Practical Issues With PBM Full Disclosure Laws

by Lawrence W. Abrams, Ph.D.

The management of the drug benefit portion of health-care plans has become the domain of contracted specialists called pharmacy benefit managers (PBMs). PBMs have come under intense attack in the past few years for not acting in the best interest of their clients, who are charging that PBMs are designing formularies that are not cost-effective. Clients argue that PBMs are "rebate chasers" who switch prescriptions to higher-cost drugs just to capture a rebate percentage and then retain an unfair portion of the rebates received. They also argue that if PBMs were subject to full disclosure under fiduciary laws, there would be a more equitable distribution of rebates and more efficient usage of prescription drugs.

The PBM business model has evolved considerably over the past ten years. A decade ago, there was no question that PBMs were working in the best interest of their clients—their only significant source of revenue was claims processing fees. The introduction of the formulary into claims processing software, however, has caused a rift between the interests of the plan sponsors and those of the PBMs. The formulary is a look-up table that PBMs have added to claims processing software that checks a prescription against a list of therapeutic equivalents preferred by the plan sponsor. The cost saving occurs when the PBM succeeds in aligning most of its clients' formularies around a single brand name drug in a therapeutic class, to the point that they collectively "move a market" and garner significant market share rebates from the preferred drug manufacturer. Market share rebates are paid directly to the PBM, who in turn pays out shares to plan sponsors.

Subjecting PBMs to the full disclosure provisions of fiduciary laws would help to resolve conflict of interest issues, but it is not the panacea that many believe. One problem is that the complex basis for rebate payouts makes it impossible to determine unequivocally what each plan should be receiving. In addition, proving breach of fiduciary duty often requires outcome as well as cost data, and fiduciary laws being introduced today are silent on the need for outcome data.

The Complex Basis of Market Share Rebates

The nature of market share rebates greatly complicates disclosure of gross and net receipts on a plan-by-plan basis. This complexity is not addressed in the fiduciary laws being considered by state legislatures throughout the country. Generic drug manufacturers do not pay any rebates to PBMs. Their efforts to sway demand are channeled into charge-back credits paid to pharmacies based on volume of purchases at the distributor level. Because PBMs and their clients can affect demand for brand drugs through formulary design, brand name drug manufacturers pay PBMs two types of rebates: volume rebates and market share rebates. Volume rebates are paid for nonexclusive placement in formularies. These rebates are a fixed percentage of volume and generally are in the 3% to 5% range. The basis for volume rebates can be determined unequivocally plan-by-plan. The basis for market share rebates is the overall market share that a PBM is able to deliver for a brand name drug over and above some minimum.

Consider the following hypothetical example. Merck offers to pay a PBM nothing if it delivers an overall 50% market share for Zocor; 5% for a 55% share; 10% for a 60% share; 15% for a 65% share; 20% for a 70%; etc. The problem is that what each individual plan "should" get cannot be determined unequivocally; there are many ways to divide up market share rebates among individual plans. Three possible formulas are: 1) equal distribution, 2) average distribution, and 3) marginal distribution. For example, assume a PBM has two plans of equal size. One plan achieves a 70% market share for Zocor, while the other achieves a 50% share. The market share for the client base as a whole is 60% and the gross rebate payout would be 10%. The equal distribution formula would pay each client 10%. The average distribution formula would pay one 20% and the other nothing.

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The third way is based on expectations and marginal contribution (the marginal distribution formula). Assume that the PBM presented each client with the same national formulary that designated Zocor® as preferable to its archrival, Lipitor®. Assuming both clients adopt the national formulary, PBMs expect each to achieve a 60% share. But, both clients decide to customize the national formulary. One client has no strong preferences either way; it includes both drugs in the formulary and assigns both the same co-payment. This "neutral customization" nets the client only a 50% share. The other client really pushes Zocor® by requiring "prior authorization" for Lipitor® on top of a higher co-payment. This "preference customization" nets the client a 70% share.

When each client decided to customize the national formulary, the PBM had told them that they would be assigned the "marginal consequences" of their discretionary acts. Based on these instructions, the PBM would be consistent in assessing one client a penalty of 5% while paying the other client a 25% rate. The gross receipt allocation among plans for any given drug is up to the discretion of the PBM. These are three reasonable distribution formulas that PBMs could choose, but there are others. The result is that it is almost impossible to question any gross receipt allocation reported by a PBM for any single plan or drug.

Data Requirement for Proving Breach of Fiduciary Duty

We now turn our attention to how full disclosure might resolve efficiency issues in practice. At the outset, it is important to recognize that there are two aspects to formulary management—design and compliance. Full disclosure of rebates may be useful in uncovering areas of inefficient formulary design, but only detailed audits of prescription transactions can uncover systematic switching that is not in compliance with the formulary.

Evidence of a switch to higher-priced drug is not sufficient to prove breach of fiduciary duty. First, one must prove that the switch was the result of a discretionary act of a PBM, and not a discretionary act of a client. If it can be determined that the switch was based on a portion of the national formulary that had been customized by a client, then a PBM cannot be held accountable for a costly switch. Second, a client's interest is best served by cost-effective formulary design, not simply a design that minimizes costs. Most cases of switching require both cost data and outcome data. Full disclosure laws require only rebate data, so there is a question of how useful this data is without related outcome data.

Table 1 presents situations where rebates may cause PBMs not to choose the most cost-effective formulary design. Full disclosure of rebate schedules and remittances is crucial for determining the cost-effectiveness of a switch in only one of the three possible situations. In the first case, there is no issue of relative therapeutic effectiveness, as both drugs are chemically equivalent. Only volume rebates are paid for off-patent brand name drugs, and the rate is too small to have an effect on the premium of the off-patent brand relative to the generic; the switch is never cost-effective, so full disclosure would add nothing to the evaluation of this switch. In the second case, it is doubtful that the switch could be justified by cost differences even after factoring rebates into the price of the on-patent brand name drug. Without outcome data, breach of fiduciary duty based on cost data alone cannot be proved. Full disclosure of rebates would not add to the evaluation of the cost-effectiveness of this switch.

It is only in the third case that full disclosure could make a difference. In this case, there is intense competition between two on-patent therapeutically-equivalent drugs for inclusion in the formulary. Outcome data are critical. Data on actual gross rebates received by the PBM also are critical. The problem is that actual payment data are not sufficient. Because the list prices of the two drugs under consideration usually are within 25% of each other, rebate levels could tip the balance the either way. Rebate data are required on all drugs in cases where the switch is between two on-patent drugs that are therapeutically equivalent. Full disclosure of actual rebates would help in this case, but it is not the panacea that many believe.

Table 1: Data Requirements for Proving Breach of Fiduciary Duty

Formulary	Switched for	Non-Formulary	PBMs Stand to Gain	Data Required to Prove Breach
1. Off-patent brand	*lower list price*	generic equivalent	*volume rebate only*	none never cost-effective
2. On-patent brand	*lower list price*	generic that is therapeutically equivalent	*volume rebate* *market share rebate*	outcome data rebates do not matter
3. On-patent brand	*lower list price*	on-patent brand that is therapeutically equivalent	*volume rebate* *market share rebate*	outcome data rebate data