### Inclusion of Antidepressants and Antianxiety Drugs on Virginia Medicaid's Preferred Drug List



# Department of Medical Assistance Services December 1, 2008

#### I. INTRODUCTION

Item 306 (R)(7) of the 2008 Appropriations Act requires that the Department of Medical Assistance Services (DMAS) exempt antidepressant and antianxiety medications used for the treatment of mental illness from the Medicaid Preferred Drug List (PDL) program. However, the Appropriations Act states that the Director of DMAS, in cooperation with the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS), shall provide a report to the Chairmen of the House Appropriations and Senate Finance Committees by December 1, 2008, on the impact on patient care and costs of including these medications in the PDL in the future. Attachment A provides a copy of Item 306 (R)(7).

In response, DMAS, in consultation with DMHMRSAS, developed this report. Although the 2008 Appropriations language only mentions antidepressant and antianxiety medications, we also address antipsychotic medications in this report because of their high utilization and the fact that including them on the PDL represents an additional opportunity for cost savings. Furthermore, based on Virginia Medicaid's experience to date with drugs for general medical treatment, as well as the Pharmacy and Therapeutics (P&T) Committee's unanimous consent (previously) regarding the inclusion of antidepressant and antianxiety medications on the PDL, DMAS and DMHMRSAS do not believe the inclusion of these drugs on the PDL will adversely impact patient outcomes.

Specifically, this report describes: (1) the antidepressant, antianxiety, and antipsychotic drug classes; (2) Virginia's PDL and the role of the P&T Committee; (3) the PDL performance; (4) Virginia Medicaid's mental health drug utilization data; (5) the history of efforts to place mental health drugs on Virginia Medicaid's PDL; (6) policies regarding mental health medications; (7) DMHMRSAS Community Pharmacy Services; (8) estimated savings of including antidepressant, antianxiety, and antipsychotic drugs on the Virginia Medicaid PDL; and, (9) the patient impact associated with including antidepressants, antianxiety, and antipsychotic drugs on the PDL.

## II. DESCRIPTION OF THE ANTIDEPRESSANT, ANTIANXIETY, AND ANTIPSYCHOTIC DRUG CLASSES

#### **Antidepressants**

Antidepressants are used to treat a variety of diseases, most notably (but not limited to): major depressive disorder, anxiety disorders, obsessive-compulsive disorder, bulimia nervosa, and a variety of panic disorders. There are several different types of depression, (e.g., psychotic, melancholic, postpartum, etc.) with a resultant lifetime prevalence of approximately 17 percent and annual prevalence of approximately 10 percent within the population. Depression can develop concurrently with several general medical conditions as well, such as asthma, diabetes, hypothyroidism, coronary artery disease, fibromyalgia, etc.

Approximately 30 percent of the depressed population actually receives antidepressant therapy, and of that population, only 30 percent actually receive a therapeutic dose and/or a therapeutic trial. There are specific predictors of response for certain antidepressant agents as well as differences in response rates, supporting the fact that treatment must be individualized and full

trials be given (*ideally defined as twelve months of therapy*). All antidepressants require a minimum of a four week trial *at adequate doses* to assess efficacy.

Antidepressants can be divided into three sub-classes because of their pharmacological properties: (1) Selective Serotonin Reuptake Inhibitors (SSRIs); (2) Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs); and, (3) Other Antidepressants (which consist of Norepinephrine and Dopamine Reuptake Inhibitors (NDRIs), Combined Reuptake Inhibitors and Receptor Blockers, Monamine Oxidase Inhibitors (MAOIs), and Tricyclics).

#### **Antianxiety Medications**

Antianxiety agents are used in the management of anxiety disorders. Many persons with anxiety experience other psychiatric conditions (e.g., depression, bipolar disorder, schizophrenia), substance abuse disorders and general medical conditions (e.g., gastrointestinal, diabetes, coronary artery disease). The lifetime prevalence of persons experiencing anxiety is approximately 5 percent and is most common in women. Over 50 percent of persons reporting symptoms of anxiety do so during childhood. The average duration of illness for those with generalized anxiety disorder is 8.5 years, but oftentimes symptoms may persist for decades.

