COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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November 1, 2010

MEMORANDUM

TO: The Honorable Bob McDonnell
Governor

The Honorable Charles J. Colgan
Chairman, Senate Finance Committee

The Honorable Lacey E. Putney
Chairman, House Appropriations Committee

The Honorable Robert D. Orrock
Chairman, House Committee on Health, Welfare and Institutions

The Honorable R. Edward Houck
Chairman, Senate Committee on Education and Health

The Honorable Benjamin L. Cline
Chairman, Joint Commission on Health Care

FROM: Gregg A. Pane, MD, MPA GP

SUBJECT: Report on Preferred Drug List Program

Item 297 (P)(8) of the 2010 Appropriations Act requires the Department of Medical Assistance Services to provide a report on the Preferred Drug List (PDL) Program no later than November 1 of each year. The report shall include the direct savings attributed to the PDL for the prior fiscal year, an estimated savings of the program for the next fiscal year, and the cost to administer the PDL. I have enclosed for your review the report for 2010.

Should you have any questions or need additional information, please feel free to contact me at (804) 786-8099.

Enclosure

Cc: The Honorable William A. Hazel, Jr., M.D., Secretary of Health and Human Resources

Annual Report on the Preferred Drug List Program

Virginia Department of Medical Assistance Services

November 1, 2010

Background and Authority for Report

Item 325 ZZ.5 of the *2003 Appropriations Act* directed the Department of Medical Assistance Services (DMAS) to establish a preferred drug list (PDL) program. The program was implemented in January 2004. In February 2004, DMAS received approval of its PDL program State Plan amendment and its supplemental rebate contracts from the Centers for Medicare & Medicaid Services (CMS).

Virginia's Preferred Drug List (PDL) Program was created to promote therapeutically appropriate pharmaceutical utilization in a cost-effective manner. The PDL Program encourages providers to prescribe drugs that are therapeutically appropriate and cost effective through the use of a PDL. Preferred drugs on the PDL can be prescribed without any additional action taken by the prescriber; non-preferred drugs require service authorization (SA) by calling or faxing the Clinical Call Center. While there are many classifications of drugs that are not subject to the PDL or service authorization (SA), the PDL contains a wide range of generic and brand name products.

Item 297 (P)(8) of the *2010 Appropriations Act* requires that DMAS provide annual reports to the Governor and General Assembly on the status of the PDL program (a copy of Item 297(P)(8) is provided as Attachment A.) DMAS has submitted reports at least annually since the implementation of the PDL program. In November 2005, DMAS conducted an extensive analysis of the outcomes of the PDL program implementation which included the estimated savings of the PDL program and the health effects on recipients. This 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. Since this study, DMAS has continued to monitor potential adverse health impacts through its Pharmacy & Therapeutics (P&T) Committee process and interaction with the provider, advocacy and stakeholder communities. To date, no major concerns have been identified.

Virginia Medicaid Pharmacy Program

Virginia Medicaid's PDL program was implemented to reduce the growth of prescription drugs costs for the fee-for-service population and to develop a mechanism for the clinical review of PDL eligible therapeutic classes of drugs by a volunteer Pharmacy and Therapeutics (P&T) Committee of community pharmacists and physicians. Between fiscal years 2000 and 2005, prescription drugs costs increased on average 10% per year from $298 million to $471 million. These significant annual increases ceased in fiscal year 2006 primarily due to the implementation of the Medicare Part D drug benefit. Approximately 136,000 recipients who previously received their prescription drug coverage through the Virginia Medicaid program began receiving most of their prescription drug coverage through the federal Medicare Part D program in January 2006.

Pharmacy & Therapeutics Committee

The P&T Committee meets in accordance with the requirements stipulated in the current Virginia Appropriations Act 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 use criteria for selected drugs; 6) developing appropriate SA procedures; and, 7) advising DMAS on other pharmacy program initiatives.

During an annual review of PDL drug classes, the P&T Committee determines PDL eligibility and designates the preferred/non-preferred status of drugs within those classes. In addition, the Committee reviews and determines PDL eligibility for new drugs in existing PDL classes marketed since the previous P&T Committee meeting. Minutes of these meetings are available on the Virginia Town Hall and the DMAS website at the following link: http://dmasva.dmas.virginia.gov/Content_pgs/pharm-home.

