBM is certain to categorize all single-source generics as brands — not generics.

Moreover, a PBM is free to categorize any multisource drug as a brand drug as long as the drug does not have, in the PBM's view, sufficient supply, or if the PBM wants to stretch its interpretation, sufficient suppliers. But what constitutes sufficient suppliers? Two? Three? Five or perhaps even six? Your guess is as good as mine, and of course, neither guess matters.

In fact, all that matters is that the PBM may select any number as its magical "sufficient supply" or "sufficient supplier" number, and may change that magical number whenever and however it decides to do so. As a result, clients with such contract definitions may find large numbers of drugs classified in ways that are illogical and unexpected.

A similar result may occur with the following commonly used PBM contract approach:

> **Drug classification:** The PBM shall use Medi-Span Master Drug Database indicators and their associated files, or indicators provided by another nationally available reporting service of pharmaceutical drug information, in helping to determine the classification of drugs (e.g., prescription vs. over–the-counter, brand vs. generic, single-source vs. multisource) for purposes of this agreement.

Under this definition, PBMs can use whatever indicators they choose, from whatever national reporting service they want, to "help" them reach whatever conclusion they want to reach about drug classification. Note that the unidentified indicators are not necessarily even determinative — they will only be used to "help" the PBM make its decisions.


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Variable definitions

Not only do PBMs' contract definitions (or lack thereof) of "brand drug" and "generic drug" allow them to misclassify drugs, but most of their contracts allow them to classify drugs for one purpose in one way, and for another purpose in another way.

Thus, when it is in the PBMs' interests to classify more drugs as brands — for instance, when determining how to invoice clients — they use their ambiguous definitions to shift more drugs into the brand category.

However, when it is in PBMs' interests to classify more drugs as generics, they magically recharacterize the drugs as generics. For example, PBMs wanting to make their generic substitution rate appear greater reclassify drugs that they invoiced as brands as generics when calculating the number of generic drugs dispensed. Similarly, if a contract calls for a PBM to pay a specified rebate "per brand drug claim," it can reclassify drugs that were invoiced as brands as generics for the purpose of calculating rebates.

Note that PBMs can also classify drugs differently at different points during the life of a contract. Thus, at the beginning of a contract, a PBM might classify all "authorized generics" as generic drugs for invoicing purposes. But some months thereafter, given the ambiguous contract definitions found in nearly all contracts, a PBM might recharacterize all authorized generics as brands. Similarly, a PBM might initially classify as generics all multisource drugs with two or more suppliers, but some months into the contract, it might decide to change its classification method for the client and require that multisource drugs have three or more suppliers to be characterized as generics.

Why can PBMs engage in such conduct? The answer is that nearly all contracts are silent about whether drug classifications must be consistent for all purposes and throughout the life of the contract. Therefore, they assert a right to classify drugs differently, for different purposes, at different times.

But do they actually have this right, given that such practices lack any integrity on their face? As a lawyer, my position is that PBMs are not legally entitled to do so, because they have not disclosed their antics to their clients, and because, arguably, the antics violate the concept of good faith and fair dealing that all contract actions must exhibit under common law.

However, the matter has not been litigated. Therefore, the jury is still out on whether this kind of conduct violates the law.

As a result, all clients of PBMs should assume that PBMs can — and do — engage in the above practices. And they should protect themselves when drafting and negotiating their own contracts with PBMs, lest their contracts be as valueless as Samuel Goldwyn's "verbal contract."

The real problem

While our discussion may appear to be hypertechnical and therefore of little consequence, PBMs' drug misclassification can eviscerate the utility of most aspects of PBM/client contracts. Here's why:

PBMs' drug classification virtually always determines their invoiced costs to clients. Drugs classified as brands contractually allow PBMs to provide relatively weak discounts (typically about AWP–12 percent to –13.5 percent). Drugs classified as generics may receive greater discounts (typically about AWP–60 percent to –70 percent). Thus, if PBMs misclassify generic drugs as brands when invoicing clients, they can charge far higher prices than they would if they categorized those drugs as generics.

Note that the AWP discounts quoted above and elsewhere in this article are based on actual AWPs, as currently reported by national reporting services, not on AWPs that PBMs adopted last year in the wake of the AWP litigation.

Moreover, the extra amounts that PBMs charge by misclassifying generics as brands may be significant. In a recent RFP that our company conducted, we quantified these extra costs for a client. We took a year of the client's claims data and classified all claims in three ways: accepting the drug classifications that appeared in the claims data from the incumbent PBM; using a PBM contestant's proposed Medi-Span definition that essentially adopted the language we had recommended; and using another PBM contestant's proposed First DataBank definition which allowed the PBM to misclassify drugs.

