Plan sponsors can take steps to ensure that the high costs of specialty drugs are controlled as much as possible through contracts with pharmacy benefit managers (PBMs). The author discusses the definitions, pricing terms and other language that should be included in PBM contracts, including maintaining a right to carve out certain specialty drugs to alternate vendors, and how to use the request for proposal (RFP) process to get the best price guarantees.

Specialty Drugs—So Special It's Time to Control Their Costs

by Linda J. Cahn

Specialty drugs are generally defined as high-cost prescription drugs that treat complex conditions and require special handling and administration. However, the most striking aspect of specialty drugs is that few prescription coverage providers are doing anything to control the drugs' costs.

Parties paying for high-cost specialty drugs—whether private corporations, unions, government entities or insurance health plans—clearly have an interest in understanding—and changing—the status quo. This article describes how payers can do so.

Start by Understanding the Data Problem

Most payers provide and pay for specialty drugs through both their health care coverage and their prescription coverage. Unfortunately, in neither instance are payers typically controlling their specialty drug costs. Thus, it is at least feasible for payers to improve cost controls for PBM-dispensed specialty drugs, whereas it is extremely unlikely payers can control costs when specialty drugs are dispensed by health care entities. Here's why.

PBMs dispense and adjudicate specialty drugs using national drug codes (NDCs)—11-digit numbers that identify with precision the drug, dosage and package size (number of units) of each drug. NDCs are assigned when a drug receives FDA approval. When a PBM dispenses and adjudicates any specialty drug, it knows exactly which drug was dispensed, the dosage level and the precise quantity. Therefore, payers can track—and potentially control—each specialty drug's cost, at each dosage level and quantity.

In contrast, health care entities typically adjudicate specialty drugs using Healthcare Common Procedure Coding System J codes. At best, a J code references the chemical name of a drug, but not the specific manufacturer, strength or package size. In other words, many different drugs are included in each specific J code. For example, J7192 represents all hemophilia recombinant Factor VIII products (Recombinate, Kogenate FS, Bioclate, Helixate).

In contrast to NDCs, J codes also do not identify the quantity dispensed. Instead, health care providers must complete a separate quantity "field" when they invoice for specialty drugs. Providers often do so by filling in the quantity as "1" regardless of the actual quantity dispensed.

Also, until a J code is assigned to a drug—typically six to 18 months after it enters the market—a catchall, nonspecific code is used for billing. For example, J3590 represents unclassified biologics, and J3490 represents other unclassified drugs. Frequently, even after a J code is assigned, providers continue to invoice for the drug using the catchall, nonspecific codes.

For all of the above reasons, it is unlikely that specialty drug costs can be controlled when health providers adjudicate drugs using J codes. Without the ability to track which drugs are being dispensed, and at what dosage level and quantity, you cannot possibly control their costs.

Accordingly, until health providers require that specialty drugs be invoiced using NDCs, PBMs offer the only possibility of controlling specialty drug costs, and you should try to move as much of your specialty drug dispensing to PBMs as is feasible. However, before doing so, you must change several provisions in your PBM contracts, as described below.

PBM/Client Contracts Lack Meaningful Specialty Drug Definitions

During the past few years, I have reviewed hundreds of PBM/client contracts, and all have contained either no definition whatsoever for *specialty drugs*, or a definition that is so "elastic" that it is essentially useless. Here are two definitions recently seen in contracts that do contain a *specialty drug* definition:

> "Specialty Drug" shall mean certain pharmaceuticals, biotech or biological drugs, which may be offered by PBM, that are used in the management of chronic or genetic disease, *including but not limited to*, injectible, infused, or oral medications, or products that otherwise require special handling, including without limitation, each drug identified on Exhibit D, *which may be amended by PBM.*
>
> "Specialty Pharmacy Drugs" means certain drugs available in the market that are not subject to the rates referenced in Exhibit A [which Exhibit contains pricing for brand and generic drugs]. . . . *Examples* of Specialty Pharmacy Drugs are biotechnology drugs and certain compounds. *Classification of a drug as a Specialty Pharmacy Drug is at the sole discretion of PBM.*

As reflected by the text in italics (which I added), in both of these definitions the PBM is free to add—or delete—any drug it wishes to the category of specialty drugs.

