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Healthcare Legislation and the Senator Brown Effect – What Should GP Professionals Be Thinking Now?

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Many in the industry are asking the obvious question, “What does it mean to Healthcare Reform now that Republican Scott Brown won the Senate seat in Massachusetts?” While it certainly appears that major legislative action will change direction, I think it is also important that we keep in mind that change is coming and we must be prepared.

I am of the personal opinion that substantial changes to Government Programs for Pharmaceutical Manufacturers are still coming sooner rather than later. There are large and contentious issues in the political debate around Healthcare Reform in the United States, such as the creation of a Public Option and potential taxes on expensive “Cadillac Plans.” There is little national debate over some substantial changes that would dramatically impact the industry, such as changing the definition of AMP, raising the base Medicaid rebate percentages (percent of AMP), expanding eligibility and changing the 340B program. The pharmaceutical industry itself seems to have accepted that these changes are coming and are bracing for the financial impact, while also focusing on other open issues in the debate, such as the creation of a period of exclusivity for bio-equivalent drugs.

The next important question is, “Which of the financial components, such as raising the base rebate percentage, will be included in the budget reconciliation process or in other, newer and maybe smaller bills?” I think that it is still prudent to anticipate that changes to core elements such as methodology, processes and systems will have a dramatic impact on the business. Some changes to core elements that, I believe, will be incorporated in the future include:

- **Changes to the definition of AMP resulting in a Higher AMP.**
A shift to a more restrictive definition of “community retail pharmacies”, as well as a reduction in the types of rebates that are excluded from AMP can result in a higher-calculated AMP.
- **An increase in base rebates.**
Such as 23.1% for Branded Products, 13% for Generic Products and 17.1% for Pediatric Products.
- **Higher Medicaid Rebates.**
An increase in the base rebate percentages will lead to a higher percentage on a higher AMP.
- **Medicaid Eligibility will be expanded.**
The first two bullets will result in a higher Unit Rebate Amount (URA) and the number of eligible participants will increase based upon expanded eligibility in the states.
- **Medicaid level rebates will be expanded.**
Expand the Medicaid Rebates to Managed Care Organizations (MCO) and to Dual Eligibles in Medicare Part D programs.
- **Base-line AMP will be applied to new formulations.**
The perceived “loophole” of some new formulations setting their own new Base-line AMP will be addressed, with a major financial impact to many manufacturers.

- **340B Program participation will expand.**

Program enhancements seem to be a certainty, with increased eligibility for additional entity types. Further, the potential impact from the changes in AMP and URA from the Medicaid side should be considered. The expansion will also have an impact on GPO purchasing.

Again, I think many, most, or all of the above items should stay on your radar. It is your role as a GP professional in the organization to keep the business informed. These changes run broader and deeper than the Final Rule. As much as the Final Rule had a deep impact, I think that the organizations saw it mainly as a compliance and operational challenge, and not a major impact on the business itself. The changes above may have a dramatic financial impact on your business and change the view of the Government Market. There may be those on the business side that saw the news of Brown's election last week and are thinking that change is not as imminent as they may have thought. We have to identify the relevant stakeholders across the organization and keep them informed of the changes that might still occur. Although I believe that it is still very much a guessing game, I think the dust will settle in the near future on some components of Healthcare Reform, as they have a significant budget impact at the Federal and State levels.