In terms of cost, the majority, if not all, of antianxiety medications have generic equivalents readily available in the market place. Unless there is a patient-specific allergy, adverse reaction, or indication, the generic equivalent is both clinically efficacious and oftentimes the most cost-effective choice.

#### **Antipsychotic Medications**

Antipsychotic medications are divided into two groups; typical (first generation) and atypical (second-generation) antipsychotics. Antipsychotics are commonly used to treat schizophrenia, mania, major depressive disorders with psychotic features and delusional disorders. They are also indicated for use in a wide range of other diagnoses such as mood disorders (e.g. bipolar disorder) even when no signs of psychoses are present. Nonpsychiatric uses include the prevention and treatment of nausea and vomiting as well as intractable hiccups and pruitis (itchy skin). The clinical course of therapy and establishing therapeutic goals utilizing antipsychotic medications include: (1) acute stabilization; (2) stabilization; and, (3) maintenance with the ultimate goal of improving functioning and quality of life. The course of treatment is variable but usually long term as complete remission of schizophrenia, for example, is uncommon.

It's important to note that during the past several years, there have been important changes in the drug marketplace for all three drug classes (antidepressants, antianxiety medications and antipsychotic medications). As a result, a number of drugs in these classes have had their patents expire, making them available as generics.

## III. VIRGINIA'S PREFERRED DRUG LIST AND THE ROLE OF THE P&T COMMITTEE

Item 325 ZZ.5 of the 2003 Appropriations Act directed DMAS to establish a PDL program. The program was implemented in phases throughout calendar year 2004. The Department implemented a "Virginia-specific" program design and supplemental rebate process that is unique among other states.

The Preferred Drug List program is a prior authorization plan that divides some Medicaid covered drugs (prescription and over the counter medications) into two categories: those that require prior authorization before they can be dispensed and those that do not. While there are many classifications of drugs that are not subject to the PDL or prior authorization, the PDL contains a wide range of generic and brand name products. There are three primary goals of the Virginia PDL program: (1) the provision of safe drug therapy; (2) effective drug therapy; and, (3) appropriate drug therapy in making available high quality medications to treat patient illnesses that provide the same therapeutic benefit at a lower price than more expensive and equivalent drugs.

In response to the 2003 Appropriations Act, a Pharmacy and Therapeutics (P&T) Committee was formed in 2004 to make clinical recommendations to DMAS regarding the administration of its PDL. The Committee is comprised of eight physicians and four pharmacists. The P&T Committee meets on a regular basis for the maintenance of the PDL. The P&T Committee directs all phases of the PDL program including: (1) selecting the therapeutic drug classes to review for possible inclusion on the PDL; (2) deciding which classes should be included on the PDL; (3) assessing the clinical efficacy of the drugs within each class under review; (4) selecting the "preferred" drugs in each class; (5) establishing clinical criteria for prescribing the drugs on the PDL; (6) developing appropriate prior authorization procedures; and, (7) advising the Department on other pharmacy program initiatives. The PDL is now a mature program, with most changes relating to the introduction of new generics in established PDL-eligible drug classes.

The P&T Committee has completed four annual reviews of PDL Phase I (September 20, 2004, October 31, 2005, October 23, 2006, October 3, 2007, and four annual reviews of Phase II (March 23, 2005, March 30, 2006, April 17, 2007 and April 22 2008) drug classes. During annual reviews of PDL drug classes, the P&T Committee determines if each of the classes should remain PDL eligible and designates the preferred/non-preferred status of drugs within those classes based on clinical and financial information. Also, at each meeting the Committee reviews all new drugs in existing PDL classes, which were not available for discussion during the previous annual review. Meetings are scheduled each quarter; however, they are not held if there is no business to be discussed/addressed.

#### IV. PREFERRED DRUG LIST PERFORMANCE

Since inception, the PDL has been largely successful in terms of provider compliance, operations, supplemental rebates, and stakeholder acceptance. In November 2005, DMAS conducted an extensive analysis of the outcomes of the PDL program implementation, the estimated savings of the PDL program, and the health effects on recipients. The study found no adverse

health impacts for persons who were switched to drugs on the PDL compared to those who were allowed to remain on non-preferred drugs.