Thus, in essentially all contracts, the lack of a definition—or the inclusion of a cleverly worded definition— results in an elastic concept of what constitutes a *specialty drug*. A PBM is free to manipulate which drugs are included in the category and free to evade whatever specialty drug pricing controls are written into the contract.

PBM/Client Contracts Lack Meaningful Specialty Drug Pricing Terms

Even if PBM/client contracts contain useful *specialty drug* definitions, those definitions are of little utility because

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contracts rarely contain meaningful pricing terms to control the PBM's profit margins on specialty drugs.

Indeed, of the hundreds of PBM/client contracts reviewed, many contain no pricing terms or pricing guarantee whatsoever for specialty drugs—notwithstanding that they are the highest cost drugs in the marketplace.

Moreover, while some contracts do contain a contract exhibit that lists scores of specialty drugs with drug-by-drug "minimum discount guarantees," the exhibit nearly always omits numerous specialty drugs. The PBM can charge whatever it wants for all omitted drugs and "take back" whatever profits the PBM may have lost by providing aggressive guarantees on the specialty drugs listed in the exhibit.

Furthermore, at the end of the exhibit—or buried elsewhere in the contract—PBMs typically include language giving the PBM the "discretion" to change its "minimum discount guarantees" whenever the PBM wants to do so. The question that must be asked is: What value could the "minimum discount guarantees" possibly have if the PBM can unilaterally change them? Though the obvious answer is "no value at all," almost all PBM/client contracts that contain minimum discount guarantees also provide PBMs with the above-described unilateral right.

In some instances, the relevant language is quite simple and easy to recognize:

> All discounts quoted [in this Exhibit] are subject to change in PBM's [Specialty Pharmacy] discretion as necessary to reflect current market conditions and availability.

In other instances, the language is part of a lengthy paragraph that many clients (and lawyers) may ignore. Here's an abbreviated version of language I have seen repeatedly in PBM/client contracts—annotated by me with italicized print and brackets to illuminate key points:

> PBM reserves the right to modify or amend the financial provisions of the Agreement in the event of: (a) a greater than 20% change in the total number of covered plan participants [it is unclear why a change in a single client's participants could justify any change in a PBM's "minimum discount guarantees"] . . . (c) any government imposed or *industry wide change* [this phrase potentially covers almost anything]. . .; (e) a change in Client's plan design [given the lack of any specificity in this statement, this phrase potentially covers any plan design change] . . .; (f) a change in the scope of services to be performed under the Agreement . . . [ditto]; (g) *PBM's actual cost experience* [this means if the PBM doesn't meet a guarantee, the PBM is free to claim it had the right to change the guarantee because of its "actual cost experience"]; or (h) changes to the methodology by which AWP is calculated or reported. . . [note that unbeknownst to most PBM clients, national reporting services change AWP reporting methodologies].

Clearly, if PBMs give themselves so many contractual "outs" for changing (or eliminating) their minimum discount guarantees, you will have little ability to control your specialty drug costs.

Draft an Effective "Specialty Drug" Definition

Lawyers with experience drafting contracts know that every contract term of consequence must be defined. Otherwise, each party is free to interpret a critical contract term in any manner the party chooses.

