



# COMMONWEALTH of VIRGINIA

## *Department of Medical Assistance Services*

November 8, 2004

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DIRECTOR

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### MEMORANDUM

**TO:** The Honorable Vincent F. Callahan, Jr.  
Chairman, House Appropriations Committee

The Honorable John H. Chichester  
Chairman, Senate Finance Committee

The Honorable Harvey B. Morgan  
Chairman, Joint Commission on Health Care

**FROM:** Patrick W. Finnerty

**SUBJECT:** Status Report on the Medicaid Preferred Drug List Program and Other  
Pharmacy Initiatives

As required by the 2003 Appropriations Act, the Department of Medical Assistance Services (DMAS) submitted a report on the Preferred Drug List (PDL) program to the Senate Finance Committee, the House Appropriations Committees, and the Joint Commission on Health Care in April 2003. While not required by the Appropriations Act, subsequent reports were submitted on June 16, 2003, September 1, 2003, and February 12, 2004. This memorandum summarizes the PDL activities and accomplishments that have occurred since the last status report, and provides information on several other pharmacy-related activities ongoing within the Department.

As you know, the PDL program was implemented in three phases (January 5, 2004, April 1, 2004, and July 1, 2004). Implementation of all three phases of the PDL program has been very successful. Attachment A provides an overview of the drug classes that were implemented in each of the three phases.

Some of the major accomplishments related to the PDL include:

- 1) the Department implemented a "Virginia-specific" program design and supplemental rebate process that is unique among other states and is working quite well;
- 2) there have been very few complaints regarding the program;
- 3) there is very high compliance rate (92%) in terms of "preferred" drugs being prescribed for Medicaid clients;
- 4) the prior authorization process and First Health Call Center are working very smoothly as evidenced by an extremely low call abandonment rate and minimal call time (now less than 2 ½ minutes);
- 5) no Medicaid recipient has been denied access to a drug under the PDL program; and
- 6) initial estimates of cost savings indicate that the required savings targets will be met.

The following paragraphs provide additional information about the status of the PDL program and other pharmacy program activities at DMAS.

### **Pharmacy and Therapeutics Committee**

The Pharmacy and Therapeutics (P&T) Committee, comprised of eight physicians and four pharmacists, directs all phases of the PDL program including: (i) selecting the therapeutic drug classes to review for possible inclusion in the PDL; (ii) deciding which classes should be included in the PDL; (iii) assessing the clinical efficacy of the drugs within each class under review; (iv) selecting the "preferred" drugs in each class; (v) establishing clinical criteria; (vi) developing appropriate prior authorization procedures; and (vii) advising the Department on other pharmacy initiatives.

The P&T Committee held eleven meetings between June 2003 and October 2004. Attachment B provides an outline of the meetings held by the P&T Committee and the decisions made at each meeting. The Committee has reviewed thirty of the top fifty drug classes to date as well as completed an annual review of thirteen of these classes for 2005. A copy of the PDL "Quick List" which identifies the drug classes included in the PDL program and the "preferred" drugs within each class is provided at Attachment C.

During the most recent meeting of the P&T Committee (October 6, 2004), the Committee reviewed, for possible inclusion in the PDL, the antidepressants (including the Selective Serotonin Reuptake Inhibitors -- SSRIs) and antianxiety medications used in the treatment of mental illness. Immediately following that meeting, I sent a memorandum to the members of the Health & Human Resources Subcommittees of the Senate Finance and House Appropriations Committees as well as the members of the Joint Commission on Health Care summarizing the P&T Committee's deliberations and

November 8, 2004

Page 3

the next steps that will be taken on this issue. A copy of my October 7, 2004 memorandum on this topic is provided at Attachment D.

### **PDL Implementation Advisory Group Activities**

In an effort to provide a mechanism for stakeholder participation and program support, DMAS established the PDL Implementation Advisory Group (PDLIAG) to provide advice to the Department regarding the implementation of the PDL program. The PDLIAG consists of representatives from pharmaceutical manufacturers, the provider community, and advocacy groups. The PDLIAG held six meetings from September 2003 through November 2, 2004. Several of the major PDL successes were the direct result of advice and support received from the members of the PDLIAG. The group recommended that DMAS: (i) determine how other states developed PDL educational processes; (ii) arrange statewide training sessions and other educational tools for providers; (iii) conduct PDL beta site testing with chain and independent pharmacies; (iv) develop policies and procedures to clarify the appeals process; (v) implement 72-hour dispensing fees for pharmacists; and (vi) enhance the PDL communications strategy. Although the initial charge of the group (implementation of the program) has been completed, the PDLIAG will continue to meet periodically to monitor progress with the PDL and other pharmacy initiatives.

### **PDL Clinical Edits (COX II Inhibitors and Long Acting Narcotics)**

In developing the prior authorization criteria for PDL drug classes, the P&T Committee decided to implement clinical edits for particular classes to ensure that drug therapy is managed appropriately based on various clinical considerations. Currently, COX II Inhibitors (used to treat inflammation) and Long Acting Narcotics classes have specific clinical edits. For the COX II Inhibitor drug class, the P&T Committee decided to implement clinical edits to ensure clinical efficacy and prevent inappropriate use. Effective July 2004, patients under age 60 with a new prescription for any COX II Inhibitor are required to obtain a prior authorization for use of the drug. The criteria for the edit also require patients to have attempted the use of two appropriate, more cost effective medications or have a pre-existing gastrointestinal disease before utilizing a COX II Inhibitor. Patients under age 60 who have been on COX II therapy between January and June 30, 2004, were able to continue their drug treatment until their current prior authorization expires or until June 30, 2005, whichever comes first.

On September 30, 2004, the Department made changes to the PDL program specific to the COX II Inhibitor drug class as a result of Merck & Co. removing Vioxx from the market. The market withdrawal of this drug affected patients, payers, and providers nationwide. Since Vioxx had been the only "preferred" drug in this class, the Department took immediate action to allow the other two drugs in this drug class (Celebrex and Bextra) to be "preferred" drugs until December 31, 2004. This is an interim step because the P&T Committee decided at its October meeting that effective January 1, 2005, Celebrex will become the sole "preferred" drug and Bextra will revert to

the “non-preferred” status. The Committee will monitor all clinical evidence and studies on COX-IIs to determine whether additional changes are warranted.