DMAS continues to monitor potential adverse health impacts through its P&T Committee process and interaction with provider, advocacy and stakeholder communities. First Health Services Corporation (FHSC), DMAS' PDL vendor, also monitors the impact of the PDL. Key findings from FHSC's monitoring activities include:

- The PDL compliance rate, measured as the percent of patients being prescribed "preferred" drugs, exceeds the compliance level (85%) needed to achieve the necessary budget savings. Although the compliance rates vary between the different drug classes, the overall compliance rate across all drug classes is 97.5%. This compliance rates indicates an acceptance among providers of the drugs available as "preferred," and supports the achievement of program savings.
- There were a total of 17,806 PDL prior authorizations (requests for non-preferred drug) and clinical prior authorizations (criteria for both preferred and non-preferred drugs, i.e., step therapy, age requirements, etc.) processed in State Fiscal Year (SFY) 2008. Among these, 80% were approved for the non-preferred drug, 19% were changed to a preferred drug and less than 1% was denied. The greatest number of prior authorizations were in the antihistamine (2<sup>nd</sup> generation), proton pump inhibitor (PPI) and sedative hypnotic classes. These are drug classes with high utilization and the brand name drugs are heavily marketed which creates the perception of necessity.
- Market share of PDL drug classes has significantly shifted as a result of the program. In September 2008, preferred drugs accounted for 89% of all claims in PDL 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.
- The average cost per prescription has decreased below the projected amount since PDL implementation. The average net-net cost per script was \$34.01 in March 2008 compared to an average net-net cost per script of \$34.80 in January 2006.
- The PDL continues to generate significant savings for the Virginia Medicaid program. Savings are driven principally by a supplemental rebate process that has worked very well. Overall, manufacturers have provided competitive pricing and the program has achieved a high compliance rate (98%). Including SFY 2008, the Department has invoiced almost \$64 million in supplemental rebates since the inception of the PDL program in January 2004. This rebate amount is in addition to the federal rebates also collected for these drugs. A comparison to the original savings estimate, which was developed over four years ago and prior to the implementation of Medicare Part D and to other pharmacy savings initiatives undertaken by the Department, is no longer meaningful. However, the PDL has clearly been a successful cost containment strategy and the supplemental rebates generated by the program are reflected in the Department's annual forecast of Medicaid expenditures.

• No major concerns have been raised regarding potential negative health effects as a result of the PDL program.

#### V. VIRGINIA MEDICAID'S UTILIZATION OF MENTAL HEALTH DRUGS

Table 1 provides Virginia Medicaid data, including total payment, claims, and number of recipients from SFY 2008, on the various mental health drug classes, including antidepressants and antianxiety medications. Combined, antidepressants and antianxiety drugs accounted for \$21,047,563 in drug spending in SFY 2008. This represents 36 percent of the total mental health drug cost in SFY 2008. Antipsychotics, on the other hand, represented 64 percent of the total mental health drug cost in SFY 2008, mainly due to the atypical antipsychotics.

Table 1: Virginia Medicaid's Mental Health Drug Utilization, State Fiscal Year 2008

| Category                | Total<br>Payment | Total<br>Claims | Average<br>Cost/Claim | *Total Unique<br>Recipients |
|-------------------------|------------------|-----------------|-----------------------|-----------------------------|
| Antipsychotics          | \$37,346,243     | 131,082         | \$284.91              | 16,762                      |
| Atypical Antipsychotics | \$36,879,664     | 120,952         | \$304                 | 15,069                      |
| Typical Antipsychotics  | \$466,579        | 10,130          | \$46                  | 1,693                       |
| Antidepressants         | \$17,922,830     | 237,513         | \$75.46               | 44,878                      |
| SSRIs                   | \$3,988,262      | 97,205          | \$41                  | 19,813                      |
| SNRIs                   | \$3,436,145      | 23,315          | \$147                 | 5,016                       |
| Other Antidepressants   | \$10,498,423     | 117,173         | \$89                  | 20,049                      |
| Antianxiety Drugs       | \$3,124,733      | 243,498         | \$12                  | 37,303                      |
| TOTAL                   | \$58,393,806     | 612,273         | \$95.37               | 98,943                      |

<sup>\*</sup>Recipients can be in more than one category.