The PDL is a mature program, with most changes relating to the introduction of new generics in established PDL-eligible drug classes. The following is a summary of the P&T Committee's activities:

- The P&T Committee has completed six annual reviews of PDL Phase I and Phase II drugs classes since its implementation, with the most recent review occurring February 2010. An additional meeting was held on April 29, 2010, to review potential new classes recommended by a consultant; *MedMetrics Health Partners & Public Sector Partner's an Affiliate of the University of Massachusetts Medical School.*

- At the October 2009, February 2010 and April 2010 P&T meetings, the Committee reviewed the following potential additions to the program:

  - New PDL Category
    - Cough and Cold Agents
  - New Therapeutic Classes (PDL Category)
    - Barbiturate and Non-Salicylate Combinations (Analgesics)
    - Narcotics - Short Acting including combination drugs (Analgesics)
    - Narcotic Lozenges (Analgesics)
    - Opioids (Analgesics)
    - Opioid Dependency (Analgesics)
    - Self-Injectable Epinephrine (Asthma /Allergy)
    - Low Molecular Weight Heparins (Cardiac Medication)
    - Platelet Inhibitors (Cardiac Medications)
    - Antihistamines – 1st and 2nd generation including combinations (Cough & Cold)
    - Decongestant and Expectorant Combinations (Cough & Cold)
    - Narcotic Antitussive and Decongestants Combinations (Cough & Cold)

- Narcotic Antitussive and Expectorant Combinations (Cough & Cold)
- Non-Narcotic Antitussives including Decongestant and Expectorant and Antihistamine Combinations (Cough & Cold)
- Skeletal Muscle Relaxants (Central Nervous System)
- Smoking Cessation Aids (Central Nervous System)
- Androgenic Agents (Endocrine and Metabolic Agents)
- Contraceptives - oral, non-oral, vaginal (Endocrine and Metabolic Agents)
- Estrogens - vaginal (Endocrine and Metabolic Agents)
- Hematopoietic Agents (Endocrine and Metabolic Agents)
- Injectable Hypoglycemic Agents: including long and short acting insulins and combinations; incretin mimetics and amylin analogs (Endocrine and Metabolic Agents)
- Progestins for Cachexia (Endocrine and Metabolic Agents)
- Progestational Agents (Endocrine and Metabolic Agents)
- Motility Agents (Gastrointestinal)
- Ulcerative Colitis – oral and rectal (Gastrointestinal)
- Alpha Blockers For BPH (Genitourinary)
- Androgen Hormone Inhibitors (Genitourinary)
- Bile Acid Sequestrants (Lipotropic)

During the aforementioned P&T Committee meetings, all classes presented and reviewed were determined to be PDL eligible. Criteria were also established for recipients' health and safety. Nine of the drug classes were added to the PDL effective January 1, 2010, eight were added April 1, 2010, and twenty seven were added July 1, 2010.

- The P&T Committee's management of the PDL continues to contribute to the increase in the overall generic utilization rate by making generic and over-the-counter (OTC) medications "preferred". This year, additional classes joined this list of predominantly generic classes (cough and cold agents, contraceptives, gastrointestinal stimulants, short acting analgesics, skeletal muscle relaxants and smoking cessation). While this does not afford the Commonwealth substantial supplemental rebates, it does reduce the overall cost per prescription.

- The P&T Committee continues to manage new generics and current brand PDL products with the "Generic Watch" program. The "Generic Watch" is a program designed to monitor the availability of new generic drugs in PDL-eligible classes as they enter the market with the goal of achieving more timely capture of cost savings that result from the market introduction of a less expensive, therapeutically equivalent agent. A new generic is not automatically a preferred product. The P&T Committee evaluates all new PDL products including new generics and determines their placement on the PDL. A brand product is maintained preferred until its generic equivalent meets the generic watch guidelines, which includes an evaluation of the net costs of the new generic product in relation to the net costs of brand product.

- The current generic utilization rates among total drugs dispensed are approximately 74.4% in SFY 2010 compared to about 71% at the end of SFY 2009.