For the Long-Acting Narcotics class, clinical criteria were developed to manage these high risk drugs, and ensure that pain management decisions are made in an appropriate and safe manner. Effective January 1, 2005, the clinical criteria will be applied for all long-acting narcotics, and will require the attempt of two short-acting narcotics (average 4 hours) prior to the use of a long acting narcotic (average 8-12 hours). The clinical criteria will not apply to patients stabilized on long-acting narcotics or those that require 24-hour pain therapy for an extended period of time. Special guidelines are also in place for the use of OxyContin and Methadone. In developing these guidelines, the P&T Committee consulted with two national pain management experts.

### **PDL Program Evaluation Results**

DMAS proactively decided to conduct a comprehensive analysis of PDL operations, utilization, and cost savings. DMAS’ Policy and Research Division has been conducting ongoing analysis of the program since its inception. The key findings of the most recent analysis are listed below. These findings were presented to the PDLIAG at its meeting on November 2, 2004.

- **Compliance** -- The PDL compliance rate, measured as the percent of patients being prescribed “preferred” drugs, remains high. While the compliance rate varies among the different drug classes, the overall compliance rate across all drug classes is 92%. This rate exceeds the compliance level (85%) needed to achieve the necessary budget savings.
- **Prior Authorization** -- There have been no denials of medications as a result of the PDL prior authorization process. Since the beginning of the program, 76% of all requests for prior authorization have been granted; for the remaining 24%, the prescribing physician voluntarily switched to the preferred drug. There have only been technical denials for retrospective payments to long-term care facilities that have already dispensed the medication but did not comply with the appropriate PDL processes. Therefore, there is no evidence that any patient has been denied access to their medications as a result of this program.
- **Call Center Operations** -- The PDL call center, managed by First Health Services, has been operating efficiently. The Call Center is responsible for receiving and evaluating prior authorizations as well as responding to other program inquiries. As of September 2004, Call Center activity has leveled off with an average of 894 calls per week and an average of 1,755 issues addressed each week. Physicians make the majority of calls and most calls involve requests for prior authorization. The Call Center staff continues to manage these calls

promptly. As of September 2004, calls were being answered within 16 seconds and the average call length was less than two and one-half minutes.

- **Market Shift** -- Market share of PDL drug classes has significantly shifted as a result of the program. In September 2004, preferred drugs accounted for 89% of all claims in PDL drug classes compared to 61% in January 2004 (prior to the PDL Program). This market shift indicates an acceptance among providers of the drugs available as "preferred," and supports the achievement of program savings.
- **Cost Savings** -- Evaluation results show the average cost per prescription has decreased below the projected amount since PDL implementation. In addition, the actual pharmacy expenditures are significantly below the Department's official forecast. While the final savings estimates have not been completed, these comparisons of actual versus forecasted expenditures indicate the program is meeting the targeted level of savings required in the Appropriations Act. These savings are driven principally by a supplemental rebate process that has worked very well (overall, manufacturers have provided competitive pricing) and the high PDL compliance rate (92%).

### **Other Medicaid Pharmacy Initiatives**

In addition to the PDL, the Department has implemented several other pharmacy initiatives during 2004 to improve the quality of services provided to its clients. Many of these initiatives also have the added benefit of saving the Commonwealth money.

- **Management of Generic Drug Utilization**

The utilization of less expensive generic drugs can provide significant cost savings in pharmacy claims. DMAS' new Mandatory Generic program helps ensure that, whenever feasible, generics are dispensed instead of more costly brand name products. The Department's state plan requires that prescriptions for multiple source drugs be filled with generic drug products unless the prescribing provider requires that the brand be used. Effective September 1, 2004, pharmacy claims are denied when a brand name drug is inappropriately dispensed rather than a generic. Provisions are in place that ensures claims are paid in those rare situations when the pharmacist must dispense the brand name, because no generics are available.

- **Maximum Allowable Cost (MAC) Pricing for Generics**

Effective December 1, 2004, the reimbursement for multiple source generic drugs will be subject to a new maximum allowable cost (MAC). MAC reimbursement, required by the 2004 Appropriations Act, is used by Medicaid programs in approximately 41 states and by most private insurers throughout the commercial

insurance market to control the cost of generic drugs. By instituting the new MAC reimbursement methodology for multiple source generic drugs, the Department will reimburse pharmacies an amount that more accurately reflects their purchase price, which is considerably less than the current Medicaid reimbursement. The MAC price is a maximum amount a certain drug will be reimbursed, based on the average price of multiple manufacturers' prices of a specific drug. The MAC price may change on a monthly basis due to market conditions; therefore, this pricing mechanism takes advantage of the cost savings of a competitive environment. If a pharmacy provider discovers that the MAC price does not accurately reflect the drug cost, and there are no alternative suppliers, a pricing review may be requested for resolution. The MAC list will be updated monthly and available on the Department's web site.

- **Coordination of Care and Threshold Programs**

The Threshold/Polypharmacy program, required by the 2003 Appropriations Act, is intended to monitor drug profiles for clinically appropriate drug utilization, improve the health and safety of recipients, enhance opportunities to reduce severe adverse drug reactions, retrospectively monitor high drug utilization, enhance continuity and coordination of care, and identify clinical misuse and fraud. This program was implemented in two steps. The first step is a Coordination of Care initiative, which focuses on recipients who may lack a primary care physician and/or a single pharmacy to coordinate and optimize their medication regimens. All physicians of patients identified with coordination of care issues, based on established criteria, received notification on October 1, 2004 of their patients' drug utilization patterns as well as an educational intervention package to consider any necessary changes to promote care coordination and reduce inappropriate drug utilization. The second step, Threshold/Polypharmacy program, expands this focus to all recipients receiving greater than nine unique prescriptions in a 30-day period. Beginning October 15, 2004, all recipients greater than nine unique prescriptions are retrospectively reviewed for appropriate drug utilization; and prescribing physicians of those with potential issues will receive letters requesting review of the information, clarification of issues, and consideration of appropriate changes.