Not identical

We then applied the proposed AWP discounts that each of the contestants had offered, which were quite similar though not identical. The difference that resulted from each of the PBM's definitions of drugs was in the millions of dollars, or 1.2 percent of the client's total annual prescription costs, with the PBM that had accorded itself the right to reclassify drugs generating far higher costs as a result of that practice.

Besides affecting a client's aggregate drug costs, PBMs' drug misclassification enables them to falsely claim that they are satisfying brand and generic contract guarantees. For example, if PBMs discover they have not satisfied both a retail brand and a retail generic contract guarantee, they can decide to recharacterize a relatively high cost generic drug (say, with an AWP discount of 40 percent) as a brand, and thus improve their ability to satisfy both guarantees. By blending the 40 percent discount into weaker discounts for other brand drugs, say of 13 percent, PBMs can improve their aggregate brand discount. Similarly, they can facilitate their ability to satisfy their generic guarantees by removing the 40 percent discount from stronger discounts available for other generics, say 70 percent.

Moreover, because PBMs' drug misclassification can enable them to satisfy their contract guarantees more easily, when they renew their contracts with existing clients or compete to win new business, they can offer what appear to be better AWP discounts, and thus purport to provide drugs at lower prices. However, in reality, PBMs' newly offered discounts may result in no better — and perhaps even worse — aggregate prices than they previously provided. After all, by classifying more drugs for invoicing purposes as brand drugs, PBMs can engage in a smoke-and-mirrors game that enables them to provide higher discounts for both brand and generic drugs while still charging the same or even higher costs.

PBMs' ability to manipulate drug classification — and their ability to classify drugs differently, for different purposes — also enables them to pay less to clients in rebates. Since most contracts require PBMs to pay a specified rebate amount "per brand drug script," all PBMs need do is classify more drugs as generics for purposes of calculating rebates, and PBMs will thus decrease the rebates owed to their clients.

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Thus, PBMs' freedom under nearly all existing contracts to misclassify drugs — and to classify drugs differently for different purposes — potentially affects virtually every aspect of drug coverage, making contract terms, and the reporting about the satisfaction of contract terms, of little, if any, value to clients.

Demand proper definitions

The usual way of choosing a PBM is to ask the contestants a series of questions, get responses, select a finalist, and then negotiate the contract. But doing so means there is no leverage whatsoever to demand and obtain different contract terms from the PBM that has been selected.

When our company conducts an RFP for our clients, we require PBMs to negotiate and finalize contracts *before* our clients determine the finalist. We use the RFP's leverage to require all PBM contestants to replace ambiguous contract definitions with definitions we have drafted that generate accurate, predictable, and enforceable drug classification outcomes.

Our definitions require PBMs to select a specified national reporting service — either Medi-Span or First DataBank — and do not allow PBMs to cherry-pick a reporting service. Moreover, because we feel that Medi-Span's drug classification system more simply and closely replicates accurate classifications, we require PBM contestants to use Medi-Span, unless they rely entirely on First DataBank and do not purchase Medi-Span data.

Our current Medi-Span contract definitions are:

Brand drug. The term brand drug shall mean the following: The multisource code field in Medi-Span contains an "M" (co-branded product), "O" (originator brand), or an "N" (single source brand); however, if the Multisource Code is "O" and there is a DAW Code of 3, 4, 5, 6, or 9, the drug shall be considered a generic drug. The parties agree that when a drug is identified as a brand drug, it shall be considered a brand drug for all purposes under this agreement.

Generic drug. The term generic drug shall mean the following: The multisource code field in Medi-Span contains a "Y" (generic). An item shall also be considered a generic drug if the Multisource Code is "O" and there is a DAW code of 3, 4, 5, 6, or 9. The parties agree that when a drug is identified as a generic drug, it shall be considered a generic drug for all purposes under this agreement. However, the parties also agree that if the PBM is provided any rebates or other financial benefits for any drug characterized under this agreement as a generic drug, the PBM shall be obligated to pass through all such rebates and financial benefits to client.

If PBMs use First DataBank, our proposed contract definition relies on a more complex definition, currently referencing four different First DataBank information fields: GI (generic indicator), II (Innovator Indicator), GMI (generic manufacturer indicator), and GNI (generic name indicator).