## VI. HISTORY OF EFFORTS TO PLACE MENTAL HEALTH DRUGS ON VIRGINIA MEDICAID'S PREFERRED DRUG LIST

DMAS' P&T Committee's first meeting to review antidepressants and antianxiety medications for inclusion on the PDL occurred on October 6, 2004, and public comments from all interested stakeholders were accepted at that time, including a psychiatric pharmacist consultant. As a result, the P&T Committee *unanimously* recommended inclusion of these classes on the PDL. Subsequently, the Committee met on December 8, 2004, to determine which drugs within these classes would be "preferred."

Despite this recommendation, the 2005 General Assembly passed a budget amendment to "exempt antidepressant and antianxiety medications used for the treatment of mental illness from the Medicaid Preferred Drug List program" (Item 326 #4c). In accordance with this legislation, there has been no action to implement these classes on the PDL and the Virginia Medicaid P&T Committee has not revisited the topic. However, in response to the 2008 Appropriations Act Item 306 (R)(7), DMAS is now revisiting this issue.

#### VII. POLICIES REGARDING MENTAL HEALTH DRUGS

#### A. Other State Medicaid Agencies

In August 2008, FHSC completed a survey of mental health medication policies of other state Medicaid agencies. All fifty states were contacted and thirty states responded. Of the states that responded, twenty-six currently have a PDL in place. Among these twenty-six states, the following information was collected:

- Nineteen (73%) of the states have or will soon implement antidepressants on the PDL/formulary;
- Fourteen (54%) states have or will soon implement antianxiety medications on the PDL/formulary;
- Seventeen (65%) of the states have or will soon implement antipsychotic medications on the PDL/formulary;
- Ten (38%) states have implemented some form of grandfathering of recipients subject to PDL guidelines for mental health medications; and,
- Eight (30%) of the states have legislation that prohibits one or more mental health medications from being included on their PDL.

Gathered from the same survey, Table 2 summarizes what states contiguous to Virginia cover in terms of antidepressants, antianxiety, and antipsychotic medications.

**Table 2: PDL Practices in States Contiguous to Virginia\*** 

| State         | Antidepressants                     | Antianxiety Medications** | Antipsychotics       |
|---------------|-------------------------------------|---------------------------|----------------------|
| Georgia       | SSRIs and SNRIs are on the PDL      | Not currently on the PDL  | Currently on the PDL |
| Kentucky      | All antidepressants are on the PDL  | Currently on the PDL      | Currently on the PDL |
| Maryland      | All antidepressants, except for the | Currently on the PDL      | Currently on the PDL |
|               | Tricyclics are on the PDL           |                           |                      |
| Tennessee     | All antidepressants are on the PDL  | Not currently on the PDL  | Currently on the PDL |
| West Virginia | SSRIs, SNRIs, and other second      | Currently on the PDL      | Currently on the PDL |
|               | generation antidepressants are all  |                           |                      |
|               | reviewed on the PDL                 |                           |                      |

<sup>\*</sup> Currently, North Carolina does not have a PDL in place.

#### B. Virginia's Medicaid Managed Care

Sixty percent of Virginia's Medicaid population is enrolled in one of five contracted managed care organizations (MCOs). The following summarizes these MCOs' (Anthem, Amerigroup, Sentara, Coventry, and Virginia Premier) policies regarding mental health medications.

<sup>\*\*</sup>Typically, there are no savings achieved from placing antianxiety medications on PDLs because the drugs in this class are mostly available generically.

- All five MCOs have one or more of the mental health medication classes on their formulary.
- All five MCOs have some form of grandfathering recipients subject to formulary guidelines for these medications.
- Four MCOs state that mental health medications are relatively inclusive on their formulary most or all drugs "preferred" (no PA required). One plan stated that brand drugs are relatively restrictive; however, generics are inclusive. Most MCOs use generics as first line agents (step therapy).
- Results of including mental health medications on the PDL include:
  - o cost savings achieved from generic utilization and formulary compliance;
  - o savings resulting from step therapy criteria (2% increase in antidepressant utilization and cost savings of approximately 30%); and,
  - o quality of care outcomes that improve appropriateness of use and care coordination.