- **Prospective Drug Utilization Review (ProDUR)**

The ProDUR program is a quality improvement program that involves a prospective review of each prescription along with the patient's drug therapy history to determine if there are potential adverse effects including, but not limited to, drug therapy duplications, contraindications, interactions and early refills. Claims with these edits will deny for payment and pharmacists must use their professional judgment in determining when to bypass the edits. Effective February 16, 2004, some ProDUR edits require pharmacists to provide

November 8, 2004

Page 7

appropriate intervention and outcome codes to override a payment denial. In addition, effective June 14, 2004, the Early Refill edits (occurs when refill of prescription is presented before 75 percent of the medication is used) that previously required the pharmacist to enter an intervention code to override the denial, now requires a phone call to the First Health Call Center to receive prior authorization based on the approval criteria.

The 2003 Appropriations Act also required the Department to review its elderly long-term care enrollees for any inappropriate use of medications. The Department, with consultation from its Drug Utilization Review Board, approved the Beers criteria, a widely accepted method for pharmacy reviews of older adults, to be conducted every six months as a retrospective review of enrollee medication profiles. The review includes all Medicaid enrollees 65 years and older, not just those in long-term care facilities. In April 2004, one thousand medication profiles were generated for all enrollees 65 years and older who met any of the Beers criteria. Letters were sent to 533 prescribers whose patients are receiving medications or dosages that are potentially inappropriate for them. These letters included information regarding a total of 731 interventions and 466 patients. Many of the letters contained more than one criteria intervention and several recipients had letters sent to more than one prescriber. No notable trend was detected in the review of these profiles; however, the large number of interventions reflects the widespread use of these medications in older adults.

We will continue to submit reports to you in the coming months to keep you abreast of the status of the PDL program and other pharmacy initiatives. More detailed information on the PDL program and other DMAS pharmacy initiatives can be found on the agency's website at [www.dmas.virginia.gov](http://www.dmas.virginia.gov). Should you have any questions or wish to discuss any of these issues, please feel free to contact me at (804) 786-8099 or send an email message to [PDLInput@dmas.virginia.gov](mailto:PDLInput@dmas.virginia.gov).

Thank you.

/pwf

Enclosures

cc: The Honorable Jane H. Woods  
DMAS Pharmacy and Therapeutics Committee  
DMAS PDL Implementation Advisory Group  
Susan Massart  
Joe Flores  
Kim Snead

## **Attachment A: Drug Classes Included in Each Phase of PDL Implementation**

### **Phase I Drug Classes ~ January 5, 2004**

- Proton Pump Inhibitors
- Nasal Steroids
- Non-Sedating Antihistamines and combination products
- Histamine-2 Receptor Antagonists
- Inhaled Beta Adrenergics
- COX-2 Inhibitors
- Inhaled Steroids
- HMG-CoA Reductase Inhibitors (Statins)
- Sedative Hypnotics
- Angiotensin Converting Enzyme Inhibitors and combination products
- Angiotensin Receptor Antagonists and combination products
- Beta blockers
- Dihydropyridine Calcium Channel Blockers
- Non-Dihydropyridine Calcium Channel Blockers

### **Phase II ~ April 1, 2004**

- Oral Hypoglycemics (Second Generation Sulfonylureas, Alpha Glucosidase Inhibitors, Biguanide Combinations, Hypoglycemic, Biguanide Type, Meglitinides, thiazolidinediones -- TZDs)
- Leukotriene Modifiers
- Analgesic- NSAIDS (non-steroidal anti-inflammatory drugs)
- Serotonin Receptor Agonists
- Onychomycosis Antifungals
- Bisphosphonates for Osteoporosis

### **Phase III ~ July 1, 2004**

- Carbonic Anhydrase Inhibitors – Ophthalmic
- Alpha 2 Adrenergics – Ophthalmic
- Beta-blockers – Ophthalmic
- Prostaglandin Inhibitors – Ophthalmic
- Antihyperkinesia/CNS Stimulants (Medications For ADD/ADHD)
- Macrolides - Adult (Antibiotics)
- Macrolides - Pediatrics (Antibiotics)
- 2nd Generation Quinolones - Systemic (Antibiotics)
- 3rd Generation Quinolones - Systemic (Antibiotics)
- 2nd Generation Cephalosporins (Antibiotics)
- 3rd Generation Cephalosporins (Antibiotics)

## Attachment B. Activities of the Pharmacy & Therapeutics (P&T) Committee

Meeting Date	Therapeutic Classes Reviewed	P&T Committee Decisions Made
June 18, 2003	None-organizational meeting only	None
June 30, 2003	<ul style="list-style-type: none"> <li>• Proton Pump Inhibitors (PPI):</li> <li>• Reduce Stomach Acid, Ulcers,</li> <li>• Gastroesophageal Reflux Disease</li> <li>• Histamine Type - 2 Receptor Antagonists (H2RA): Reduce Stomach Acid, Ulcers, Gastroesophageal Reflux Disease</li> <li>• Antihistamines: Allergies</li> <li>• Congestion, Itching</li> <li>• Nasal Steroids: Allergic Rhinitis</li> </ul>	All four classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase I in January 2004.
August 12, 2003	<ul style="list-style-type: none"> <li>• Selective COX II NSAID Inhibitors: Inflammation, Arthritis, Pain</li> <li>• HMG-CoA Reductase Inhibitors: Reduce Cholesterol Levels</li> <li>• Sedative Hypnotics: Sleep</li> <li>• Beta Adrenergics: Asthma</li> <li>• Inhaled Corticosteroids: Asthma</li> </ul>	All five classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase I in January 2004.
September 3, 2003	<ul style="list-style-type: none"> <li>• Angiotensin Converting Enzyme Inhibitors (ACEI)-Hypertension (High Blood Pressure), Cardiac Disease</li> <li>• Angiotensin II Receptor Antagonists (ARB)-Hypertension- (High Blood Pressure), Cardiac Disease</li> <li>• Calcium Channel Blockers- Hypertension- (High Blood Pressure), Cardiac Disease</li> <li>• Beta Adrenergic Blocking Agents (Beta Blockers)- Hypertension- (High Blood Pressure), Cardiac Disease</li> </ul>	All four classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase I in January 2004.
October 15, 2003	<ul style="list-style-type: none"> <li>• No classes were reviewed</li> </ul>	Committee decided on the "preferred" and "non-preferred" drugs for the Phase I PDL drug classes to be implemented in January 2004.
November 11, 2003	<ul style="list-style-type: none"> <li>• Oral Hypoglycemics (excludes first generation sulfonylureas)-Diabetes</li> <li>• Leukotriene Modifiers-Asthma</li> <li>• Bisphosphonates-Osteoporosis</li> <li>• NSAIDs- Inflammation, Pain</li> <li>• Serotonin Receptor Agonists- Headaches</li> <li>• Oral Antifungals- Fungal Infections</li> </ul>	<p>All six classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase II in April 2004.</p> <p>Revisions were made to the clinical criteria for the first thirteen drug classes.</p>
January 6, 2004	<ul style="list-style-type: none"> <li>• Carbonic Anhydrase Inhibitors – Ophthalmics-Glaucoma</li> <li>• Alpha 2 Adrenergics – Ophthalmics-Glaucoma</li> <li>• Beta-blockers – Ophthalmics-Glaucoma</li> <li>• Prostaglandin Inhibitors – Ophthalmics- Glaucoma</li> </ul>	<p>All four classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase II in April 2004.</p> <p>Committee decided on the "preferred" and "non-preferred" drugs for some Phase II drug</p>