Given that a core goal of any PBM/client contract must be to control the cost of every specialty drug—throughout the contract term—every PBM client must draft a *specialty drug* definition that will include all specialty drugs in the market at the beginning of the contract and all "new-to-market specialty drugs" thereafter. Here's how you can do so:

- Define the phrase *specialty drug* by stating that it includes all drugs that are listed on an exhibit list—or on amendments to the exhibit list.
- Draw up a list of every specialty drug currently on the market and attach that list to the end of the proposed contract.
- Draft contract language that allows you to regularly and continually

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update the list through amendments, and make sure to do so throughout the contract term (at least quarterly).
- Contractually require the PBM to notify you every time a new-to-market specialty drug is dispensed from the PBM's specialty drug pharmacy, which will enable you to more easily amend your contract exhibit list without continuously relying on outside experts to do so.

Make clear that any contestant that fails to accept the specialty drug terms—or fails to provide binding minimum discount guarantees for every drug on your exhibit list—is likely to be eliminated from the RFP.

This process will ensure that the specialty drug definition is all-inclusive—at the beginning of contract and throughout the contract term.

The contract's specialty drug exhibit list currently should include approximately 650 specialty drugs (broken down by generic product identifier/generic sequence number drug description combinations). If your contract's exhibit list identifies only a few hundred specialty drugs, you should be aware that your PBM is in a position to charge whatever it wants for numerous specialty drugs that are not on the exhibit list.

Require Pass-Through Pricing

Pass-through pricing is the latest concept sweeping the prescription coverage marketplace. Simply explained, it requires a PBM to invoice a client for every drug dispensed based on the PBM's precise cost for the drug.

Unfortunately, almost no PBM contracts provide pass-through pricing for specialty drugs. Instead, most contracts allow PBMs to pay for specialty drugs at one (undisclosed) price, but charge clients a far higher (unspecified) price for the same drugs. In so doing, PBMs make undisclosed profit spreads on every specialty drug dispensed.

Moreover, given that the PBM's purchase price need not be disclosed—and the PBM's invoice price to its client is not specified (or can be changed in the PBM's discretion)—the amount of the PBM's profit spread is unknown and elastic. Thus, most PBMs increase their profit margins by buying specialty drugs at low prices and selling them at far higher prices, rather than using their marketplace leverage to decrease their clients' costs.

To change the status quo, you should draft an entirely different form of PBM contract and require your PBM to provide pass-through pricing for every specialty drug dispensed. That means the PBM must invoice your plan using the PBM's actual cost for the drug. If the PBM uses a subsidiary specialty pharmacy to dispense specialty drugs, the PBM must invoice your plan based on the PBM's actual acquisition cost, and the methodology for determining and verifying actual acquisition cost must be specified in the contract (FIFO, LIFO, WAAC, etc.). If the PBM uses a third-party vendor pharmacy to dispense specialty drugs, the PBM must invoice your plan based on the actual amount the PBM reimburses the vendor, and a methodology for verifying said amount must be included in the contract.

Obtain Minimum Discount Guarantees Through Skillfully Conducted RFPs

To ensure that each PBM's pass-through prices are competitive and as good as are available in the marketplace, you should also contractually require your PBM to provide a minimum discount guarantee for each specialty drug on the contract exhibit list (and all list amendments). The best way to do so is to extract these guarantees during PBM requests for proposals (RFPs), when several PBM contestants must compete to win your business. To do so, at the beginning of your RFP, draft a form of contract with entirely different contract terms:

- Among other matters, include a *specialty drug* definition that cross-references to an exhibit list that identifies every specialty drug currently in the marketplace.
- Include contract language that requires the PBM to provide pass-through pricing for every specialty drug dispensed.
- Draft language that requires the PBM's pass-through pricing to be at least as good as the specialty drug minimum guaranteed discounts identified on the exhibit list, and leave a blank space next to each drug on the list.

After drafting the contract, transmit it to all PBM contestants together with all your other RFP documents, and require each PBM contestant to provide its best minimum discount offer for each specialty drug by filling in the blanks on the specialty drug exhibit list. Make clear that any contestant that fails to accept the specialty drug terms—or fails to provide binding minimum discount guarantees for every drug on your exhibit list—is likely to be eliminated from the RFP. Also make clear that a PBM finalist will not be awarded the business until it has executed its contract and bound itself to provide the guarantees contained in the contract.

