Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 30-50; 30-80; 30-130 –Department of Medical Assistance Services
Amount, Duration and Scope of Services: Prior Authorization of Pharmacy Services, Preferred Drug List, and Utilization Review of High Drug Thresholds; Methods and Standards for Establishing Payment Rates-Other Types of Care Pharmacy Services
June 9, 2004

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G 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. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

Pursuant to Item 325 ZZ of the 2003 Appropriations Act, the proposed regulations will permanently authorize DMAS to implement a preferred drug list and prior authorization requirements for prescription drugs as determined by the Pharmacy and Therapeutics Committee. Additionally, pursuant to Items 325 UU and VV of the 2003 Appropriations Act, the proposed changes will permanently implement utilization review for the use of high numbers of prescription drugs by institutionalized and non-institutionalized recipients. Finally, a few of the proposed changes improve the clarity of the Virginia Maximum Allowable Cost methodology. The proposed permanent rules have been implemented in practice in January 2004 under emergency regulations.

Estimated Economic Impact

The proposed regulations contain rules for Medicaid pharmacy fee-for-service coverage. Prescription drug coverage is an optional benefit that all states currently choose to provide. This benefit is provided to all recipients under the managed care and fee-for-service delivery models. While approximately 300,0000, or 58% of the total Medicaid recipients receive pharmacy benefits through managed care organizations, about 220,000 recipients, or 42%, receive pharmacy benefits through the fee-for-service model. These regulations apply to the fee-for-service component of the Medicaid pharmacy benefits.[1]

The cost of providing Medicaid pharmacy benefits has been rising rapidly throughout the nation. The expenditures have shown double-digit annual growth over the last decade. Virginia Medicaid's experience has been no different. The fee-for-service pharmacy expenditures have grown from $194 million in fiscal year 1997 to $356 million in fiscal year 2002, showing an average annual growth of 11% during this period. And, this growth has occurred despite the decreases in recipient enrollment in the Medicaid fee-for-service population that resulted from managed care expansions and cost saving initiatives already implemented.[2] According to DMAS, based on national studies, the main factors contributing to the growth in pharmacy costs are the discovery of new drug treatments, the increased use of drugs in treatment of various health conditions, the increased advertising by drug manufacturers, and the growth in the elderly and disabled populations. These factors increase expenditures either by increasing the average cost per unit, or by increasing utilization, or both. Thus, it seems worthwhile to identify the relative contribution of utilization and cost per unit to the growth in pharmacy expenditures.

The Medicaid claims database contains data on pharmacy expenditures, utilization, and federal rebates. The table on the next page identifies the relative contributions of utilization and cost per unit to the growth in expenditures net of federal rebates.[3] The table shows that the pharmacy expenditures net of federal rebates increased from $194 million in FY 1997 to $219

[1] Source: Status Report, Development of a Preferred Drug List Program by the Virginia Department of Medical Assistance Services, April 2003.
[2] One reason that expansions did not dampen the growth significantly is the fact that recipients with highest drug costs are not included in these expansions.
[3] The rebates are assumed to be received by a three-quarter lag. The percentage growth is calculated as the difference in logs.

Contributions of utilization and cost per unit to growth in pharmacy expenditures:

Year	Rx Expenditures	% Growth	Contribution of Utilization	Contribution of Cost Per Unit
FY97	$194,711,928	8%	16%	84%
FY98	$219,063,798	12%	21%	79%
FY99	$247,940,200	12%	27%	73%
FY00	$299,566,835	19%	4%	96%
FY01	$336,551,486	12%	10%	90%
FY02	$356,989,293	6%	32%	68%
Average		**11%**	**16%**	**84%**

million in FY 1998, exhibiting a growth rate of 8%. Increased utilization accounted for 16% of this growth and increased cost per unit accounted for 84%. The contribution of costs to expenditure growth has been consistently higher than the contribution of utilization between 1997 and 2002. The data indicate that the increasing cost of drugs is mainly responsible for the growth in Virginia Medicaid pharmacy expenditures while increasing utilization contributes a relatively smaller amount to the same growth.