Meeting Date	Therapeutic Classes Reviewed	P&T Committee Decisions Made
		<p>classes to be implemented in April 2004.</p> <p>Committee approved the process for the review of new drugs within PDL drug classes.</p>
February 9, 2004	<ul style="list-style-type: none"> <li>• Narcotics: Long Acting-Chronic Pain</li> <li>• Antihyperkinesis/CNS Stimulants (Meds for ADD/ADHD)</li> <li>• Macrolides – Adult/Pediatric (Antibiotics)</li> <li>• 2<sup>nd</sup> Generation Quinolones- Systemic (Antibiotics)</li> <li>• 3<sup>rd</sup> Generation Quinolones- Systemic (Antibiotics)</li> <li>• 2<sup>nd</sup> Generation Cephalosporins (Antibiotics)</li> <li>• 3<sup>rd</sup> Generation Cephalosporins (Antibiotics)</li> </ul>	<p>Six classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes were implemented in PDL Phase III in July 2004. Decisions were held for the Long Acting Narcotics class.</p> <p>Cox II drug will remain PDL eligible with an appropriate clinical criteria.</p>
April 21, 2004	<ul style="list-style-type: none"> <li>• No classes were reviewed</li> </ul>	<p>Committee decided on the “preferred” and “non-preferred” drugs for Phase III drug classes implemented in July 2004.</p> <p>Committee approved the clinical criteria for Phase III drug classes. Revisions were made to the proposed clinical criteria for long acting narcotics.</p> <p>Final COX II clinical criteria were approved for implementation on July 1, 2004.</p> <p>Process for the review of combination drugs was established.</p> <p>Annual drug class review process was established.</p>
September 20, 2004	<ul style="list-style-type: none"> <li>• Proton Pump Inhibitors (PPI): Reduce Stomach Acid, Ulcers, Gastroesophageal Reflux Disease</li> <li>• Histamine Type - 2 Receptor Antagonists (H2RA): Reduce Stomach Acid, Ulcers, Gastroesophageal Reflux Disease</li> <li>• Antihistamines: Allergies, Congestion, Itching</li> <li>• Nasal Steroids: Allergic Rhinitis</li> <li>• Selective COX II NSAID Inhibitors: Inflammation, Arthritis, Pain</li> <li>• HMG-CoA Reductase Inhibitors: Reduce Cholesterol Levels</li> <li>• Sedative Hypnotics: Sleep</li> <li>• Beta Adrenergics: Asthma</li> <li>• Inhaled Corticosteroids: Asthma</li> <li>• Angiotensin Converting Enzyme Inhibitors (ACEI)-Hypertension (High Blood Pressure), Cardiac</li> </ul>	<p>Committee conducted annual review of Phase I PDL drug classes. All thirteen classes were appropriate for inclusion in the PDL program. All drugs in these classes were considered clinically effective. These classes will be re-implemented in January 2005.</p> <p>The Committee approved a PDL Multi-source and Product Availability Policy.</p> <p>Committee approved the final clinical criteria for long acting narcotics.</p> <p>Committee decided on the “preferred” and “non-preferred” drugs for Phase I drug classes implemented in January 2005, with the exception of HMG CoA Reductase Inhibitors (Statins).</p>

Meeting Date	Therapeutic Classes Reviewed	P&T Committee Decisions Made
	Disease <ul style="list-style-type: none"> <li>• Angiotensin II Receptor Antagonists (ARB)-Hypertension- (High Blood Pressure), Cardiac Disease</li> <li>• Calcium Channel Blockers- Hypertension- (High Blood Pressure), Cardiac Disease</li> <li>• Beta Adrenergic Blocking Agents (Beta Blockers)- Hypertension (High Blood Pressure), Cardiac Disease</li> </ul>	
<b>October 6, 2004</b>	<ul style="list-style-type: none"> <li>• Antidepressants (Selective Serotonin Reuptake Inhibitors – SSRIs, Serotonin Norepinephrine Reuptake Inhibitors – SNRIs, and Other Antidepressants)</li> <li>• Antianxiety Drugs (Benzodiazepine and other classes)</li> </ul>	<p>Committee conducted a review of antidepressants and antianxiety medications, and recommended they be included in the PDL program. All drugs in these classes were considered clinically effective. Clinical criteria will be developed. (The 2004 Appropriations Act requires that, if these drug classes are recommended for inclusion in the PDL, they not be added prior to July 1, 2005 and that a report be presented to the 2005 General Assembly. DMAS and the P&amp;T Committee will comply with these requirements.)</p> <p>Committee decided on the “preferred” and “non-preferred” drugs for the annual review of HMG CoA Reductase Inhibitors (Statins) to be implemented with Phase I in January 2005.</p> <p>Committee decided on the “preferred” and “non-preferred” drugs for the COX II Inhibitors due to a recent market change.</p>

**Attachment C: PDL “Quick List”**

Attachment C: PDL "Quick List"



Virginia Medicaid Preferred Drug List  
 Posted 9/30/04  
 Effective September 30, 2004



First Health Clinical Call Center  
 1-800-932-6648  
 Fax 1-800-932-6651

Effective September 30, 2004, the preferred status of Non-Steroidal Anti-Inflammatory – COX II Inhibitors has been changed until further notification

