Special Report on the Analysis of the Fiscal Year 2008 Fiscal Impact of the Implementation of "Average Manufacturer Price"



Virginia Department of Medical Assistance Services November 1, 2008

Authority for the Report

According to Item 306 (U)(4) of the 2008 Appropriations Act, upon the later of April 15, 2008, or 90 days after the effective date of the regulation that the United States Secretary of Health and Human Services must promulgate under Section 6001(c)(3) of the 'Deficit Reduction Act of 2005,' Pub. L. No. 109-171, the Department of Medical Assistance Services (DMAS) shall report to the Governor and the chairmen of the Senate Finance and House Appropriations Committees the amount of savings anticipated in the Medicaid Forecast as a result of this change in federal law. In the event that anticipated pharmacy savings exceed the amount of savings assumed in the Medicaid Forecast, DMAS shall make recommendations concurrently with the report regarding the adjustment of pharmacy dispensing fees based on the impact of changes in local pharmacy reimbursements. (Appropriations Act Language is attached as Appendix A.)

Background

The Deficit Reduction Act (DRA) established a new Federal Upper Limit (FUL) calculation, which represents the maximum the federal government will pay to states in federal matching funds for multi-source drugs (generics) dispensed through state Medicaid programs. The FUL is one of four different pricing methodologies used to reimburse pharmacies for prescription drugs in Virginia's Medicaid program. The new FUL was to be calculated at 250% of the lowest Average Manufacturer Price (AMP) in a generic drug class. The AMP is a calculated price which more accurately represents the price that a pharmacy pays to acquire a drug.

The DRA changes were prompted by a series of 2004 reports by both the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) showing that Medicaid payments to pharmacies for generic drugs were higher than what pharmacies were actually paying for those drugs. The GAO and OIG found that states were overpaying for drugs because they were using commercial drug pricing guides as the basis for setting state reimbursement levels. The investigation of these drug price "compendia" documented that these prices were artificially inflated, especially for generic drugs.

One goal of the DRA was to encourage states to pay pharmacies more appropriately for the estimated acquisition cost of generic drugs. Prior to the DRA, actual drug prices were considered proprietary information and were only used by the Centers for Medicare & Medicaid Services (CMS) to calculate rebates; even CMS was prohibited by law from disclosing AMPs.

Discussion

The original effective date of January 1, 2007, for this regulation was delayed to allow for additional public comment, and the regulation was to have taken effect on October 1, 2007, and the calculated AMP-based FULs to take effect for pharmacy payment on January 30, 2008. However on December 19, 2007, United States Judge Royce C. Lamberth signed an order constituting a preliminary injunction that blocked the Medicaid pharmacy reimbursement final rule issued by the CMS. The temporary injunction was the result of a motion by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacist Association.

The order stated:

- 1. CMS will not use any Average Manufacturer Prices (AMPs) to calculate pharmacy reimbursement rates.
- 2. CMS may use AMPs solely for purposes of calculating the rebates that manufacturers pay to states. This protects state budgets.
- 3. CMS will not post AMPs on a website and will not disclose AMPs to States or anyone else outside of the administration. States will not be able to use AMPs to establish reimbursement rates for drugs.

Due to this court ruling, DMAS was not able to submit actual cost savings to the Governor and the Chairmen of the Senate Finance and House Appropriations Committees for state fiscal year 2008.

Since the filing of this injunction, on July 15, 2008, following President Bush's veto, Congress overturned the President's action by passing H.R.6331 - the Medicare Improvements for Patients and Providers Act of 2008. With this action, H.R.6331 became law. This measure delays the AMP Medicaid Reimbursement until October 1, 2009. Specifically, it states that the Secretary of HHS shall not, prior to Oct 1, 2009, finalize, implement, enforce, or otherwise take any action in imposing AMP. In addition, the bill postpones the public posting of AMP data until the 2009 deadline.

Conclusion

The 2008 Appropriations Act language requires the Department to report to the Governor and the Chairmen of the Senate Finance and House Appropriations Committees the anticipated Medicaid savings from using AMP-based FULs. As discussed, the temporary injunction that was ordered by the Federal court in December 2007 prohibited CMS from publishing AMP data. Subsequent Congressional action further delays the publication of AMP-based FULs until after October 1, 2009. Therefore, the Department is unable to fulfill the legislative mandate at this time. However, the Department will continue to monitor this situation, and issue a report ninety days after the publication of AMP data.

ATTACHMENT A

Item 306(U)(4) of the 2008 Appropriations Act

U.4. The department shall conduct an analysis of the fiscal impact of the implementation of "Average Manufacturer Price" (AMP), as required by the federal Deficit Reduction Act of 2005, Public Law 109-171. Upon the later April 15, 2008, or 90 days after the effective date of the regulation that the United States Secretary of Health and Human Services must promulgate under Section 600(c)(3) of the "Deficit Reduction Act of 2005," Pub. L. No. 109-171, the department shall report to the Governor and the chairmen of the Senate Finance and House Appropriations Committees the amount of savings anticipated in the Medicaid Forecast as a result of this change in federal law. In the event that anticipated pharmacy savings exceed the amount of savings assumed in the Medicaid Forecast, the department shall make recommendations concurrently with the report regarding the adjustment of pharmacy dispensing fees based on the impact of changes in local pharmacy reimbursements.