There have been significant concerns about the rapidly increasing pharmacy expenditures. It appears that, unless increasing pharmacy costs create significant savings in other areas of the Medicaid program and revenues grow at comparable rates, the historical growth path of pharmacy expenditures will eventually force reductions in other programs in Medicaid as well as other government services. Data indicate that the portion of pharmacy expenditures within the total Virginia Medicaid budget has been increasing (e.g. from 8.9% in 1997 to 11.9% in 2002). The portion of Medicaid as a fraction of the total state budget has been increasing not only in Virginia, but also throughout the United States.

Preferred Drug List

Increasing pharmacy expenditures triggered initiatives to contain costs. One of the new initiatives is the implementation of a preferred drug list (PDL). A preferred drug list allows a state to negotiate and obtain supplemental rebates from pharmaceutical manufacturers. This approach to contain costs could be justified on several economic grounds.

In a third party payer system such as Medicaid, the *principal-agent relationships* among the doctor, patient, and the payor may be imperfect. A principal agent relationship occurs when one person, an agent, acts on behalf of another person, the principal. In this context, a doctor acts on behalf of the Medicaid agency when he prescribes a medicine. Since Medicaid pays for the prescriptions, the doctors may not fully consider the cost of prescription drugs, which may lead to higher pharmaceutical costs for the Medicaid agency.

A doctor also acts on behalf of the patient, which would require him to be aware of the best treatment available as well as the substitutability among alternative treatments. However, not all doctors may be fully aware of substitutability among the therapeutically equivalent drugs. These therapeutically equivalent drugs may be sold at different prices. This may result in prescribing higher price drugs for the same therapeutic benefits.

Whether it is the imperfect *principal agent relationship* between the prescriber and the payor, or between the prescriber and the patient, insofar as the manufacturers can charge a higher price for a product while there is no therapeutic advantage, the demand for that product does not reflect the social benefits that could be expected from it.

Additionally, a manufacturer may induce the demand for a particular drug through *non-price competition* strategies such as advertising, distinctive packaging, styling, coloring, and similar techniques, rather than reducing price. The main goal of non-price competition strategies is to differentiate a product from other close substitutes as much as possible and develop consumer loyalty, which gives market power to charge higher prices. In this sense, advertising, for instance, can alter the prescription patterns of doctors or the preferences of Medicaid recipients for a particular drug thereby allowing the manufacturer to charge higher prices than would be possible in the absence of advertising. The presence of non-price competition further exacerbates the imbalance between the social costs and the social benefits of a Medicaid prescription drug. This imbalance calls for government intervention. The proposed PDL program aims to alleviate this imbalance by introducing a demand side pressure on the manufacturers.

A PDL discourages the prescription of expensive non-preferred drugs while encouraging prescription of cost effective preferred drugs. It does so by employing two instruments: prior authorization and state supplemental rebates.

A preferred drug list establishes two groups of drugs: one group that does not require prior authorization before reimbursement will be authorized and one group that does require prior authorization before the Medicaid agency will authorize payment. The drugs on the list may be dispensed without a required prior authorization. The drugs not on the list require prior authorization. Thus, a PDL relies on the incentives provided to prescribing physicians who determine the demand for individual pharmaceutical products.

Prescription of a drug that is not on the PDL requires the physician to obtain prior authorization from a central office. Thus, physicians may be unwilling to prescribe drugs that are not on the PDL, depending on the physician's evaluation of his patient's medical needs. In other words, a PDL increases the costs of prescribing a drug that is not preferred and provides incentives to physicians to prescribe drugs that are on the list. The costlier is the prescribing of a non-PDL drug, the stronger are the incentives. Thus, establishing prior authorization requirements is an essential component of the implementation of a PDL.

The second essential component of a PDL is the system of state supplemental rebates offered by pharmaceutical manufacturers that are considered when selecting the preferred drugs for the PDL. Unless there are rebates associated with using drugs on the PDL, no savings would materialize. State supplemental rebates reduce the cost per unit for a given drug and help contain growing pharmaceutical expenditures. Given that the cost per unit is the main contributor to growth in Virginia's pharmacy expenditures, this initiative appears to be well targeted.