Bolded Drugs do not require prior authorization

**ANALGESICS**

**NON-STERIODAL ANTI-INFLAMMATORY DRUGS**

- Diclofenac Potassium
- Diclofenac Sodium
- Diflunisal
- Etodolac
- Fenopropfen
- Flurbiprofen
- Ibuprofen
- Indomethacin
- Indomethacin SR
- Ketoprofen
- Ketoprofen ER
- Ketorolac
- Meclofenamate Sodium
- Mobic®
- Nabumetone
- Naproxen
- Naproxen Sodium
- Oxaprozoin
- Piroxicam
- Sulindac
- Tolmetin Sodium

- Cefaclor ER
- Cefaclor Suspension
- Ceftin® 125 mg (until generic available)
- Ceftin® Suspension
- Cefuroxime
- Cefzil®
- Cefzil® Suspension
- Lorabid®
- Lorabid® Suspension

Requires Prior Authorization

- Ceclor®
- Ceclor CD®\*
- Ceftin®\*

**NON-STERIODAL ANTI-INFLAMMATORY – COX II INHIBITORS**

- Bextra®
- Celebrex®

**ANTIBIOTICS – ANTIINFECTIVES**

Requires Prior Authorization

- Anaprox®\*
- Anaprox DS®\*
- Ansaid®\*
- Arthrotec 50®
- Arthrotec 75®
- Cataflam®\*
- Clinoril®\*
- Daypro®\*
- Dolobid®\*
- Feldene®\*
- Indocin®\*
- Lodine®\*

**ORAL ANTIFUNGALS – ONYCHOMYCOSIS**

- Lamisil®

Requires Prior Authorization

- Sporanox®

**CEPHALOSPORINS – 2<sup>ND</sup> GENERATION**

- Cefaclor

**QUINOLONES – 2<sup>ND</sup> GENERATION**

- Cipro®
- Cipro® Suspension
- Cipro XR®

Requires Prior Authorization

- Ciprofloxacin (brand available without PA)
- Ofloxacin
- Floxin®
- Maxaquin®
- Noroxin®

**QUINOLONES – 3<sup>RD</sup> GENERATION**

- Avelox®
- Avelox ABC Pack®

Requires Prior Authorization

- Levaquin®
- Tequin®
- Zagam®

**ASTHMA – ALLERGY**

**ANTIHISTAMINES – 2<sup>ND</sup> GEN**

- Alavert®
- Claritin D® (OTC only)
- Loratadine Syrup
- Loratadine Tablets

CR, ER, SR, XL, XR, SA, LA = Extended Release  
 PA expires \*Generic available without PA

HCT = Hydrochlorothiazide  
 ® = Registered Tradename

\*\* = less than 60 years of age, existing therapy patients grand fathered until 6/30/05 or until existing

Attachment C: PDL "Quick List"



Virginia Medicaid Preferred Drug List  
Posted 9/30/04  
Effective September 30, 2004



First Health Clinical Call Center  
1-800-932-6648  
Fax 1-800-932-6651

Effective September 30, 2004, the preferred status of Non-Steroidal Anti-Inflammatory – COX II Inhibitors has been changed until further notification

**Bolded Drugs do not require prior authorization**

Requires Prior Authorization

- Allegro<sup>®</sup>
- Allegra D<sup>®</sup>
- Clannex<sup>®</sup>
- Clarithin<sup>®</sup>
- Clarithin D 12 hour<sup>®</sup> (Rx)
- Clarithin D 24 hour<sup>®</sup> (Rx)
- Clarithin Redi-Tab<sup>®</sup>
- Clarithin<sup>®</sup> Syrup\* (No PA req. for under age 6)
- Zyrtec<sup>®</sup>
- Zyrtec D<sup>®</sup>
- Zyrtec<sup>®</sup> Syrup (No PA req. for under age 2)

Requires Prior Authorization

- Proventil<sup>®</sup>\*
- BETA ADRENERGIC**
- /CORTICOSTEROID INHALER**
- COMBINATIONS**
- Advair Diskus<sup>®</sup>
- INHALED SYSTEMIC**
- GLUCOCORTICOID**
- AeroBid<sup>®</sup>
- AeroBid M<sup>®</sup>
- Azmacort<sup>®</sup>
- Flovent<sup>®</sup>
- Pulmicort Respules<sup>®</sup>
- QVAR<sup>®</sup>
- Requires Prior Authorization
- Flovent Rotadisk<sup>®</sup>
- Pulmicort Turbuhaler<sup>®</sup>

**BETA ADRENERGICS- SHORT**

- ACTING**
- Albuterol
- Alupent<sup>®</sup> MDI
- Combivent<sup>®</sup>
- Maxair Autohaler<sup>®</sup>
- Proventil<sup>®</sup> HFA
- Ventolin<sup>®</sup> HFA

Requires Prior Authorization

- Proventil<sup>®</sup>\*
- Ventolin<sup>®</sup>

**BETA ADRENERGICS – LONG**

- ACTING**
- Foradil<sup>®</sup>
- Serevent Diskus<sup>®</sup>
- Serevent<sup>®</sup>

**BETA ADRENERGICS FOR**

- NEBULIZERS**
- Accuneb<sup>®</sup>
- Albuterol sulfate
- Duoneb<sup>®</sup>
- Metaproterenol
- Xopenex<sup>®</sup>

**CARDIAC MEDICATIONS**

**ACE INHIBITORS**

- Captopril
- Captopril HCT
- Enalapril
- Enalapril HCT
- Lisinopril
- Lisinopril HCT

Requires Prior Authorization

- Accupril<sup>®</sup>
- Accuretic<sup>®</sup>
- Aceon<sup>®</sup>
- Altace<sup>®</sup>
- Benazepril
- Capoten<sup>®</sup>\*
- Capozide<sup>®</sup>\*
- Fosinopril
- Lotensin<sup>®</sup>
- Lotensin HCT<sup>®</sup>
- Mavik<sup>®</sup>
- Moexipril
- Monopril<sup>®</sup>
- Monopril HCT<sup>®</sup>
- Prinivil<sup>®</sup>\*
- Prinzide<sup>®</sup>\*
- Uniretic<sup>®</sup>
- Univas<sup>®</sup>
- Vasoretic<sup>®</sup>\*
- Vasotec<sup>®</sup>\*
- Zestoretic<sup>®</sup>\*
- Zestril<sup>®</sup>\*

