Major Changes Ahead: Medicare Drug Benefit to Affect the Entire Drug-Distribution Chain

by Stephen Barlas

It is pretty scary when the senators who are writing an important piece of federal legislation don’t understand its provisions—but that is how complicated the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is. This legislation will impose revolutionary changes on pharmacy players too. More on that in a moment.

Regarding the considerable confusion over the language in the Medicare bill that President Bush signed in December 2003, following is a brief exchange that took place on the Senate floor during the last week of November between Senators Dianne Feinstein and Max Baucus, both Democrats. (Mr. Baucus also negotiated with Republicans about the bill, making him a supposed “expert” on its contents.)

Sen. Feinstein: Isn’t it also true that if a plan chooses to use a formulary, it must include at least two drugs in each therapeutic category or class, unless the category or class only has one drug and that the plan must use pharmacy and therapeutic committees that consist of practicing physicians and pharmacists to design their formularies?

Sen. Baucus: Yes, this is true.

Actually, Senator Baucus, you are wrong. Here is what the provision does say:

In general—the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

In fact, according to a Senate staffer who worked on the wording of that provision, the language there and elsewhere in the section could actually be interpreted as encouraging formularies to include only the safest and most effective drug within each therapeutic category. Physicians can appeal to the pharmacy benefit manager (PBM) to provide another drug that is not on the formulary; nowhere, however, does it say that formularies must have at least two drugs in each class.

Being able to restrict formularies probably suits PBMs fine, but they might not be very happy about some of the other provisions in the bill. For example, sponsors of the Medicare prescription drug plans (PDPs), to be available in 2006, must provide its Medicare customers with “access to negotiated prices used for payment for covered part D drugs.” The plan must also give the secretary of the Department of Health and Human Services aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers.

These are radical requirements. These types of concessions are the same ones that a number of U.S. attorneys around the country have been trying to get access to in order to be able to build a legal case against PBMs for bilking Medicare and Medicaid. It is the kind of information large companies want from their PBMs but have been unable to obtain. The unwillingness of PBMs to turn over that kind of information led to the recent loss of two big contracts for AdvancePCS.

Raymond McCaskey, president of a company that operates three Blue Cross/Blue Shield plans, told The Wall Street Journal that he was dropping AdvancePCS in favor of a small company called Prime Therapeutics because, in effect, Prime was much more independent from the drug manufacturers.

“I think our market message around transparency and around disclosure of revenue streams in beginning to resonate,” said Tim Dickman, chief executive officer of Prime.

In fact, it resonated all the way to Capitol Hill.

As for the pharmacy networks that the drug plans will set up, the bill is very prescriptive. PBMs, for example, will not be able to lean toward mail order. Networks must be based on the military’s TRICARE access standards, which require that (1) 90% of plan enrollees in urban areas will have access to a retail pharmacy within 2 miles, 90% of suburban plan enrollees will have access to a retail pharmacy within 5 miles, and 70% of rural plan enrollees will have access to a pharmacy within 15 miles.

Whether enrollees buy their drugs from retail or mail-order pharmacies, they must be informed at the time of receipt of any price difference between the drugs they are holding and the lowest-cost generic drugs that are therapeutically equivalent and bioequivalent. This is a somewhat incredible provision, too. At present, pharmacists give out no price comparison information unless asked—and they are probably asked only rarely. The only thing not required by the bill is a big sign at the checkout counter that says “BUY GENERIC, DUMMY.”

The bill goes even further in empowering pharmacists. The new plan would be required to have a medication therapy management program; the retail pharmacy industry calls this “pharmaceutical care management.” Pharmacists would be paid to counsel consumers with an eye toward lowering the plan’s and the consumer’s out-of-pocket costs as well as improving health outcomes. Relatively few of these programs exist today.

The Medicare bill is full of these pitfalls and possibilities, so make sure to read the bill . . . carefully.