Based on the federal Centers for Medicare and Medicaid Services' agreements with the pharmaceutical manufacturers, the Commonwealth has already been receiving federal rebates from pharmaceutical manufacturers. The proposed PDL program allows the Commonwealth to negotiate for state supplemental rebates from the manufacturers above and beyond the rebates obtained through federal agreements. According to DMAS, more than 30 states either have implemented or are planning to implement a preferred drug list in their Medicaid programs. PDL programs have been common among the private managed care organizations. Furthermore, some states participate in a pooled preferred drug list.

Demanding supplemental rebates for all drugs may not be feasible because of clinical differences that relate to health and safety concerns. For example, there may be no therapeutically equivalent alternative to a drug, thereby preventing it from a "non-preferred"

status on the PDL. Also, in some cases, prior authorization may interfere with established complex drug regimens. Thus, not all drugs could be included in the PDL solely based on the supplemental rebates. The Pharmacy and Therapeutics Committee (the committee) addresses these issues.

Item 325 ZZ of the 2003 Appropriation Act outlines the make up and duties of this committee. The statutory language requires that the committee be composed of 8 to 12 members including the Commissioner of the Department of Mental Health, Mental Retardation and Substance Abuse Services, or his designee, with a ratio of two physicians for every pharmacist. One of the physicians must be specialized in psychiatry and one in care for the aging. Similarly, one of the pharmacists must have clinical expertise in mental health drugs and one in community-based mental health treatment. The members do not receive any compensation other than travel and lodging expenses.

Duties of the committee include (i) establishing therapeutic classes of drugs for inclusion on the PDL; (ii) identifying the specific drugs in each class that will be included in the PDL; (iii) establishing appropriate exclusions for certain medications used for the treatment of serious mental illnesses such as bi-polar disorders, schizophrenia, and depression; (iv) establishing appropriate exclusions for certain medications used for the treatment of brain disorders, cancer, and HIV-related conditions; (v) establishing exclusions for therapeutic classes in which there is only one drug in the class, or there is very low utilization, or for which it is not cost-effective to include the drug in the PDL; and (vi) establishing appropriate grandfather clauses when prior authorization would interfere with established complex drug regimens that have proven to be clinically effective.

The statute, pursuant to the federal regulations, also requires that the prior authorization decisions should be made within 24 hours and a 72-hour emergency supply of a drug may be provided when requested by a provider.

The Appropriation Act sets the fiscal goal of the PDL program. The statue requires at least $18 million total funds savings including general fund and federal matching funds in fiscal year 2004 and at least $36 million total funds annually thereafter.

The development of the Virginia PDL program has been in progress. For its design, DMAS has collected input from 28 stakeholder groups including physicians, pharmacists,

pharmaceutical manufacturers, consumer advocates, service providers, and other interested parties. Academic health centers, several medical societies, the Virginia Pharmacy Congress, and other provider associations have been asked to provide nominees for the committee membership. Out of the approximately 100 possible classes of drugs comprising about 182,000 different drugs, the committee has already reviewed 35 classes covering approximately 300 drugs that account for a high proportion of Medicaid pharmacy expenditures. The following describes the steps taken in the development of Virginia Medicaid PDL.

1) The committee recommends which therapeutic classes should be subject to the PDL,
2) For each therapeutic class, drugs are recommended based on clinical efficacy,
3) Of the recommended drugs, the committee reviews manufacturer bids for supplemental rebates to determine cost effectiveness,
4) Final PDL includes clinically effective drugs with or without supplemental rebates,
5) Non-preferred drugs are available through prior authorization.

The Appropriation Act requires the Pharmacy and Therapeutics Committee to make all critical decisions. One of these critical decisions is inclusion of a drug in a therapeutic class of drugs. The proposed regulations and conversations with DMAS indicate that the therapeutic classes are defined broadly to include drugs that may be neither chemically identical nor pharmacologically equivalent, but have comparable therapeutic effects. This also means that the therapeutic classes may include on-patent drugs as well as generics.