By requiring each PBM contestant to adhere to these RFP procedures, you are placed in an entirely different position: Your new PBM will have to pass through its actual cost for every specialty drug, and that cost has to be at least as good as the specified minimum discount guarantee the PBM offered during the RFP.

Moreover, by requiring every PBM contestant to submit drug-by-drug guarantees in binding contracts during the RFP, it is possible to compare and thereafter negotiate with each contestant over its proposed guarantees. Thus, the RFP can be used to extract better and better discount guarantees from each PBM contestant.

For example, the table reflects the discounts initially proposed during an RFP by a PBM contestant—and the discounts the same PBM contestant proposed and agreed to two months later at the end of the RFP—for a few of the most commonly used specialty drugs included on the contract exhibit.

Given the number of times each of the drugs shown in the table was dispensed for the client in question, the improved minimum discount guarantees for just the five listed drugs represented a potential annual savings of more than $100,000.

Table

PBM Contestant's Initial and Final Proposed Discounts

Drug	Initially Proposed Discount Guarantee	Subsequently Proposed Discount Guarantee
Atripla (tab)	AWP-10%	AWP-17%
Enbrel (SRCLK inj 50 mg/ml)	AWP-17.5%	AWP-18.5%
Pegasys (kit)	AWP-16%	AWP-19%
Prograf (cap 1 mg)	AWP-10%	AWP-18%
Gleevac (tab 400 mg)	AWP-10%	AWP-18%

Create a Contractual Right to Carve Out Certain Specialty Drugs

By using the RFP to obtain binding minimum discount guarantees for each specialty drug from each PBM contestant, you will also be able to compare PBM contestants' discount guarantees. In so doing, you will obtain an understanding of the range of discounts available for each drug, and the savings you can generate if you obtain the best discounts on each drug.

It is reasonably likely that some PBM contestants will offer relatively weak discounts on some drugs (like average wholesale price (AWP) minus 18% on Sandostatin SR), and other contestants offer far stronger discounts (such as AWP minus 26% on the same drug, with the latter discount enabling a payer to save approximately $450 every time the prescription is dispensed). Indeed, during an RFP, enormous discrepancies are typically seen on numerous drugs, such as Ribasphere (AWP minus 19% vs. AWP minus 70%, with the latter providing a possible savings for payers of approximately $600 per prescription) and Irinotecan HCDL (AWP minus 18% vs. AWP minus 60%, with the latter providing a possible savings of approximately $1,200 per prescription dispensed).

By learning the range of discounts available during an RFP, you will be positioned to carve out certain specialty drugs from coverage at the beginning of a new contract if the PBM that you ultimately select as a finalist is unwilling to provide optimal discounts on every specialty drug.

Moreover, you can—and should—position yourself contractually to carve out specialty drugs after the contract begins, ensuring that you can consistently obtain the best minimum guaranteed discount available, throughout the life of the contract, including on new-to-market specialty drugs.

Note that most PBM/client contracts contain *exclusivity provisions* that require clients to use their selected PBMs for all prescription coverage matters. You should make sure to eliminate all such exclusivity provisions and replace them with provisions that allow you to carve out specified services, including the provision of some or all specialty drugs, and the right to negotiate contracts with alternative specialty drug pharmacies.

Demand a Pass-Through of All "Financial Benefits" Related to Specialty Drugs

Although most specialty drugs are single source products, many do compete with other products in their therapeutic category. As a result, an increasing number of specialty drug manufacturers are attempting to increase their drugs' market shares by offering rebates and other forms of discounts to PBMs.

