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Manufacturer Windfall Rebates: CHANGE ON THE HORIZON



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he transfer of drug coverage for the dual eligible beneficiaries from Medicaid to Medicare Part D has come under scrutiny by Congress for alleged profit windfalls for manufacturers. The implications of the windfall issue for the pharmaceutical industry are vast. Manufacturers with a large Medicare book of business need to be mindful of this — and other changes ahead.

In light of the sea change in government response to current issues, understanding and navigating the future pharma waters will be complex.

Manufacturers should seek to partner with those who understand the issues, as well as the laws governing those issues, to help with the journey.

Strategies for future success may include reassessing formularies and reevaluating pipeline portfolios. Right now, however, it is important to address these issues and be a force for continuing private negotiation of pricing for Part D Plans (PDPs). Whatever change is on the horizon, manufacturers must begin planning now.

Manufacturers with a large Medicare book of business may need to assess potential current and future liabilities to the government, depending on whether rebates will be retrospective or begin at a future, determined date. This, in turn, may have a large impact on future pricing negotiations as well as research and development efforts.

HEALTHCARE A TOP PRIORITY

Of all the priorities set by the new administration, President Obama has made healthcare one of the top priorities. Provisions in the \$1.1 trillion CY 2010 White House budget call for improving Medicare's long-term sustainability so that beneficiaries can continue to rely on this critical program. The ever-increasing population older than the age of 65 historically suffers from a variety of chronic conditions and uses a substantial amount of resources. Accordingly, measures that have been called

on to strengthen Medicare are designed to encourage high quality and efficient care while reducing excessive payments.

The viewpoint of the Obama Administration is that Medicare Part D will continue to evolve as the healthcare landscape continues to change. If Medicare is going to remain a viable health benefit, without exhausting the trust funds, how the program will be paid for needs to be addressed. Plan structures will also continue to evolve. It is too early to determine how the drug plan benefit will play out. Will PDPs phase out, or will the number of plans diminish in response to increased regulation and oversight? If the coverage gap continues as a concern, and cost shifting to members continues, the effect of the increasing economic burden on Medicare beneficiaries will require examination and action. Therefore, based on the administration's position, the horizon just got closer. Greater government involvement in the negotiation of drug pricing is ahead.

The probability of a filibuster-proof Democratic majority will allow the Obama administration to drive and influence health policy

changes as early as this year. Among the many challenges manufacturers can expect to face, the disparity between rebates for Medicare and Medicaid will be a key issue. In July 2008, Representative Henry Waxman, Chair of the House Government Reform and Oversight Committee, released a major report on the rebate issue. “Medicare Part D: Drug Pricing and Manufacturing Windfalls” provided background and analysis supporting the argument that private Medicare Part D insurers pay significantly higher prices for prescription drugs than do those for the Medicaid program.

A special population — those citizens older than 65 who fall below the federal poverty level — are considered dual eligible for both Medicare and Medicaid, and receive a larger benefit. Before the introduction of Part D in January 2006, dual eligibles received their prescription medications via state Medicaid programs. Beginning in the early 1990s, manufacturers were required to pay a federally mandated 15.1% rebate to participate in Medicaid. In addition, some states required supplemental rebates to be listed on the state Preferred Drug List (PDL) — those supplemental rebates not subject to “best price.” With the advent of the Medicare Part D program, the dual eligibles’ prescription drug benefit was shifted from Medicaid to Medicare. Manufacturers became able to negotiate directly with payers, many of them offering discounts significantly less than the 15.1% required for Medicaid, hence creating the “windfall” perception — and the disparity between Medicare and Medicaid.

KEY FINDINGS

The Medicare Part D “Windfall” report provided a number of key findings, which will continue to be a source of focus for government action.

The House Government Reform and Oversight Committee identified those manufacturers and drugs for which the government was paying 30% more for dual eligibles under Part D. The therapeutic areas identified are prevalent in the elderly population: psychosis, Alzheimer’s disease, asthma, and stroke. The costs totaled a significant \$3.74 billion.

The Centers for Medicare and Medicaid Services (CMS) has directed that Part D formularies include all or substantially all drugs

in the following six protected drug classes, which contain 16 of the 100 top-utilized drugs:

- Antidepressants
- Antipsychotics
- Anticonvulsants
- Immunosuppressants (to prevent rejection of organ transplants)
- Antiretrovirals (for the treatment of infection by retroviruses, primarily HIV)
- Antineoplastics (only those chemotherapy drugs that generally are not covered under Medicare Part B)

Part D plans have been notified by CMS that they must continue to provide coverage of these drugs in 2010, consistent with the policy already in place. As a result, enrollees who are already taking drugs in these six classes will not be discouraged from continuing their current treatment due to drug utilization management techniques, such as step edits (requirement of beginning with a lower-cost drug), quantity limitations, and/or prior authorization.

The administration is attempting to move toward mandated rebates and repeal of the government noninterference clause between private payers and manufacturers. Among this group, manufacturers of cardiovascular and CNS drugs — categories of high use in the elderly population — stand to be most affected by potential change.

IMPLICATIONS

Implications of these findings will set up situations that affect a variety of players. Anticipating, understanding, and partnering to develop strategies to address these situations will be vital steps in helping manufacturers move successfully toward an expanding, rather than a contracting, horizon.