The inclusion in a therapeutic class of drugs affects the market for each of the manufacturers of drugs included in the cluster. The inclusion in a therapeutic class has the implication that the drugs included in a cluster are in fact good substitutes for each other without any significantly different therapeutic outcomes. In other words, the *de facto* degree of substitutability among the drugs is high. Thus, a PDL may educate some doctors about the substitutability of different drugs to achieve the same therapeutic outcome. This new knowledge to some doctors about the availability of other good alternatives may affect their prescribing patterns and increase the level of competition in the therapeutic cluster.

In addition to the informational aspect of a PDL and probably more importantly, no prior authorization for drugs on the PDL provides incentives to Medicaid recipients and physicians to discount the actual or perceived differences among drugs in the same cluster. As the effect of product differentiation is dampened among the drugs in the same cluster, firms lose their significant market power and consequently these manufacturers may start becoming more aggressive competitors to maintain or bolster their current market share.

In this more competitive environment, manufacturers must make some strategic decisions as the committee requests a bid from the manufacturers that represent their best price or "net cost" for the supplemental rebate. According to DMAS, the committee considers many factors when determining selection of a drug on the PDL; the offer of the rebates from manufacturers is only one consideration. There is no uniform methodology, but a general "cost effectiveness" guideline to determine the "net cost" price in the supplemental rebates. For example, the committee may consider a lower rebate from a manufacturer with large market share when weighing the risks associated with moving patients from one drug to another therapeutically equivalent drug in the same cluster. Also, the committee may consider a drug in the PDL even if the manufacturer does not provide a supplemental rebate provided there is a clinical, therapeutic reason.

On one hand, manufacturers have incentives to offer the lowest possible supplemental rebate and on the other hand they have incentives to be on the PDL. However, the size of the supplemental rebates and the probability they will be on the PDL may be inversely related. The best strategic response for a manufacturer is then to offer the minimum amount of supplemental rebates while maintaining an acceptable chance to be included in the PDL. Other possible factors may allow a manufacturer to be on the list with a smaller rebate offer. For example, if the manufacturer knows that there are risks associated with moving many patients from its product to an alternative, it would be less willing to offer a large rebate because it knows that the committee may face some risk and probably is willing to accept a lower rebate to avoid that risk. Conversely, if the other manufacturers in the same cluster offer high rebates, then a particular manufacturer may be forced to offer high rebates as well. The presence of such factors would affect the manufacturers' bargaining power and the size of potential rebates they may offer.

One of the major challenges for the manufacturers is correctly assessing the threshold rebate level at which the committee will accept the bid for inclusion in the PDL. For example, if a firm were allowed to bid different rebate levels sequentially, it would be able to find out exactly what that level is. Because the committee will update the PDL annually, it is difficult for a firm to assess the preferences of the committee in the short run.[4] The uncertainty about the acceptable threshold rebate level would likely cause some firms to bid high and some others to bid low. Thus, some firms may end up offering more rebates than acceptable to the committee and some others may offer less and lose their market share.

It is worth noting that the decision of a manufacturer may be further complicated if there are cross-market effects. A manufacturer may be subject to cross-country or private insurance company reference pricing. Some countries or insurance companies set the reference price at the lowest price accepted by the manufacturer from other customers or from a number of other countries. For example, the reference price in Canada may be affected by the prices in the United States. Thus, a manufacturer may maintain a high price despite the loss of Medicaid market share if it faces greater losses from reducing prices elsewhere. In short, the strategic response of manufacturers would also take into account spillover price effects to other markets if there are any.

Moreover, implementation of the PDL may lead to reduced costs. As mentioned, the PDL strips off some of the benefits that would be expected from product differentiation. This means that if the Medicaid pharmaceutical market is a large enough market for a manufacturer, every dollar invested in non-price competition techniques has a lower rate of return. Thus, firms relying heavily on non-price competition would be expected to cut advertising costs or other costs associated with creating a differentiated product.[5]

The committee also will have to make some strategic decisions to maximize rebate collections. Once they receive a bid for supplemental rebates, they must decide whether to accept or reject the offer. If they do not accept an offer, they will forego the proposed supplemental rebates, but perhaps other drugs in the same cluster that are already on the PDL

[4] However, some learning will likely take place if the bids are made publicly available. Also, manufacturers with many drugs may have a better assessment of the committee's preferences.