Preferred Drug List Program Operations and Performance

DMAS costs for PDL administration include a contract with First Health Services Corporation (FHSC) during the SFY 2010. FHSC responsibilities included clinical call center management, supplemental rebate contracting, and clinical support of the P&T Committee. The administrative costs for PDL-related services during SFY2010 were approximately $1.75 million. FHSC's contract ended on June 28, 2010 as described below.

On behalf of DMAS, FHSC operated a 24 hour, 7-day per week call center which was responsible for responding to enrollee and provider concerns; providing education; and handling service authorizations and pharmacy related activities. In addition, the FHSC Call Center answered inquires from providers related to pharmacy claims transmissions. Below is a summary of the call center's performance for fiscal year 2010.

- There have been few complaints about the clinical call center and the PDL program in general. All complaints were resolved administratively.

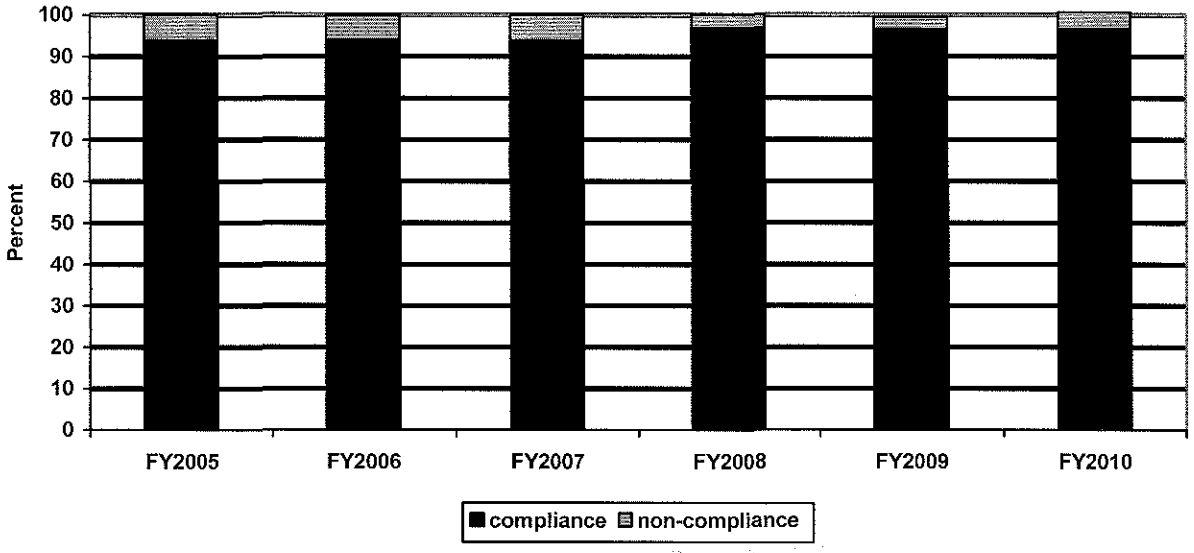
- Call center management and the SA processes met established contractual guidelines, including average speed to answer rates, low call abandonment rate, and minimal call time.

- In FY 2010, 24,463 PDL SAs (requests for non-preferred drug) and clinical SAs (criteria for both preferred and non-preferred drugs, i.e., step therapy, age requirements, etc.) were processed. Among these, 68% were approved for the non-preferred drug, 32% were changed to a preferred drug and less than 1% were denied.

- Many of the PDL denials have been related to billing issues with pharmacy providers who request authorization of non-preferred drugs after the drug has been dispensed to the Medicaid recipient. Denials are more common among long-term care providers who bill retrospectively. It is important to note, that these are denials of payment rather than denial of access to drugs in that the recipient received the medication in advance of the request.

The compliance rate in terms of "preferred" drugs being prescribed for Medicaid recipients remains high, currently at 96.7 % across all classes subject to the PDL. This compliance rate exceeds the compliance level needed to achieve the necessary budget savings (see Figure 1).