**LEUKOTRIENE INHIBITORS**

- Accolate<sup>®</sup>
- Singulair<sup>®</sup>

**NASAL STEROIDS**

- Flonase<sup>®</sup>
- Flunisolide
- Nasalide<sup>®</sup>
- Nasarel<sup>®</sup>

Requires Prior Authorization

- Beconase AQ<sup>®</sup>
- Nasacort<sup>®</sup>
- Nasacort AQ<sup>®</sup>
- Nasonex<sup>®</sup> (No PA req. for under age 4)
- Rhinocort Aqua<sup>®</sup>
- Tri-Nasal<sup>®</sup>

Requires Prior Authorization

- Lexxel<sup>®</sup>
- Tarka<sup>®</sup>
- Teczem<sup>®</sup>

**ANGIOTENSIN RECEPTOR**

**ANTAGONISTS**

- Benicar<sup>®</sup>
- Benicar HCT<sup>®</sup>
- Diovan<sup>®</sup>
- Diovan HCT<sup>®</sup>
- Micardis<sup>®</sup>
- Micardis HCT<sup>®</sup>

Requires Prior Authorization

- Atacand<sup>®</sup> /Atacand HCT<sup>®</sup>
- Avalide<sup>®</sup>
- Avapro<sup>®</sup>
- Cozaar<sup>®</sup>
- Hyzaar<sup>®</sup>
- Teveten<sup>®</sup> /Teveten HCT<sup>®</sup>

**BETA BLOCKERS**

- Acebutolol
- Atenolol
- Atenolol /Chlorthalidone
- Betaxolol
- Bisoprolol Fumarate
- Bisoprolol /HCTZ
- Coreg<sup>®</sup>
- Labetalol
- Metoprolol
- Nadolol
- Pindolol
- Propranolol
- Propranolol/HCTZ
- Sorine
- Sotalol
- Sotalol AF
- Timolol

**ACE INHIBITORS/**

**CALCIUM CHANNEL BLOCKERS**

- Lotrel<sup>®</sup>

CR, ER, SR, XL, XR, SA, LA = Extended Release  
PA expires  
\*Generic available without PA

HCT = Hydrochlorothiazide  
® = Registered Tradename

\*\* = less than 60 years of age, existing therapy patients grand fathered until 6/30/05 or until existing



**Effective September 30, 2004, the preferred status of Non-Steroidal Anti-Inflammatory – COX II Inhibitors has been changed until further notification**  
**Bolded Drugs do not require prior authorization**

Requires Prior Authorization

Betapace<sup>®</sup>  
Betapace AF<sup>®</sup>  
Blocadren<sup>®</sup>  
Carrol<sup>®</sup>  
Corgard<sup>®</sup>  
Corzide<sup>®</sup>  
Inderal<sup>®</sup>  
Inderal LA<sup>®</sup>  
Inderide<sup>®</sup>  
innopran XL<sup>®</sup>  
Kerlone<sup>®</sup>  
Levator<sup>®</sup>  
Lopressor<sup>®</sup>  
Lopressor HCT<sup>®</sup>  
Sectral<sup>®</sup>  
Tenoretic<sup>®</sup>  
Tenormin<sup>®</sup>  
Timolide<sup>®</sup>  
Toprol XL<sup>®</sup>  
Trandate<sup>®</sup>  
Zebeta<sup>®</sup>  
Ziac<sup>®</sup>

Requires Prior Authorization

Adalat CC<sup>®</sup>  
Cardene<sup>®</sup>  
Cardene SR<sup>®</sup>  
Procardia<sup>®</sup>  
Procardia XL<sup>®</sup>

**CALCIUM CHANNEL BLOCKERS -  
NON-DIHYDROPYRIDINE**

Cartia XT<sup>®</sup>  
Diltia XT<sup>®</sup>  
Diltiazem  
Diltiazem (extended/sustained release)  
Taztia XT<sup>®</sup>  
Verapamil  
Verapamil (extended/sustained release)

Requires Prior Authorization

Calan<sup>®</sup>  
Calan SR<sup>®</sup>  
Cardizem<sup>®</sup>  
Cardizem CD<sup>®</sup>  
Cardizem LA<sup>®</sup>  
Cardizem SR<sup>®</sup>  
Covera-HS<sup>®</sup>  
Dilacor XR<sup>®</sup>  
Isoptin SR<sup>®</sup>  
Tiazac<sup>®</sup>  
Verelan<sup>®</sup>  
Verelan PM<sup>®</sup>

**CALCIUM CHANNEL BLOCKERS -  
DIHYDROPYRIDINE**

Afedibab CR<sup>®</sup>  
Dyncirc<sup>®</sup>  
Dyncirc CR<sup>®</sup>  
Nicardipine  
Nifediac CC<sup>®</sup>  
Nifedical XL<sup>®</sup>  
Nifedipine ER  
Nifedipine – immediate release  
Nifedipine SA  
Norvasc<sup>®</sup>  
Plendil<sup>®</sup>  
Sular<sup>®</sup>

Pravachol<sup>®</sup>  
Zocor<sup>®</sup>

Requires Prior Authorization

Caduet<sup>®</sup>  
Crestor<sup>®</sup>  
Lipitor<sup>®</sup>  
Mevacor<sup>®</sup>

**CENTRAL NERVOUS  
SYSTEM DRUGS**

**CNS STIMULANTS/ADHD  
MEDICATIONS**

Adderall XR<sup>®</sup>  
Amphetamine Salt Combo  
Concerta<sup>®</sup>  
Dextroamphetamine SR  
Dextrostat<sup>®</sup>  
Focalin<sup>®</sup>  
Metadate CD<sup>®</sup>  
Metadate ER  
Methylin<sup>®</sup>  
Methylin ER<sup>®</sup>  
Methylphenidate  
Methylphenidate SR  
Pemoline  
Ritalin LA<sup>®</sup>  
Strattera<sup>®</sup>

Requires Prior Authorization

Adderall<sup>®</sup>  
Desoxyn<sup>®</sup>  
Dexedrine<sup>®</sup>  
Dexedrine Spansules<sup>®</sup>  
Ritalin<sup>®</sup>  
Ritalin SR<sup>®</sup>

Cylert<sup>®</sup>  
Provigil<sup>®</sup>

**SEDATIVE HYPNOTIC NON-  
BARBITURATES**

Estazolam  
Flurazepam  
Restoril<sup>®</sup> 7.5 mg (until generic  
available)  
Temazepam  
Triazolam

