Agency Response to Economic Impact Analysis

The Department of Medical Assistance Services (DMAS) has reviewed the Economic Impact Analysis prepared by the Virginia Department of Planning and Budget, concerning its proposed regulations for Preferred Drug List (PDL), Pharmacy and Therapeutics Committee, state supplemental rebates, and high drug thresholds, and is in agreement with the overall conclusions of the report.

However, the agency provides the following comments about several of the concepts discussed in the analysis:

1. The analysis appears to draw an incorrect correlation between a drug manufacturer's rebate offer and the inclusion of that manufacturer's drug in the agency's Preferred Drug List. There is no such direct relationship. In fact, the P&T committee has refused to include certain products, for example Oxycontin, as preferred on its PDL list in spite of the manufacturer's offer of a rebate due to other overriding clinical concerns. In other cases, there are drugs on the PDL for which no supplemental rebate has been offered (Strattera, for example) and the P&T committee included these drugs as preferred in the PDL because of strong clinical considerations. The offer of or the amount of a manufacturer's supplemental rebate is not the primary consideration by the Pharmacy and Therapeutics Committee in evaluating drugs for inclusion on or exclusion from the Preferred Drug List. Clinical efficacy is always the primary consideration.

2. The analysis indicated that drug manufacturers could bid sequentially to determine the lowest acceptable rebate that would be acceptable to the P&T Committee. Drug manufacturers cannot bid sequentially to test the committee to determine the lowest rebate amount that would be acceptable, essentially bargaining their way on to the Preferred Drug List. It is irrelevant whether or not drugs in the same class are perfect substitutes for each other.

3. The analysis stated that the manufacturers would base their decisions on whether to offer supplemental rebates on production costs. References to drug manufacturers' decisions, regarding whether or not to offer rebates, being dependent on the average drug production costs being less than or equal to the after-supplemental-rebate-price alludes to

the use of a reference pricing mechanism. Virginia does not use such a mechanism in its PDL program. Although this was part of the RFP for the PDL contract, this model was not implemented. Instead Virginia, after speaking with numerous interested parties and experts, created a new contracting model that is different from the reference-pricing concept.

4. The analysis stated that the use of such rebates by the state would affect research and development business decisions made by manufacturers. Whether the drug manufacturers choose to offer state supplemental rebates is solely their decision. The decisions of the P&T Committee have no relationship to the business decisions made by the drug manufacturers regarding research and development of new pharmaceuticals. The P&T committee decision is based on clinical evidence, medical practice, and price.

5. The analysis suggestion that the P&T Committee should consider the effects of non-price competition costs on the ability of a manufacturer to offer rebates is not relevant. This is outside of the Committee's statutory mandate and therefore not possible to implement and irrelevant to the process. The P&T committee is not responsible for negotiating with manufactures and price is a secondary consideration to clinical efficacy. This concept has no foundational basis. There is no State in the country that has its P&T committee involve itself in price competition. This is inconsistent with the concept and charge of a P&T committee.

6. The statements that the drug manufacturers may engage in activities to secure favorable decisions or may collude or may offer fringe benefits to encourage doctors to engage in prior authorization with each other to fix prices describe activities which violate the federal and state anti-kickback statutes, and therefore, are prohibited activities.