[5] For some firms, reduced advertising spending may actually increase costs if the average cost of producing lower output levels is much higher than the average cost of operating at higher output levels.

would increase their market share. Thus, if the drugs in the same cluster are perfect therapeutic substitutes, the committee would expect at least as large savings as those offered by other manufacturers in the cluster. If the drugs in the cluster are not perfect substitutes, or have some superior characteristics, then the committee would probably be willing to accept a lower offer for consideration in the PDL.

The committee should consider some distinctive characteristics of the pharmaceutical market. For example, the committee should recognize the differences between on-patent and generic drugs when considering rebate levels. Contrary to the common belief, the pricing principles for firms with some market power, or with a distinctive product has little to do with the cost of production. These firms look at the demand and set the price to maximize profits whether it is a generic product or an on-patent product. In general, we would expect on-patent drugs to have the market power to charge higher prices than generics.[6]

The decision to participate in the state supplemental rebates, however, is a complex one but includes the average cost of production. If the average cost is less than or equal to the after supplemental rebate price, firms would participate. In general, we would expect an on-patent drug to have a higher average cost than the generic version because of the research and development (R&D) expenditures. In short, because the average costs of on-patent drugs are greater than the average costs of generics by the amount of R&D expenditures among other factors, we would not expect on-patent drugs to be able to reduce their after rebate prices to the level that may be offered by the generic drugs. However, because on-patent drugs may be selling at much higher prices in the market, the size of the rebate offered by an on-patent drug may exceed that offered by a generic equivalent.

The committee should also recognize the potential effects of their decisions on R&D activity and new drug developments. The main motivation behind investing in pharmaceutical R&D is the anticipated economic profits for the duration of a patent. The greater the supplemental rebates expected from on-patent drugs, the lower the net present value of an R&D investment project. The lower the net present value of a project is, the less likely it is to be

[6]It is possible that a generic drug may be more distinctive than an on-patent drug in the eyes of the consumers, enjoy stronger consumer loyalty, and consequently may be sold at a higher price than the patented close substitute.

undertaken. The potential adverse incentives would be greatest if the committee expects on-patent drugs to reduce their after rebate prices to the level that may be offered by generics.

The proposed PDL may affect various types of on-patent drugs differently. Some drugs are issued patents for incremental improvements in already existing pharmaceutical products while some others are issued for truly original products. The former could be classified into an already existing therapeutic cluster while the latter could not be. Because there are no other close substitutes for original products they are relatively immune from competition. This feature of the PDL would give firms incentives to manage research and development in a way that places them outside of PDL competition. So, we may see the firms redirecting available R&D resources to original products rather than incremental innovations in existing drugs. The net benefit from such original projects may be higher than it might otherwise be for other projects.

The committee should also consider the effects of non-price competition costs on the ability of a manufacturer to offer rebates. As discussed before, the main purpose of the investment into non-price competition is to increase the perceptions of the consumers and doctors, so that a higher price can be charged in the marketplace. Also, we know that the decision to offer supplemental rebates depends on the average cost of production. So, even if a manufacturer offers an after rebate price that is equal to the average cost, the Medicaid program may still be financing some of the costs associated with non-price competition. In these cases, it would be informative to know not only the average cost, but also the components making up the average cost to understand whether the after rebate price is consistent with public benefits.

A PDL will encourage the pharmaceutical manufacturers to differentiate their prices. While the manufacturer would be in a position to charge lower prices for Medicaid recipients than perhaps for some private payers, this is commonplace among the firms operating in markets with some market power. A firm with some market power can and will discriminate prices if it can separate consumers according to their willingness to pay and prevent resale of the product in the secondary market. This is why airlines have a first class, a business class, and an economy class. Airlines also charge more for tickets on short notice and charge less for seniors or students. This is also why retailers offer the same product at different prices with or without coupons or a membership card. Charging different prices for different consumers with different willingness to pay is not only a well-known and accepted economic phenomenon that enables

firms to maximize profits, but also cause the output level to exceed the level that would result if only a uniform price can be charged.