Requires Prior Authorization

Ambien<sup>®</sup>  
Dalmane<sup>®</sup>  
Doral<sup>®</sup>  
Halcion<sup>®</sup>  
ProSom<sup>®</sup>  
Restoril<sup>®</sup>  
Somnote<sup>®</sup>  
Sonata<sup>®</sup>

**DIABETES**

**ORAL HYPOGLYCEMICS –  
ALPHA GLUCOSIDASE INH.**

Glyset<sup>®</sup>  
Precose<sup>®</sup>

**ORAL HYPOGLYCEMICS –  
BIGUANIDES**

Metformin/ Metformin XR  
Glucophage XR 750mg (until generic  
available)

Requires Prior Authorization

Glucophage<sup>®</sup>  
Glucophage XR<sup>®</sup>

CR, ER, SR, XL, XR, SA, LA = Extended Release  
PA expires

HCT = Hydrochlorothiazide  
® = Registered Tradename

\*\* = less than 60 years of age, existing therapy patients grand fathered until 6/30/05 or until existing



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 Bolded Drugs do not require prior authorization

**ORAL HYPOGLYCEMICS –****BIGUANIDE COMBINATIONS**

Avandamet<sup>®</sup>  
 Glucovance<sup>®</sup>  
 Metaglip<sup>®</sup>

**ORAL HYPOGLYCEMICS –****MEGLITINIDES**

Starlix<sup>®</sup>

Requires Prior Authorization

Prandin<sup>®</sup>

**ORAL HYPOGLYCEMICS – 2ND  
GENERATION SULFONYLUREAS**

Glipizide/ Glipizide ER  
 Glyburide  
 Glyburide Micronized

Requires Prior Authorization

Amaryl<sup>®</sup>  
 Diabeta<sup>®</sup>  
 Glucotrol<sup>®</sup>  
 Glucotrol XL<sup>®</sup>  
 Glynase<sup>®</sup>  
 Micronase<sup>®</sup>

**ORAL HYPOGLYCEMICS –****THIAZOLIDINEONES**

Actos<sup>®</sup>  
 Avandia<sup>®</sup>

**GASTROINTESTINAL****HISTAMINE-2 RECEPTOR  
ANTAGONISTS (H-2RA)**

Ranitidine

Requires Prior Authorization

Axid<sup>®</sup>  
 Cimetidine  
 Famotidine  
 Nizatidine  
 Pepcid<sup>®</sup>  
 Pepcid<sup>®</sup> Suspension  
 Tagamet<sup>®</sup>  
 Zantac<sup>®</sup>  
 Zantac Effervescent<sup>®</sup>  
 Zantac<sup>®</sup> Syrup (No PA req. For under  
 age 12)

**PROTON PUMP INHIBITORS**

Prilosec<sup>®</sup> OTC  
 Protonix<sup>®</sup>

Requires Prior Authorization

Aciphex<sup>®</sup>  
 Nexium<sup>®</sup>  
 Omeprazole (No PA req. for under age  
 12)  
 Prevacid<sup>®</sup> (No PA req. for under age 12)  
 Prevacid SoluTab<sup>®</sup>  
 Prevacid Susp<sup>®</sup> (No PA req. for under  
 age 12)  
 Prilosec<sup>®</sup>

**MISCELLANEOUS****OSTEOPOROSIS AGENTS –****BISPHOSPHONATES**

Actonel<sup>®</sup>

Requires Prior Authorization

Fosamax<sup>®</sup>

**SEROTONIN RECEPTOR  
AGONISTS (Triptans)**

Imitrex<sup>®</sup> (kit, nasal, tablets, vial)

Maxalt<sup>®</sup>  
 Maxalt-MLT<sup>®</sup>

Requires Prior Authorization

Amerge<sup>®</sup>  
 Axert<sup>®</sup>  
 Frova<sup>®</sup>  
 Relpax<sup>®</sup>  
 Zomig<sup>®</sup>  
 Zomig ZMT<sup>®</sup>

**GLAUCOMA – ALPHA-2****ADRENERGICS**

Alphagan P<sup>®</sup>  
 Brimonidine tartrate  
 Iopidine<sup>®</sup>

Requires Prior Authorization

Alphagan<sup>®</sup>\*

**GLAUCOMA – BETA-BLOCKERS**

Betaxolol HCl  
 Betimol<sup>®</sup>  
 Betoptic S<sup>®</sup>  
 Carteolol HCl  
 Levobunolol HCl  
 Metipranolol  
 Timolol Maleate  
 Timolol Maleate (gel-forming)

Requires Prior Authorization

Betagan<sup>®</sup>\*

Ocupress<sup>®</sup>\*

Optipranolol<sup>®</sup>

Timoptic<sup>®</sup>\*

Timoptic XE<sup>®</sup>\*

**GLAUCOMA – PROSTAGLANDIN  
ANALOGS**

Lumigan<sup>®</sup>  
 Travatan<sup>®</sup>  
 Xalatan<sup>®</sup>

Requires Prior Authorization

Rescula<sup>®</sup>

Attachment C: PDL "Quick List"



Virginia Medicaid Preferred Drug List  
Posted 9/30/04  
Effective September 30, 2004



First Health Clinical Call Center  
1-800-932-6648  
Fax 1-800-932-6651

*Effective September 30, 2004, the preferred status of Non-Steroidal Anti-Inflammatory – COX II Inhibitors has been changed until further notification*  
**Bolded Drugs do not require prior authorization**

**Phone Numbers for DMAS  
PDL Program**

First Health Clinical Call Center  
PA Requests  
Fax: 1-800-932-6651  
Tel: 1-800-932-6648  
Note: Fax requests are responded to within 24 hours. For urgent requests, please telephone.  
Note: Not all medications listed are covered by all DMAS programs. Check individual program coverage.  
For program drug coverage information, go to [virginia.ftsc.com](http://virginia.ftsc.com) or [dimas.virginia.gov](http://dimas.virginia.gov)

\* Indicates a generic is available without prior authorization

CR, ER, SR, XL, XR, SA, LA = Extended Release  
PA expires \*Generic available without PA HCT = Hydrochlorothiazide  
© = Registered Tradename \*\* = less than 60 years of age, existing therapy patients grand fathered until 6/30/05 or until existing