Figure 1
Medicaid PDL Compliance/Non-Compliance Rates



Supplemental Rebate Contracting Process & Savings Estimates

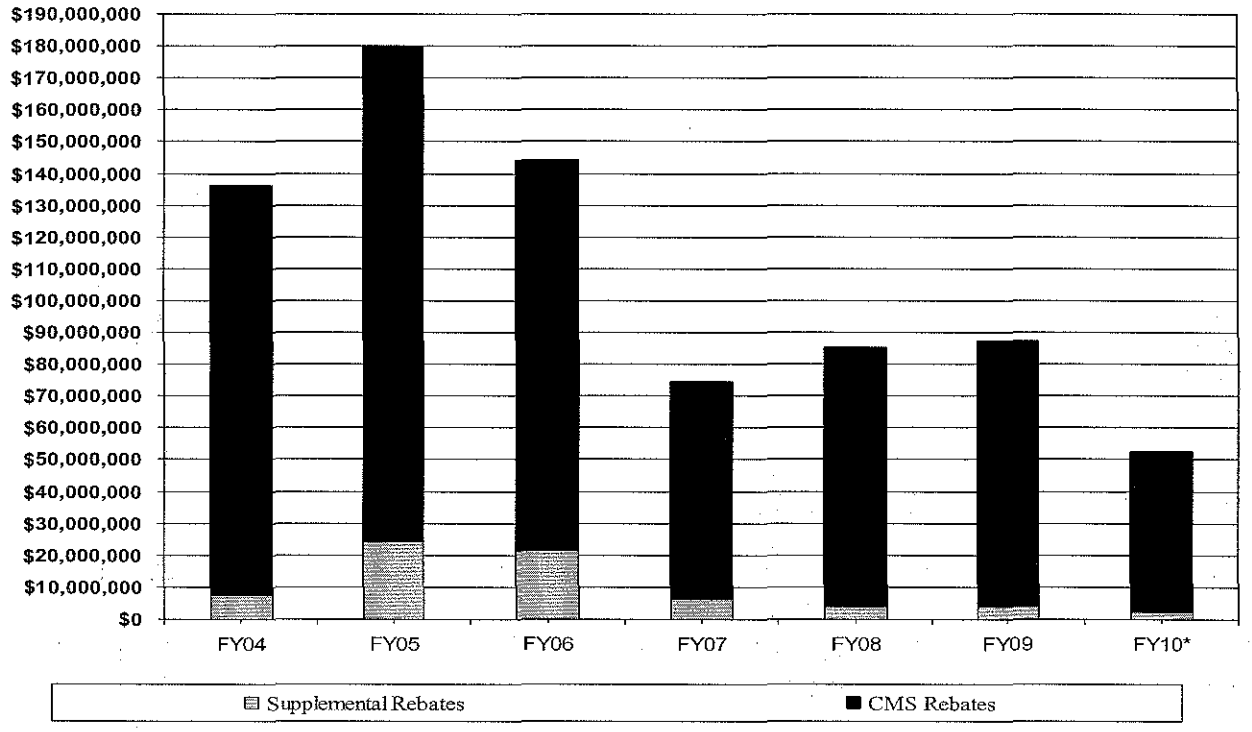
The PDL was developed with significant cooperation from many pharmaceutical manufacturers who agreed to provide aggressive drug pricing and supplemental rebates in the design of a Virginia-specific PDL. DMAS solicits Virginia-specific contracts for pricing and supplemental rebates directly with manufacturers for all single-source brand products in the PDL eligible therapeutic classes.

Since the inception of the PDL program in January 2004, DMAS has invoiced over $70.5 million in supplemental rebates (see Figure 2). This amount is in addition to the federal rebates collected for these drugs. Supplemental rebates have declined in recent quarters because of higher federal mandated rebates tied directly to changes required by the Deficit Reduction Act of 2005, which took effect in 2007. In addition, several expensive brand drugs lost patent protection and are now available generically and not subject to supplemental rebates. It should be noted that the generic formulations of these drug reduce the overall cost of these drugs for both the State and Medicaid recipients even without supplemental rebates. DMAS continues to actively manage new generic drugs to market, making them non-preferred until they are deemed less expensive than their brand counterparts net federal and (if applicable) supplemental rebates.