#### C. Virginia's State Employee Health Plan

Antidepressants, antianxiety, and antipsychotic medications are included on Virginia's State Employee Health Plan (COVA Care) formulary. Under this program, covered brand-name and generic drugs are categorized into three specific tiers, and each tier is assigned a different co-pay level. Brand names are more expensive than generics.

#### D. Commercial Insurance Plans

Most commercial health insurance plans also include antidepressants, antianxiety, and antipsychotic medications on their formularies.

#### VIII. DMHMRSAS COMMUNITY PHARMACY SERVICES

DMAS reimburses for pharmacy services delivered to Virginia Medicaid recipients, whereas the DMHMRSAS Community Resource Pharmacy (CRP) provides pharmacy services (including supplying and covering major services) to eligible individuals seen throughout the Virginia DMHMRSAS statewide system of community based care. The Virginia Community Services Board and Behavioral Health Authority (CSB/BHA) partners are responsible for oversight and management of the local and state funds that support behavioral healthcare and treatment for Virginia's medically indigent population.

In 2006, the operational structure and the direction of the CRP underwent a significant change. After a number of years of operational and financial issues, it became apparent to DMHMRSAS that major redirection of effort would be necessary for the CRP to regain a place of efficiency and effective service delivery. As a result, the Commissioner of DMHMRSAS established a DMHMRSAS P&T Committee to provide guidance and oversight to the CRP and facility pharmacies. The DMHMRSAS P&T Committee is made up of a wide range of professionals from the CRP, the Central Office, Community Services Boards, and DMHMRSAS facilities. The primary goal is to support the CRP in its independence, but build on strong alliances to aid in the effort of improving service delivery while providing safe, cost effective and appropriate drug therapy.

The CRP formulary is limited in scope to psychotropic medications and represents the needs of the clients who receive services for community based behavioral healthcare. Drug categories included on the formulary include anticonvulsants; antipsychotics; antidepressants; antianxiety agents; anticholinergics; and, agents used for the treatment of drug and alcohol dependence. A formulary management process and procedure is in place whereby generic medications, as available, are automatically substituted for more expensive, branded medications. The formulary management process is managed by the State DMHMRSAS P&T Committee in support of the specific goals and principles noted below.

Generally, the goal is that drugs within a given drug class will be included in the formulary based on their having significant value in terms of their efficacy, safety, pharmacodynamics, pharmacokinetics, sites of action and side effect profiles. Additionally, the DMHMRSAS Position Statement<sup>1</sup> includes six general principles to guide formulary decisions to include access and effective utilization in prescribing these medications. These principles include<sup>2</sup>:

- 1. Treatment with psychoactive medications, like any other treatment, should be individualized in order to optimally promote an individual's recovery;
- 2. Treatment with psychoactive medication should be as effective, safe, and well tolerated as possible for the individual;
- 3. Treatment with psychoactive medication should consider personal/individual preferences and vulnerabilities;
- 4. Treatment with psychoactive medication should provide value in terms of improved quality of life to the individual service receiver;
- 5. Treatment choices should be informed by the best current evidence and must evolve in response to new information; and,
- 6. Cost considerations should guide psychoactive medication selection once the preceding principles are met.

Furthermore, the following factors are considered when specific drugs or drug classes are reviewed for formulary <u>inclusion</u>: (1) efficacy, effectiveness and safety; (2) dosing interval and side effect profile; (3) cost (the impact of cost on a drug's inclusion in the formulary is an important

<sup>&</sup>lt;sup>1</sup> The Position Statement refers to both the National Association of State Mental Health Programs Directors' (NASMHPD's) Position Statement (in part) and DMHMRSAS' P&T's Position Statement for the Community Resource Pharmacy because the Committee adopted these principles as written.

