Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 30-80 – Methods and Standards for Establishing Payment Rates – Other Types of Care: Pharmacy Services
Department of Medical Assistance Services
December 30, 2008

Summary of the Proposed Amendments to Regulation

Pursuant to Chapter 879 of the 2008 Acts of Assembly, Item 306 CC, the proposed regulations establish a new reimbursement methodology for specialty drugs. The proposed regulations have already been in effect under emergency regulations since October 2008.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

Pursuant to Chapter 879 of the 2008 Acts of Assembly, Item 306 CC, the proposed regulations establish a new reimbursement methodology for specialty drugs. Specialty drugs are drugs that are bio-engineered in laboratories from living cells rather than chemicals to treat diseases such as cancer, multiple sclerosis, and hepatitis-C. They may also include growth hormone agents. Unlike most other drugs, their production may not be replicated easily. The key element in their production is not the chemicals used but rather the process by which the living cells are bio-engineered. This bio-engineering process is non-public information often considered "a trade secret" which is not subject to expiration like a patent may be. These characteristics create a monopolistic market for specialty drugs. In the absence of competition, the market price is set by the seller (irrespective of the cost of production) that maximizes the revenues. For example, even though a specialty drug may cost only a few dollars to produce, its price may be in thousands of dollars.

According to a 2004 analysis by the Department of Medical Assistance Services (DMAS), annual per patient costs of specialty drug therapies can range from $6,000 to $350,000

annually. Also, it is estimated within the fee-for-service component of the Virginia Medicaid program, about $18 million annually is spent on specialty drugs related to only five chronic or genetic conditions. Also, DMAS analysis revealed that nationwide total population spending on specialty medications grew 26.6 percent in 2003. Given the high per patient costs and the fast growth in utilization and innovation, Medicaid specialty drug expenditure growth appears to be vulnerable.

Prior to the emergency regulations, specialty drugs were reimbursed just like any other drugs. The reimbursement was the lowest of i) the federal Upper Drug Limit, ii) the higher of either the lowest Wholesale Acquisition Cost (WAC) plus 10%, or the second lowest WAC plus 6%, iii) the provider's usual and customary charge to the public, or iv) the estimated Acquisition Cost. The proposed regulations establish that specialty drugs shall be reimbursed by the lowest of i through iv and also WAC price plus WAC percentage which is identified each year for all generic code numbers. This year WAC percentage in effect is 4.75%. The proposed changes give DMAS the ability to apply a different reimbursement price specific to specialty drugs and also the ability to designate specialty drugs by publishing them on its website.

Economic theory supports the use of concentrated market buying power (such as the one Medicaid has) to negotiate and reduce the price set by a monopoly (such as the producers of specialty drugs). Note that the neither the monopolistic seller nor the monopsonistic buyer even consider the cost of production while trying to determine the prevailing market price. Instead, the market price is determined by the relative bargaining powers of the unique seller and large buyer. In that sense, the proposed regulations are well justified in the sense that it gives DMAS an additional bargaining power when purchasing these drugs for the Medicaid recipients.

Since the proposed regulations are already implemented under emergency regulations, no savings are expected immediately upon promulgation of the proposed regulations. However, DMAS estimates that roughly about $250,000 annually may be saved in total funds upon promulgation of the proposed new pricing methodology for specialty drugs. Due to Medicaid funding mechanism, one half of the savings are expected to accrue to the Commonwealth while the rest are expected to accrue to the federal government. On the other hand, DMAS estimates that approximately $63,750 initially and approximately $75,000 on ongoing basis is needed to be

paid to private contractors to implement and maintain the proposed new specialty drug reimbursement methodology.

Businesses and Entities Affected

The proposed regulations affect the prices of specialty drugs. Roughly about 20 manufacturers are estimated to be supplying the specialty drugs whose prices may be affected by the proposed changes.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

The effect on the employment in Virginia may be positive as the demand for contractor services to administer the new methodology is likely to increase.

Effects on the Use and Value of Private Property

The direct effect on the use and value of private property in Virginia is not known with any certainty but not anticipated to be significant.

Small Businesses: Costs and Other Effects

The proposed regulations are not likely to directly affect small businesses as the directly affected entities are drug manufacturers that cannot be considered small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact

The proposed regulations are not anticipated to directly affect any entity that may be considered a small business.

Real Estate Development Costs

No real estate development costs are expected.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.H of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.H requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities

to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, Section 2.2-4007.H requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.