Manufacturer reluctance to participate and contract with PDPs and Medicare Advantage Part D plans (MA-PDPs)

CMS regulations regarding formulary coverage may have hindered the ability of PDPs to negotiate cost savings comparable to those traditionally secured for commercially covered lives. Additionally, restriction of formulary choice is another concern for manufacturers.

The Veterans Administration (VA) has a highly restricted formulary, which is set by the federal government. Compounding the issue is the fact that manufacturers must price drugs for the VA at 24% below prices offered to non-federal purchasers. If they don’t, all drugs of the manufacturer will be excluded from other government programs, including Medicaid and Medicare Part B. Finally, pricing restrictions may limit income and hinder the ability of manufacturers to continue to fund research and development.

Continued decline of Medicare PDPs and disruption in continuity of care

Negotiated prices that are passed to plans may decrease their ability to remain competitive. This may result in a reduced number of available plans and disruption in continuity of care as displaced members scramble to find a new plan that is local and that has the prescriptions they need. The number of stand-alone PDPs increased from 2006 to 2007 but remained relatively stable in 2008. In May 2009, however, both Coventry and WellCare plans announced they will not participate in MA-PDP next year because of the reduction in payments they receive. Participants in a recent roundtable discussion on the future of Medicare Part D Drug Plans published in the Journal of Managed Care Pharmacy were in agreement that PDPs will be phased out over time and will be transitional until beneficiaries convert to Medicare Advantage Part D plans. The participants all concluded that the number of stand-alone PDPs will continue to decrease over the next few years.

Potential for increased premiums to members and their inability to pay

Part D has been more successful than predicted, accounting for almost half of all spending on prescription drugs. More seniors than ever before have gained access to more drugs at affordable prices. Formularies for the two PDPs with the greatest enrollment carried 97% of the most widely used branded drugs. A recent Kaiser study noted that 80% of seniors are very or somewhat satisfied with Part D, and 89% of dual eligibles surveyed stated they were happy with the program.

VIEW on Medicare

Whatever change is on the horizon, now is the time for planning and acting.

However, rapidly rising costs will surely affect Part D. These costs may be offset through increased cost shifting to members, who may not be in a position to pay increased premiums. Another result may be the inability of patients to afford some or all of their medications, setting the stage for hospitalizations and the need for other, more costly care as a result of medication nonadherence.

WHAT TO EXPECT

Rep. Waxman of California has a long history of healthcare reform, dating back to the 1984 Waxman-Hatch Act. Among his stated priorities, is improving the functioning and fairness of Medicare's prescription drug benefits.

As Chair of the House Government Reform and Oversight Committee, he will be introducing legislation for policy change. With a majority Democratic Congress, the likelihood is that "windfall" rebates will be enacted for CY2010.

However, there are some important counterpoints to the findings of the "Medicare Part D Windfalls" report that deserve consideration.

Opponents of the report note that Medicare Part D was not designed to follow the model for the VA or Medicaid, and, therefore, it is difficult to make comparisons between negotiated rebates for these groups. And while the government may seek to negotiate pricing for Medicare, there is no guarantee that government-mandated price negotiations will result in substantial cost savings either. An independent Congressional Budget Office analysis

determined that the government would not be able to negotiate lower prices than PDPs.

CONCLUSIONS

Change is definitely on the horizon, with possible scenarios that include:

- Policy change. Manufacturers would have to pay the government the difference between what they would pay Medicaid versus negotiated contracts with private payers.
- "Snowball" effect. Federally mandated rebates would be required for all Part D beneficiaries, not just the dual eligibles. The dual eligible group is only a small part of the very large Medicare population. Requiring the rebate for all, therefore, introduces a much more prohibitive burden for manufacturers by expanding the discount to a large population. Because the Medicare population is so large, everyone would receive a discount, effectively changing price structures.
- Retrospective rebates. Rebates may have to be paid to the government from the inception of Part D (January 2006) and not just going forward. This option generates a large source of government revenue at a time when the government has authorized a huge outlay of resources for a variety of initiatives.

Clearly, this issue is complex, and manufacturers must consider its import. Manufacturers with a large Medicare book of business

may need to assess potential current and future liabilities to the government, depending on whether rebates will be retrospective or begin at a future, determined date. This, in turn, may have a large impact on future pricing negotiations as well as research and development efforts. But it is important to remember that Medicare was never designed to be like other government programs, and retrofitting often does not work. Therefore, it is important to consider both sides of this issue and speak up for the viability of continuing to privately negotiate pricing for PDPs. Identifying and developing appropriate strategies to address this and other issues will be key now and in the coming years. Manufacturers must be mindful of the changes ahead and work with vision to maintain and extend their horizons. Understanding these issues, the law, and the climate as this challenging landscape unfolds will support the development of strategies necessary to succeed in this rapidly changing pharma environment. Whatever change is on the horizon, now is the time for planning and acting.

Editor's Note: Mr. Warburton has 17 years of industry experience, including managed market strategic development and implementation on both the client and agency sides of the business. Mr. Warburton can be reached at matthew_warburton@surgehealthcare.com. Ms. Kelly has extensive expertise in managed care at all levels, from its inception as a force in the marketplace to the present. She can be reached at carleen_kelly@surgehealthcare.com. ♦