Industry warily eyes new Medicare drug plan

On January 1 a new subsection of Medicare, known as Part D, was launched under intense industry scrutiny. Biotech companies whose revenue depends, for a non-negligible part, on government reimbursment of prescription drugs for citizens 65 years of age and older, have been pushing to get their innovative products covered. And although industry has been coy about commenting on the new rules, companies are worried that the plan will not cover drugs for rare diseases and will reduce the incentive for industry to innovate.

Regulations authored by the Centers for Medicaid and Medicare Services (CMS) provide the roughly 3,000 Part D drug plans wide leeway in setting prices. Each plan individually negotiates wholesale prices with manufacturers. Plans generally offer very low copayments for generic medicines and 'preferred brands' while placing roughly two dozen self-administered biotech medicines in higher payment tiers. Most biotech medicines are dispensed at a hospital or a physician's office and are therefore covered under traditional Medicare rather than Part D.

For instance, Medco Health Solutions, based in New Jersey, one of ten companies rolling out plans nationwide rather than regionally, charges $4 per month for generic medicines and $17 per month for preferred brands. But a month's supply of Amgen's arthritis treatment Enbrel (etanercept) will cost beneficiaries $957; Roche's HIV drug Fuzeon (enfuvirtide) runs at $480.

Officially, the industry does enthusiastically embrace the program, which estimates suggest will pour some $70 billion annually into pharmaceutical and biotech coffers. Jayson Slotnik, director of reimbursement and economic policy at the Biotechnology Industry Organization, says, "We believe it's a tremendous opportunity to increase access to our therapies."

But the enthusiasm carries a caveat. "Right now we are concerned that some of the pricing is discriminatory, vis-a-vis specialty [biotech] medicines, and even more so for orphan disease products," Slotnik cautions.

First of all, Part D, does have a catastrophic cap of $3,600 annually, after which beneficiaries pay 5% of prescription costs—which could still equal thousands of dollars. Subscribers needing biotech medicines will reach the cap quickly. "It's forcing them to have all of these costs at the beginning of the year," says Slotnik. Jennifer Leone, a spokesperson for Medco, says that she understands the pricing concerns, but adds, "I just don't think it's a barrier. It's added assistance to people who don't have any type of benefit right now. Without us they'd be paying a lot more."

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The new Part D program could prove to be a headache for biotech companies trying to get their innovative drugs covered

What is more, industry concerns about Part D surfaced in mid-2004, when the CMS unveiled a draft model formulary. Developed by United States Pharmacopeia (USP), the formulary serves as the basis for CMS guidelines regarding which drugs plans must cover. It identifies 146 classes of medicines, and plans are required to pay for at least two drugs per class. The biotech industry responded by complaining that the scheme left a number of its medicines in the lurch. In particular, BIO was worried that plans would be allowed to exclude new targeted anti-cancer medicines and medicines for orphan diseases.

CMS took the concerns into consideration, and in August 2005 issued a ruling that Part D plans must cover "all or substantially all" medicines for cancer, HIV/AIDS, depression and other mental health categories. The ruling was based on a review of other formularies, particularly those used by Blue Cross and Blue Shield in covering federal employees.

However, the ruling did not address concerns over tiered pricing. In addition, it singled out two biotech medicines, Fuzeon (enfuvirtide) and Iressa (gefitinib), as exempt from the rule, explaining that the exclusions were "consistent with our review of commonly used formularies." With regard to Fuzeon—the first of the relatively new class of HIV/AIDS medicines known as fusion inhibitors approved in 2003—a lobbyist working for Roche who asked not to be identified said, "I just don't know why they're taking it lightly. It's an innovator drug."

According to USP, 74% of Part D plans adopted its model formulary. Plans must also pass a 14-point CMS checklist that Bill Zeruld, vice president for corporate and international planning at USP qualifies as "quite robust." He says, "It's not just a rubber stamp."

But the saga is not over yet. Late last year, USP unveiled its model formulary for 2007, again prompting concerns from BIO. In a January 6 letter, the organization calls USP's scheme "arbitrary" and recommended expanding the number of drug classes. The letter notes that the number of classes remained steady, at 146, despite the approval in 2005 of "many innovative therapies and new indications." And again, BIO voiced strong concern regarding drugs for orphan diseases.

CMS offers beneficiaries an appeal process whereby they can ask for better coverage of a particular medicine, but it is stacked against medicines placed in higher payment tiers. The question for beneficiaries, says industry lobbyist Daniel Kracov, a partner at Washington-based Arnold and Porter, "is how many hoops will they have to jump through. Patients have to dig deeper and figure out how each plan handles their drug."

In the long run, BIO worries that the Part D guidelines will discourage companies from pursuing treatments for rare diseases.

Companies contacted by *Nature Biotechnology* say it is too soon to evaluate whether Part D will affect product development. A Genentech spokesperson simply comments that because Medicare is the company's largest payor, the prescription drug program "represents an important area of focus for 2006." But according to Kracov, it's precisely because the Part D is a potentially bigger payor than traditional Medicare that companies are rushing to develop take-home medicines. "Absolutely, it's affecting product development. Companies that are thinking about infusion products are now thinking about whether they need to make subcutaneous products."

Kracov concludes, "The longer term issue is concern about this wave of very beneficial but very expensive biotech products coming down the pike and what kind of budgetary impact they're going to have." He adds, "As Part D evolves, there is going to be closer and closer scrutiny of the high prices of the specialty biologics. It's going to be interesting."

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