While our First DataBank definition sometimes results in different and more drugs being classified as generics than our Medi-Span definition, it has the disadvantage of being more complex, since First DataBank does not have a single field that identifies a drug as being "generic."

Note that if some PBM contestants agree to classify drugs using Medi-Span, and others want to rely on First DataBank, to ensure an apples-to-apples comparison, a PBM client (or its consulting company) must analyze each of the PBMs' offers by running the client's claims data against each classification system. An additional step can also be taken, namely, inputting Medi-Span's AWPs for those PBMs using the Medi-Span definition to classify drugs, and inputting First DataBank's AWPs for those PBMs using the First DataBank definition to classify drugs, since the two reporting services do not necessarily use the same AWPs for all drugs.

Require definition adjustments

In contrast to the typical definitions in nearly all PBM/client contracts, our recommended definitions, based on specific national reporting service information fields, provide PBM clients with auditable and enforceable definitions for "brand drug" and "generic drug." However, a client may still be vulnerable to drugs being classified incorrectly if Medi-Span and/or First DataBank alter their methodology for coding drugs for any of the contractually referenced information fields. Note that a client selecting a PBM that relies on First DataBank is more vulnerable to this potential concern, since the First DataBank definition relies on far more variables than does the Medi-Span definition.

To protect against all such vulnerability, the contracts that our company drafts for clients contain the following language:

In the event the above-referenced national reporting service changes its methodology related to any of the above-referenced information fields — or its methodology for coding drugs in connection with the above-referenced information fields — PBM is obligated to inform client of such changes within 30 days of learning of the changes, and the parties will thereafter meet and agree in writing on any contract changes that may be necessary to enable the parties to maintain the same economic position and obligations as are set forth in this agreement.

Many PBMs will accept airtight definitions

Notwithstanding that almost all current PBM/client contracts lack meaningful brand drug and generic drug definitions, our company has found that many PBMs — including some larger PBMs — are willing to accept airtight contract definitions, provided that their clients and their consulting firms take the following two steps:

1. Structure RFPs to ensure that contracts are fully negotiated and executed by each semifinalist as a binding contract offer before selecting a finalist.

2. Make clear that airtight definitions for brand drug and generic drug are mandatory if a PBM is to be selected as the finalist.

By requiring contestants to bind themselves to all contract terms during RFPs — and stating clearly

that certain contract terms must be accepted if the PBMs expect to win RFPs — clients use the RFP's leverage to obtain contracts that they want, rather than have the PBMs dictate contracts.

Some PBMs may accept better contract definitions but want to insert language giving them the right to override the definitions in unspecified circumstances. Obviously, this would make the contract susceptible to manipulation and such language should therefore be rejected.

However, an override right might be acceptable if five additional requirements are satisfied:

- The PBM must identify in the contract the specific overrides that it will be entitled to exercise.
- The PBM must agree that it can only exercise its override right to classify what would otherwise have been a brand as a generic.
- The PBM must agree that if a drug is reclassified by way of an override, the re-classification will be used for all purposes under the contract.
- The PBM must agree to flag and disclose to the client all overrides in claims data.
- The PBM must be required to pass through all rebates and other third party financial benefits in connection with all drugs, including all brand drugs that are reclassified by way of overrides as generics.

Note also that not all PBMs are willing to provide airtight contract definitions. If they are not willing to do so, you might want to ask why. Their answers are likely to underscore the importance of insisting on airtight contract definitions.

Among the answers you are likely to hear is, "We need the ability to change our classification system on a daily, or at least weekly, basis; therefore, we can't possibly pin ourselves down to inflexible definitions for brand drug and generic drug."

You might respond: "My goodness! If you are changing drug classifications so often, how can we as a client possibly audit the contract guarantees that are based on drug classification unless we just accept whatever it is that you are doing to constantly reclassify drugs?"

Here's another PBM explanation you might hear: "Our method of classifying drugs is proprietary, and we do not want to give any other PBM the opportunity to discover it."

"Really," we urge you to respond, "what could you possibly be doing to classify drugs that could be so unusual that you would need to keep your methodology from being disclosed, not only to your own clients, but to competitive PBMs?"

When all PBM clients begin to demand airtight contract definitions, all PBMs will have to accept better definitions if they want to retain and increase the number of their clients.

More important, PBM clients will be taking their first step in obtaining contracts with real value.

Until then, as Samuel Goldwyn might have put it, PBM/client contracts will barely be worth the paper they are written on.

Next month, Linda Cahn will explain how health plans can maximize generic cost savings.

"You will bargain away what little integrity you have left for what little job security you can gain."