The goal of the PDL is to carefully balance the clinical attributes of a product against the financial impact and ultimately select products that best meet the needs of those enrolled in the Virginia Medicaid program. Due to the many interconnected cost savings initiatives in the pharmacy program, it is difficult to determine the savings attributable solely to the PDL. However, the supplemental rebate calculations noted above, along with the high compliance rate of using preferred agents, illustrate that the program is generating savings for the Commonwealth. The significant decline in rebates beginning in the first quarter of FY06 (Figure 2) was due to the implementation of the Medicare Part D program which resulted in approximately 136,000 Medicaid recipients getting prescription medications through Medicare,

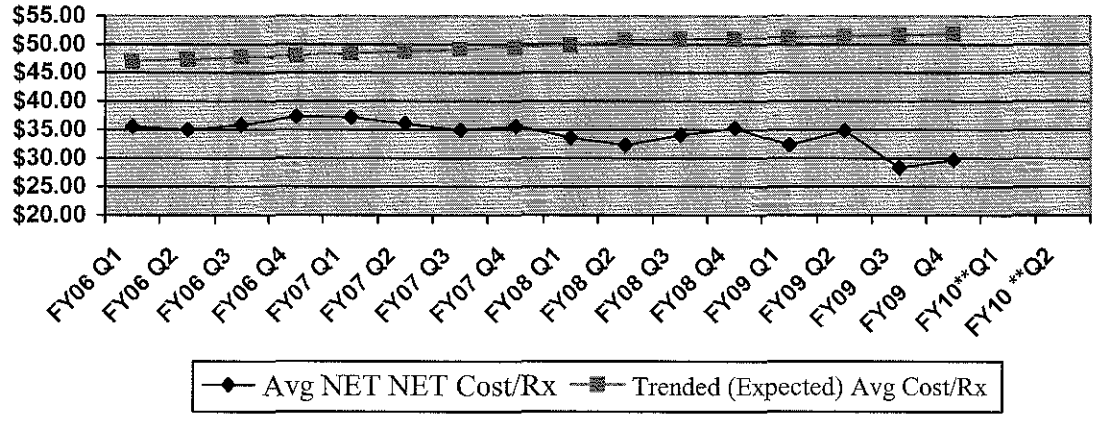
rather than Medicaid. As a result, fewer prescriptions are paid by Medicaid and fewer rebate dollars are collected from manufacturers.

Figure 2
Trend in Federal and Supplemental Rebates Invoiced
*2010 Q1 and Q2 CMS and Supplemental rebates not available at the time Includes Q3 and Q4 Only (FY 2004-2010)



As shown in Figure 3, the average net-net cost per script was $35.25 in 4Q FY08 compared to an average net-net cost per script of $29.69in 4Q FY09, a 15.8% decrease. It is notable that since January 2006, the average net-net cost per script has remained in the $29-37 dollar range, which is well below the expected trended average cost.

Figure 3
Net-Net Cost (FY 2006-10)



***2010 Q1 and Q2 CMS and Supplemental rebates not available at the time this report was completed**

Communications and Public Input

DMAS maintains a website (dmasva.dmas.virginia.gov) at which stakeholders can view notices and information about the PDL program. Stakeholders can access all documents related to the PDL, P&T Committee, as well as other pharmacy program initiatives. DMAS also has a dedicated email address (pdlinput@dmas.virginia.gov) for interested parties to submit PDL-related comments, concerns, or information to DMAS and/or the P&T Committee.

DMAS has partnered with ePocrates®, a leading drug information software application for handheld computers (PDAs) and desktop computers, to provide providers electronic access to the Virginia Medicaid PDL Quicklist. eProcrates® users can download the PDL Quicklist to their PDAs through the ePocrates® formulary link. In addition, providers can download the Quicklist from the Virginia DMAS website.

New Pharmacy Services Administration Contract

On June 28, 2010, a new Pharmacy Services Administrator contract became effective. The new contract was awarded to Provider Synergies, an Affiliate of Magellan Medicaid Administration This new contract is responsible for the following activities:

- ***Pharmacy Services Consultation and Support***: Consulting and supporting DMAS regarding trends in the pharmaceutical industry and changes in national, state and federal government policies that have the potential to impact the Virginia Medicaid pharmacy program.