<sup>&</sup>lt;sup>2</sup> Adapted from: Parks et al. Principles of Antipsychotic Prescribing for Policy Makers, Circa 2008. Translating Knowledge to Promote Individualized Treatment. NASMHPD. (Accessed from the Internet at <a href="http://www.nasmhpd.org/general\_files/publications/med\_directors\_pubs/NASMHPD%20Principles%20of%20Antipsychotics%20final.pdf">http://www.nasmhpd.org/general\_files/publications/med\_directors\_pubs/NASMHPD%20Principles%20of%20Antipsychotics%20final.pdf</a>, 9/11/08).

consideration. This factor is of particular importance when comparing several drugs within the same therapeutic class. Although cost is an important issue, providing high quality patient care remains the highest priority and will not be compromised by cost considerations); (4) availability of alternative drugs (any drug added to the formulary must have advantages in efficacy and safety, dosing interval and side-effect profile, or cost. An alternative drug can often be deleted when a more effective drug is added); (5) recommendations of clinical staff; and, (6) look-alike/sound-alike criteria (consideration will be given to look-alike/sound-alike criteria in selecting formulary drug in order to avoid the potential for medication errors).

Through collaboration and support, an improved service delivery system has evolved that can be measured through improved efficiency, cost effectiveness and the ability to reach additional community consumers while working within the existing budget.

## IX. ESTIMATED SAVINGS OF INCLUDING ANTIDEPRESSANT, ANTIANXIETY, AND ANTIPSYCHOTIC DRUGS ON VIRGINIA MEDICAID'S PREFERRED DRUG LIST

FHSC estimated the potential savings of implementing antidepressants and antianxiety drug classes on the Virginia Medicaid PDL. Including the antidepressants and antianxiety drug classes on the PDL program could generate annual estimated savings of \$514,820 in general funds (GF) or \$1,029,639 in total funds (assuming grandfathering). An estimated additional \$1,338,856 in total funds (\$669,428 GFs) could be generated if atypical antipsychotics were added to the PDL program. These estimates are based on SFY 2008 actual paid claims for Virginia Medicaid, and FHSC's projections of both the possible supplemental rebates and potential market share agreements with specific antidepressant drug class manufacturers.

As shown in Table 3 (next page), the estimated savings of \$1,029,639 in total funds is mainly attributable to the SSRI class (\$929,639) and the SNRI class (\$100,000). Virtually no savings are achieved from the antianxiety class because the drugs in this class are mostly available generically, and there are no supplemental rebates associated with the drug class. The costs associated with the antianxiety class are being well managed by the Virginia's Maximum Allowable Cost (MAC) Program and the mandatory generic edit.

It is important to emphasize that 4 of the 5 brand name SSRIs (Celexa, Paxil, Prozac and Zoloft) have generic equivalents and the other (Lexapro) will be available in 2009. Once all the products have generic equivalents, the SSRI subclass will be similar to the antianxiety class and will produce very little savings, unless new, more expensive, brand name drugs are introduced into the class in the future.

**Table 3: Projected Savings, by Drug Class** 

| Category Name           | *Potential Savings<br>(Total Funds) |  |
|-------------------------|-------------------------------------|--|
| Antipsychotics          | \$1,338,856                         |  |
| Atypical Antipsychotics | \$1,338,856                         |  |
| Typical Antipsychotics  | \$0                                 |  |
| Antidepressants         | \$1,029,639                         |  |
| SSRIs                   | \$929,639                           |  |
| SNRIs                   | \$100,000                           |  |
| Other Antidepressants   | \$0                                 |  |
| Antianxiety Drugs       | <b>\$0</b>                          |  |
| TOTAL                   | \$2,368,495                         |  |

<sup>\*</sup>Estimated savings are based on recommended changes (with SNRI step edit, market share movement and supplemental rebates comparable to National Medicaid Pooling Initiative (NMPI) rates). Estimated savings assume grandfathering.

#### X. PATIENT IMPACT & SUMMARY

Inclusion of drugs on the PDL that are used to treat mental health disorders may be expected to have an effect similar to the effect on a general medical population exposed to a PDL for general medical treatment. Furthermore, the experience to date with the DMAS PDL should be instructive as the inclusion of antidepressants, antianxiety, and antipsychotic drugs is considered. However, the notion of placing antidepressants, antianxiety, and antipsychotic medications on Virginia's PDL is unsettling for some mental health advocacy groups because they believe that access to drugs will be restricted, consumers will be required to switch medications, and consumer choice will be limited.