Implementation of the PDL may encourage rent-seeking behavior at the individual manufacturer level. The rents are economic benefits in excess of those that would be possible under the supplemental rebates. Some manufacturers may find it in their best interest to devote some resources to obtain favorable decisions. The rent seeking may take many forms such as purposefully challenging the information used by the committee to establish therapeutic equivalence or to determine the size of rebates. Although it may be in the best interest of an individual company to seek rents, this represents an economic loss for the society.

The drug manufacturers may also be inclined to offer fringe benefits to doctors in an effort to encourage them to obtain prior authorization rather than participating in the PDL. It may be the case that the cost of these benefits may be much lower than the supplemental rebates that must be given up as supplemental rebates. Again, such behavior would undermine the economic benefits expected from the implementation of the proposed PDL program.

There is the possibility for collusive actions in a cluster of drugs. Even though many forms of collusive behavior to reduce competition are illegal, firms may still try to limit competition through some other ways. For example, they may practice tacit collusion, or some firms may start acting as a leader in the cluster and others may act as followers in an effort to affect after rebate prices. The main goal of such collusive behavior is to maximize the total industry profit rather than the individual firm profits. Thus, it would definitely undermine the cost containment goal of the PDL program. However, for a collusive behavior to exist certain prerequisites must be met depending on the type of collusion and usually there are great gains from deviating from the collusive strategy and cheating other members in the pact. Whether such collusive behavior is likely to surface following the implementation of the PDL is not known.

The PDL program seems to have a good potential to minimize efficiency losses resulting from over-use of free pharmaceuticals. Because of the third party payor system, manufacturers may charge a higher price, which causes welfare losses. The proposed PDL program would reduce such losses. Also, the PDL's ability to discourage non-price competition and encourage price competition for most pharmaceutical manufacturers would likely produce some gains for

the society. As the degree of competition increases, the market offers more output for a lower price. During this transition, firms lose much of their above normal profits and buyers start receiving these profits as lower prices for the goods. Consequently, a welfare transfer from firms to consumers, or the Commonwealth in this case, occurs. Interestingly, the consumer welfare gains exceed the pharmaceutical firms' losses. This is because the more competitive the market is, the smaller is the misallocation of scarce resources or inefficiency costs (deadweight losses). In short, the total welfare gains exceed the total welfare losses, which benefit the society as a whole. If an analogy may be offered, this is similar to not only more equally redistributing the pie but also increasing the size of the pie for the society as whole.

The fiscal impact of the proposed PDL includes the expected savings from lower pharmaceutical prices. As mentioned before, the Appropriation Act requires $18 million total fund savings in state and federal funds in FY 2004 and $36 million total funds in the following years. These savings represent the transfer of resources from drug manufacturers to the Commonwealth on behalf of the Medicaid recipients being the consumers. With the PDL program in place, the pharmaceutical manufacturers would have to let go of some of the consumer surplus (a measure of consumer welfare).

However, these savings would require some investment in administrative resources. DMAS already has a qualified contractor. This contractor has established a call center to administer the prior authorization process. The ongoing review of clinical data would require staff support for the committee. The committee will focus on the clinical data for drugs that are claimed to be therapeutically different in addition to analyzing all the clinical data available for all drugs in the selected therapeutic classes. This approach would reduce what would otherwise be a daunting task to a manageable level. Furthermore, there will likely be some administrative costs associated with appeals. According to DMAS, since the implementation of the PDL in January 2004, there have been no denials of prior authorization requests received and DMAS believes that the number of appeals would be less than one percent of the total prescriptions. According to DMAS, the cost of the administration of this program is about $1.4 million.

Additionally, the PDL may be modified to generate more or less savings if desired. The size of the savings depends on the product coverage of the PDL, state supplemental rebates,

market prices, and the prescribing behavior of doctors. The committee may exert some influence on these factors.