- ***Pharmacy Call Center:*** Operating a comprehensive 24 hour, 7-day per week toll-free telephone call center capable of responding to enrollee and provider concerns; providing education; and handling SAs and pharmacy related activities.

- ***PDL Program:*** Reviewing and maintaining a PDL program for the Medicaid and FAMIS fee-for-service populations and supporting the P&T Committee in selecting preferred drugs that are safe and therapeutically effective and are the most cost-effective.

- ***Service Authorization:*** Administering the Service Authorization program.

- ***Maximum Allowable Cost (MAC) and Specialty Maximum Allowable Cost (SMAC) Program***: Administering a MAC and SMAC program to control the cost of multi-source generic drugs and specialty drugs by setting a maximum reimbursement amount.

A new contract for CMS and supplemental rebates invoicing was awarded to SXC effective June 28, 2010.

Federal Health Care Reform and the DMAS PDL Program

The recent passage of the federal Patient Protection and Affordable Care Act (PPACA), which includes a provision that increases the minimum rebate percentage for single source and innovator multi-source drugs, may have a major financial impact on supplemental rebate

collection by DMAS and its contractor. This difference between the old and new rebate percentage is to be invoiced at 100% to the Federal Centers for Medicare & Medicaid Services (CMS). This change in rebate calculation is likely to have an impact on the ability of DMAS and other state Medicaid programs to obtain the level of supplemental rebates previously obtained from drug manufacturers, at least in the short term, because supplemental rebates are tied to CMS rebates, which will become much larger. DMAS has not determined, at the time of this report, the dollar amount of this impact, but should have a much clearer idea within the next 12 months.

In addition to this change, the PPACA also allows states with contracted Medicaid Managed Care Organizations (MCOs) that provide direct pharmacy benefits to collect CMS rebates on this benefit. This change may have an impact on the pharmacy benefit management (PBM) components of these MCO contracts. MCO PBMs will likely see a reduction in rebates and discounts provided by drug manufacturers due to this change. DMAS will need to evaluate whether or not all of the prescription drugs covered by MCO PBMs are eligible for CMS rebates. This rebating component will also impact current capitation rates provided to MCOs. DMAS has not determined, as of the date of this report, the financial impact this change, but is actively evaluating it.

Conclusion

The Virginia Medicaid PDL Program continues to operate efficiently and effectively with very few complaints from providers or clients. Medicaid clients are receiving high quality prescription medications at a substantially reduced cost to the Commonwealth. Despite a significant decline in fee-for-service pharmacy clients, expenditures, and rebates due to the implementation of Medicare Part D and past managed care expansions, the PDL continues to be a very successful program. Much of the success of the program is attributable to a highly effective P&T Committee.

Acknowledgements

DMAS wishes to acknowledge the medical and pharmacy providers, members of the DMAS P&T Committee, public and private stakeholders, and pharmaceutical manufacturers who have participated in the development, implementation and maintenance of the preferred drug list program and other pharmacy program initiatives.

Attachment A
Item 297 (P) (8) of the 2010 Appropriations Act

The department shall provide to the Governor; the House Committees on Appropriations, and Health, Welfare and Institutions; the Senate Committees on Finance, and Education and Health; and the Joint Commission on Health Care a report on the Preferred Drug List (PDL) Program no later than November 1 of each year. The report shall include the direct savings attributed to the PDL for the prior fiscal year, an estimated savings of the program for the next fiscal year, and the cost to administer the PDL.

Attachment B
P&T Committee Members and Profession

NAME	PROFESSION
Randy Axelrod, M.D.,Chairman	Physician
Gill Abernathy, M.S., R.Ph.	Pharmacist
Rachel M. Selby-Penczak, M.D.	Physician
Avtar Dhillon, M.D.	Physician
Vacant (currently recruiting for replacement)	Physician
Mariann Johnson, M.D.	Physician
Mark Oley, R.Ph., Vice Chairman	Pharmacist
Sue Cantrell, M.D.	Physician
Tim Jennings, Pharm.D.	Pharmacist
Renita Driver, Pharm.D.	Pharmacist
Krishna Madiraju M.D.	Physician
James Stewart III with alternate Michele Thomas, Pharm.D	Commissioner, Department of Behavioral Health and Developmental Services