DMAS and DMHMRSAS believe that these concerns and any potential negative impacts on consumers can be mitigated by taking the National Association of State Mental Health Program Directors (NASMHPDs) Medical Directors' recommendations into consideration.<sup>3</sup>

While one approach included in the NASMHPD's recommendations would be an open formulary with unrestricted access to all medications, the NASMHPD recognizes that there would not be any cost savings associated with an open formulary because the possibility of a market shift to less costly drugs would be eliminated. However, the following set of recommendations from the NASMHPD provides a framework of how to construct a PDL with these drug classes that would provide some savings and minimize any potential negative impact on patients. The recommendations are consistent with DMAS' P&T Committee's 2004 recommendations to include antidepressants and antianxiety medications on DMAS' PDL. NASMHPD's Medical Directors' recommendations include:

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<sup>&</sup>lt;sup>3</sup> Adapted from: Parks et al, Circa 2008.

- A simple and flexible prior authorization system. A properly managed PDL program could be expected to have minimal to no negative impact on a consumer population when prior authorization is restricted to drugs that have one or more counterparts in the formulary, and that have not been widely used in disorders the current prescription is intended to treat. A clear description of what circumstances would support prior authorization would need to be made available to providers. Through a prior authorization process, providers would gain access to evidence-based treatment guidelines that enable consistent and informed choices that would have a significant positive effect on quality of life and effectiveness of treatment.
- *Grandfathering should be allowed.* If a medication is known to be safe and effective for a patient, that medication should continue to be made available to the patient, regardless of its "preferred" status.
- A PDL should provide access to a range of medications that may have varying side effects, dose strengths, and differing degrees of effectiveness on different consumers. During the past several years, there have been important changes in the drug marketplace. The overall effect has been to lessen the impact of one particular drug as having unique or clearly superior effectiveness. Nonetheless, there remain variations in individual responses to drugs that make having a full selection at the provider's disposal important.
- Coordination of pharmacy formularies or policies (DMAS, Community Service Boards, DMHMRSAS facilities, jails, inpatient facilities, outpatient facilities) would contribute to the reduction of conflicting and unavailable medication regimes as consumers move from one service area or resource to another. When all providers know which drugs are available across the system of care, which require prior authorization under what circumstances (exceeding dose ranges, off-label use, polypharmacy in the same drug class) and which drugs are not available, the likelihood of a consumer being deprived of needed medications may be reduced, and the quality of care may be enhanced.

DMAS and DMHMRSAS cannot predict with certainty the outcome of adding mental health drugs, including antidepressants, antianxiety, and antipsychotic medications, to DMAS' PDL. However, based on experience with other drugs, DMAS and DMHHRSAS conclude that the patient impact will not be significant. Therefore, DMAS and DMHMRSAS believe that a carefully developed PDL that contains a reasonable range of medications within a drug class, coupled with a carefully designed prior authorization provision, can be expected to have minimal patient impact.

If the General Assembly authorizes DMAS to move forward with placing antidepressants, antianxiety, and antipsychotic drugs on the PDL, DMAS will ultimately rely on the recommendations and expertise of the two psychiatrists, six physicians, and four pharmacists who serve on the P&T Committee. DMAS will also consult with a Board Certified Psychiatric Pharmacist, as the Department did in 2004. Furthermore, if antidepressants, antianxiety, and antipsychotic medications are added to DMAS' PDL, DMAS will closely monitor patient impact

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<sup>&</sup>lt;sup>4</sup> There are exceptions, such as Clozapine, which remains the gold standard for treatment resistant schizophrenia.

through its P&T Committee process, interaction with provider, advocacy and stakeholder communities, as DMAS currently does with its PDL for general medical treatment.

#### ATTACHMENT A

#### 2008 Appropriations Act, Item 306 (R)(7)

The Department of Medical Assistance Services shall exempt antidepressant and antianxiety medications used for the treatment of mental illness from the Medicaid Preferred Drug List program. The Director of the Department of Medical Assistance Services, in cooperation with the Department of Mental Health, Mental Retardation and Substance Abuse Services, shall provide a report to the Chairmen of the House Appropriations and Senate Finance Committees by December 1, 2008, on the impact on patient care and costs of including these medications in the Preferred Drug List in the future.