# COMMONWEALTH of VIRGINIA

## Department of Medical Assistance Services

PATRICK W. FINNERTY  
DIRECTOR

October 7, 2004

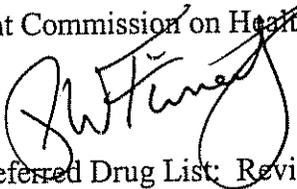
SUITE 1300  
600 EAST BROAD STREET  
RICHMOND, VA 23219  
804/786-7933  
800/343-0634 (TDD)  
www.dmas.state.va.us

### MEMORANDUM

**TO:** Members of the Health and Human Resources Subcommittee  
House Appropriations Committee

Members of the Health and Human Resources Subcommittee  
Senate Finance Committee

Members of the Joint Commission on Health Care

**FROM:** Patrick W. Finnerty 

**SUBJECT:** Status Report on Preferred Drug List: Review of Antidepressants and Antianxiety Medications

As you know, Item 326 BB(7) of the 2004 Appropriations Act provides that if antidepressants and antianxiety medications used in the treatment of mental illness are not exempted from the preferred drug list (PDL), the Department of Medical Assistance Services (DMAS) should defer inclusion of these drug classes in the PDL until July 1, 2005. In addition, the Appropriations Act language requires that prior to including these drug classes in the PDL, a plan must be submitted to the Governor and the General Assembly by January 1, 2005 outlining what steps will be taken to minimize adverse impacts on consumers, educate providers, and ensure that inclusion in the PDL is evidenced-based, clinically efficacious, and cost-effective. I have enclosed a copy of Item 326 BB(7) for your review.

I am writing to provide a status report on the actions taken by the Pharmacy & Therapeutics (P&T) Committee regarding these drug classes. The P&T Committee met yesterday to review antidepressants (including SSRIs) and antianxiety drugs, and to receive public comment from mental health advocates and others. Among the P&T Committee members present at the meeting were the Committee's two psychiatrists and a physician who is the President of the National Patient Advocate Foundation. The Committee also consulted with a Board-Certified Psychiatric pharmacist who helped review and discuss various clinical issues associated with these drug classes.

The P&T Committee received and reviewed written comments from various interested parties and heard oral testimony from several speakers, including representatives of the Psychiatric Association of Virginia, the National Alliance for the Mentally Ill (NAMI), the Mental Health Association of Virginia, and practicing psychiatrists. Among the issues raised by those who addressed the Committee were: (i) a strong desire to keep open access to all of the various antidepressant and anti-anxiety drugs, (ii) concerns about the potential impact of switching between different drugs within the classes, and (iii) the need for special considerations for pediatric patients.

Following the public comment period, the P&T Committee reviewed clinical information on the drug classes as well as a summary of the literature that contains the results and findings of clinical studies. The Committee then held extensive discussions about various clinical issues, including those raised during the public comment period. Specific issues discussed by the P&T Committee included: (i) the advisability of having several "preferred" drugs in each class, (ii) the potential need to include a "grandfathering" provision such that patients who currently are taking a medication would not have to switch to a different drug, and (iii) the potential need to have special considerations for pediatric patients. The Committee also discussed the benefits of other quality improvement programs such as that sponsored by Eli Lilly and Comprehensive Neuroscience, Inc. (CNS). Administering this type of program would be complementary with the PDL. (Several other states, including Missouri and Indiana, have implemented the Lilly/CNS program. DMAS currently is working with Eli Lilly and CNS who have offered to implement this program in Virginia at no cost to the Commonwealth. The Psychiatric Association of Virginia, which supports this approach, also has been involved in these discussions.)

At the conclusion of its discussion, the P&T Committee voted unanimously that the antidepressants and the anti-anxiety drugs are "PDL-eligible." This means the P&T Committee believes that with appropriate clinical criteria to address the concerns raised during the meeting (e.g., number of "preferred" drugs, grandfathering, special considerations for pediatric patients, etc.), these drug classes can be included in the PDL. Deciding that a drug class is "PDL-eligible" is just the first step in the process of including a drug class within the PDL. The most critical step in the process is the next step at which time the Committee determines what the clinical criteria should be and how many drugs would be "preferred" in each class. These discussions will take place at the Committee's next meeting, which we anticipate will be scheduled for late November. Please remember that at no time would Medicaid patients be denied access to a drug that their physician determines is needed.

As with all other drug classes that have been reviewed and determined by the P&T Committee to be "PDL-eligible," First Health Services (DMAS' PDL contractor) will now contact the manufacturers of the drugs in these classes to seek supplemental rebate offers. At the next P&T Committee meeting, the members will review the supplemental rebate offers, develop their recommended clinical criteria, and recommend which drugs would be "preferred" in each class. These actions will enable us to submit a detailed report to the Governor and the General Assembly by January 1, 2005.

I want to emphasize that the actions taken thus far and the next steps in the process of reviewing these drug classes are being taken by DMAS and its P&T Committee with the full understanding that no actions to implement any of these recommendations will occur until July 1, 2005. We fully recognize that the General Assembly wants to review these recommendations during its 2005 legislative session to ensure it is agreeable with our approach and/or to make any changes it deems appropriate.

Should you have any questions regarding this matter, please do not hesitate to contact me. I may be reached at (804) 786-8099. In addition, complete information on the entire PDL program and other pharmacy initiatives can be found at the DMAS website: [www.DMAS.virginia.gov](http://www.DMAS.virginia.gov). Thank you.

/pwf

Enclosure

cc: The Honorable Jane H. Woods  
Members of the Pharmacy and Therapeutics Committee  
Members of the Board of Medical Assistance Services  
Joe Flores  
Susan Massart  
Kim Snead  
William Murray

## Department of Medical Assistance Services

2004 Virginia Acts of Assembly  
Special Session I  
Chapter 4

### Item 326

BB.7. If the Department of Medical Assistance Services does not exempt antidepressants and antianxiety medications used for the treatment of mental illness from the Medicaid Preferred Drug List (PDL) program, it should defer inclusion of such drug classes from the PDL until July 1, 2005. Prior to including these drug classes in the PDL Program, the Department shall provide a plan for inclusion, which stipulates mechanisms to minimize adverse impacts on consumers, to ensure appropriate provider education that will promote effective prescribing practices that are medically indicated, and to ensure that inclusion is evidence-based, clinically efficacious and cost-effective. The Department shall report the plan to the Governor and Chairman of the House Appropriations and Senate Finance Committees and the Joint Commission on Health Care by January 1, 2005.