Unfortunately, very few payers benefit from specialty drug rebates and discounts because most PBMs insert language like the following language somewhere in their client contracts that enables the PBMs to retain all such financial benefits:

> "Rebates" means the rebates, including base and market share rebates, collected by PBM in its capacity as a group purchasing organization . . . *but specifically excluding any rebates paid with respect to utilization of Specialty Drugs.* (Italics added.)

By including such language in contracts, PBMs deprive clients of the most obvious and direct means to obtain specialty drugs savings.

To alter the status quo, you should eliminate all such language from your contract and include language specifically requiring your PBM to pass through all financial benefits related to all specialty drugs from all third parties. You must also include a contract definition for *financial benefits* making clear that the phrase references all arrangements that could provide any financial value, including but not limited to all rebates, discounts, administrative fees, credits, grants, etc. You must also include a contract definition for *third parties* making clear that the phrase includes not only drug manufacturers, but other third parties such as wholesalers and distributors.

You should also use the RFP process to compare each PBM contestant's financial benefit pass-through ability by requiring each to provide financial benefit guarantees in the contracts they submit.

Thus, the proposed contract that you (or your consultant) drafts and bids out in an RFP should not only require each PBM contestant to provide pass-through pricing on each specialty drug dispensed, and a pass through of all rebates and other financial benefits the PBM receives on specialty drugs, but it should also contain blank lines for each PBM contestant to fill in related to its proposed financial benefit guarantees, such as the following:

> PBM agrees that its pass-through of all third-party Financial Benefits will be at least as favorable to Client as the following guarantees:
> $ _____ per retail prescription dispensed
> $ _____ per retail 90 prescription dispensed
> $ _____ per mail prescription dispensed

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$ _____ per specialty drug dispensed"

Demand Right to Renegotiate Guarantees and a Default Discount Guarantee for New-to-Market Specialty Drugs

Given that available discounts on specialty drugs are continuously changing, it is imperative that you not lock your plan into a three-year contract containing pricing terms and exhibit list guarantees that are fixed and incapable of being changed.

Instead, you should draft and demand a "right to renegotiate and amend" your contract, coupled with a "right to terminate the contract with or without cause" on 90 days' notice. By coupling the right to renegotiate with a right to terminate without cause, you will ensure that your PBM renegotiates in good faith, whenever you choose to exercise renegotiation rights. And if the PBM fails to do so, you will be able to find another PBM that will.

Note that the right to renegotiate should specifically include the drug-by-drug minimum discount guarantees obtained on each specialty drug, as well as the per script financial benefit guarantees.

Given that new specialty drugs are continuously entering the marketplace, a PBM contract must also provide cost controls for all new-to-market drugs. Before you begin an RFP, you should draft contract language that requires the PBM to provide a *default discount guarantee* for all new-to-market specialty drugs dispensed from the specialty drug pharmacy, and leave a blank line in the proposed contract to allow each PBM contestant to identify the default discount guarantee it is willing to provide. Many PBMs are willing to provide surprisingly strong default discount guarantees.

The proposed contract should not only contain language related to default discount guarantees, but should also give you the right to amend the specialty drug exhibit with all new-to-market specialty drugs, at least quarterly. It should also enable you to negotiate minimum discount guarantees for all such newly available specialty drugs and to renegotiate existing guarantees when better guarantees are available.

Specialty Drugs' Ever-Increasing Costs

There is much that every payer can do to better monitor and control its specialty drug costs. With the average cost of a specialty drug prescription rapidly approaching $2,000, and the annual cost of many specialty prescriptions exceeding $100,000, it is time for all payers to do so.

Simply stated, specialty drugs are too special to ignore. **B&C**

Linda J. Cahn is the founder and president of Pharmacy Benefit Consultants, a nationwide consulting company that assists insurance companies, corporations, unions and coalitions in conducting PBM RFPs and using the leverage of the RFPs to draft, negotiate and execute improved PBM contracts. Cahn received a bachelor's degree from Princeton University and a law degree from Hofstra Law School.

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