The PDL's impact on long-term savings is more difficult to assess. The difficulty arises because as time passes there is more uncertainty about the benchmark expenditures that would be used to calculate savings. This uncertainty arises from the behavioral changes that would have occurred in the absence of the PDL. For example, it is more accurate at the end of the first year to look at the actual expenditures and benchmark expenditures that would be realized without the PDL to calculate savings. In the following years, one does not have many options, but continues to assume that the same market conditions prior to PDL remain unchanged even though it may not be true.

Also, it is unrealistic to expect that the PDL would stop growth in pharmaceutical expenditures. As discussed, following the PDL, manufacturers could start deciding to offer state supplemental rebates based on their average production costs. As their average costs increase, we should expect to see an increase in pharmaceutical expenditures. However, the growth rate of the pharmaceutical expenditures with the PDL should be less than the growth rate without the PDL, as firms would be prevented from taking advantage of imperfect principal agent relationships and non-price competition strategies.

There is likely to be some impact on the Medicaid recipients. They may end up with a shorter list of drugs (not subject to prior authorization) to achieve the desired therapeutic results, or their physicians may have to obtain prior authorization for the same drug they are already using. The drugs in a cluster that is established by the therapeutic equivalence approach are subject to heterogeneity in performance, effects, absorption, contra-indications, and undesired effects. Heterogeneity would be larger in a broader cluster. Patient diversity may further add to the degree of heterogeneity. It would not be surprising to see some manufacturers not participating in the PDL program whose products may then be subject to prior authorization requirements. In as much as the committee would strive to determine the therapeutic equivalency among the alternative drugs, the possibility of at least a few recipients using prescriptions that must be prior authorized in order to access their best therapeutic treatment cannot be ruled out. Thus, some recipients may have to make extra trips to their physicians' offices and their pharmacies.

Another less clear effect on recipients and their physicians is the lost value of actual or perceived benefits from product differentiation. For privately paying customers, it can be argued that the ability to choose from a wider range of close substitutes has a value as consumers show willingness to pay for perceived benefits of product differentiation. For example, many privately paying consumers may pay extra to buy a specific brand of aspirin. However, since Medicaid pharmacy benefits are publicly funded, we do not know how much value, if any, the recipients attach to the perceived differences in drugs.

The proposed PDL program may also introduce additional costs for physicians if they choose to prescribe drugs that are not preferred. These costs are related to obtaining prior authorization from a central office. Thus the physician must decide whether the value of prescribing a non-preferred drug exceed the costs of obtaining prior authorization. If the *principal-agent relationship* is not perfect between the patient and the physician, potential for adverse health effects on recipients may be exacerbated. On the other hand, in some cases physicians might not have perfect information about the availability of a low cost drug that meets the quality of a more expensive drug and may be exerting some unnecessary costs on the Medicaid program. A PDL would reduce such costs based on the therapeutic decisions made by the committee.

The pharmacy providers may also be affected. The claims system checks whether a prescribed drug is on the preferred drug list or not prior to authorizing payment for the claim. When a prescribed drug is not on the list, the pharmacist may have to contact the prescribing doctor's office, in the event the physician hasn't obtained the prior authorization. Therefore there is likely to be some additional costs for the pharmacy providers. However, these costs would be incurred in cases when a doctor writes a non-preferred drug unintentionally. If the doctor wishes to prescribe a non-preferred drug, there is a proactive prior authorization process. The proactive prior authorization process would minimize the potential costs on pharmacists when a non-preferred drug is prescribed.

It is important to realize that the proposed PDL program differs from many standard regulations in the sense that it does not impose direct costs on manufacturers. The participation in the state supplemental rebates, while contingent upon giving up some profits, is voluntary. So, we would expect those firms that would continue to make profits when offering

supplemental rebates, would continue to participate in the program. Those that do not wish to participate in the state supplemental rebate program, and have a "non-Preferred" status can still serve Medicaid clients through the prior authorization process. Similarly, the doctors can prescribe and recipients can access non-preferred drugs by obtaining a prior authorization.

In conclusion, the proposed PDL program seems to have a good potential to create fiscal savings for the Commonwealth without introducing any gross economic inefficiencies relative to benefits expected from it. It does so by mitigating the inefficiencies arising from imperfect principal agent relationships and encouraging drug manufacturers to compete in prices rather than allocating their resources for non-price competition. Incentives to compete in prices reduce inefficiencies resulting from market power, information imperfections, and agency imperfections. The main result is the recovery of some of the consumer surplus from manufacturers to the Commonwealth and the avoidance of deadweight losses. However, a PDL also creates small-scale inefficiencies particularly for manufacturers of innovative drugs for which a therapeutic cluster exists and for some recipients, physicians, and pharmacists. Such inefficiencies would be perhaps much greater under an alternative cost containment regulation as PDL maintains most market forces intact. For example, compared to price controls, the PDL leaves pharmaceutical companies free to set their prices for the rest of the market.

High Drug Thresholds

The proposed regulations also establish permanently utilization review requirements in cases where recipients use high numbers of prescription drugs. Item 325 UU of the 2003 Appropriation Act mandates DMAS to require prior authorization of prescription drugs for non-institutionalized recipients when more than nine unique prescriptions have been prescribed within a 180-day period. Similarly, Item 325 VV of the 2003 Appropriation Act requires prior authorization of drugs for institutionalized recipients when more than nine unique prescriptions have been prescribed within a 30-day period.

Individual dispensing pharmacies do not have access to all the information on drugs that may be dispensed through other pharmacies. Also, utilization review of such cases requires case-by-case analysis of the recipients' drug profiles by a trained pharmacist, as it cannot be computerized. DMAS expects about 112,000 cases per year where the nine-prescription threshold may be exceeded. The reviews will be conducted through a contractor.

The estimated cost of the contract to implement review and prior authorization requirements for high drug thresholds is about $1.2 million. One of the main benefits of the proposed change is the reduced potential for drug fraud and abuse. Also, recipients with high utilization of drugs are often frail and elderly. A review of their complete drug profiles may prevent some drug-to-drug interactions, overdoses, and inappropriate dosages and consequently reduce the potential risks to health and safety of these recipients. DMAS expects to save about $4.2 million state and federal funds by the review of excess utilization cases.

Other

Pursuant to a request by the federal Centers for Medicare and Medicaid Services, the proposed regulations will also clarify that the Virginia Maximum Allowable Cost, the reimbursement methodology by which DMAS calculates payment for generic drugs, is the 60th percentile cost level for the generic unit-dose drugs and 75th percentile cost level for other non-unit-dose generic drugs. Also, it will be clarified that the unit-dose dispensing fee is $5 per recipient per month per pharmacy provider. None of these clarifications will result in a change in current methodology, policy, or expenditures. Thus, no significant economic effects are expected from these clarifications.

Businesses and Entities Affected

The proposed regulations may affect up to 100,000 Medicaid recipients per month, 27,000 medical providers and prescribers, 1600 pharmacy providers, and 43 pharmaceutical companies.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth.

Projected Impact on Employment

The proposed regulations are expected to reduce the production of drug manufacturers who choose not to participate in the PDL, but at the same time increase the production of those who gain market share from participating in the PDL. This would result in a reduction in demand for labor by some manufacturers, but an increase in demand for labor by some other manufacturers. Also some drug producers may invest less in research and development (R&D) directed toward incremental improvements in existing drugs and reduce demand for labor while

others may increase investment in R&D directed to development of original drugs and increase demand for labor. The anticipated changes in demand for labor would reduce or increase employment in the Commonwealth depending on which manufacturers are located in Virginia and how they are affected by the PDL. Also, physician offices that insist on prescribing non-preferred drugs and some pharmacies may need additional staff to obtain prior authorizations. The significance of this effect on demand for labor is unknown.

Effects on the Use and Value of Private Property

Drug manufacturers participating and not participating in the PDL would probably experience a reduction in their profits. Similarly, manufacturers with R&D activities directed to incremental improvements in existing drugs may experience a reduction in their future stream of profits. The value of Virginia drug manufacturer businesses would decrease to the extent they are affected by these Medicaid rules. Furthermore, the profitability of some physician offices and pharmacies may be slightly hurt due to administrative costs associated with prior authorization for non-preferred drugs. The value of the physician and pharmacy businesses would also decrease as their profitability declines.