Attachment C
Drug Classes Currently Included on the PDL

PDL Phase I Drug Classes – Preferred drug status revised on January 1st of each year

- Hepatitis C
- Angiotensin-Converting Enzyme Inhibitors (includes combination products)
- Angiotensin II Receptor Blockers (includes combination products, as well as renin inhibitors)
- Beta blockers
- Calcium Channel Blockers (includes dihydropyridine & non-dihydropyridine agents)
- Direct Renin inhibitors
- Lipotropics (includes HMG CoA Reductase Inhibitors (Statins), Fibric Acids, Niacin Derivatives, Niacin/Statin combinations, Omega3, CAI, Bile Acid Sequestrants)
- Phosphodiesterase 5 Inhibitor for Pulmonary Arterial Hypertension
- Low Molecular Weight Heparins
- Sedative Hypnotics *(includes* Benzodiazepine and Other Sedative Hypnotics)
- Growth Hormones
- Hematopoietic Agents
- Progestins for Cachexia
- H2 Antagonists
- Proton Pump Inhibitors (PPIs)
- Ulcerative Colitis *(includes oral and rectal agents)*
- BPH treatment *(includes Alpha Blockers For BPH and Androgen Hormone Inhibitors)*
- Electrolyte Depleters
- Urinary Tract Antispasmodics
- Topical Immunomodulators
- Antihistamines -Second Generation (LSAs)
- Beta Adrenergics
- Inhaled Corticosteroids
- Nasal Steroids
- COPD-Anticholinergics
- Self-Injectable Epinephrine

PDL Phase II Drug Classes – Preferred drug status revised on July 1st of each year

- Barbiturate Analgesic & Non-salicylates analgesic *(and combinations)*
- Narcotics *(Includes Long Acting , Short Acting, combinations, and Lozenges)*
- Non-Steroidal Anti- Inflammatory Drugs (NSAID) *(includes Cox-2 Inhibitors)*
- Opioid Analgesic
- Opioid Dependency
- Topical Agents & Anesthetics
- Oral Antifungals
- Second and Third Generation Cephalosporins
- Second and Third Generation Quinolones – Systemic
- Macrolides - Adult and Pediatric
- Otic Quinolones
- Topical Antibiotics

- Herpes Antivirals
- Influenza Antivirals
- Topical Antivirals
- Platelet Inhibitors
- Non-Ergot Dopamine Receptor Agonists
- Serotonin Receptor Agonists (Triptans)
- Skeletal muscle Relaxants
- Antihyperkinesis/CNS Stimulants (Medications for ADD/ADHD)
- Smoking Cessation
- Acne agents (*includes Combination Benzoyl Peroxide & Clindamycin Products)*
- Topical Retinoids & Combinations
- Topical Agents For Psoriasis
- Androgenic Agents
- Oral Contraceptives
- Intra-vaginal Contraceptives
- Transdermal Contraceptives
- Injectable Hypoglycemics (includes all types of insulins, incretin mimetics, exenatide)
- Oral Hypoglycemics *(includes Second Generation Sulfonylureas, Alpha-Glucosidase Inhibitors, Biguanides, Biguanide Combinations, Meglitinides, Thiazolidinediones, DPPIV inhibitor)*
- Oral Agents for Gout
- Progestational Agents
- Virginal Estrogens
- Mobility Agents
- Self Injectable Immunomodulators for RA
- Multiple Sclerosis Agents
- Ophthalmic Glaucoma *(Includes Alpha-2 Adrenergic, Beta-blockers, Carbonic Anhydrase Inhibitors, Prostaglandin Inhibitors)*
- Ophthalmic Anti-Inflammatory
- Ophthalmic Antibiotics (Includes *Quinolones & Macrolides)*
- Ophthalmic Antihistamines
- Ophthalmic Mast Cell Stabilizers
- Bisphosphonates and Calcitonins for Osteoporosis
- Cough & Cold (*includes; Antihistamines: 1st generation, Antihistamines & Expectorant combination, Expectorant, Narcotic Antitussive & decongestant combos, Narcotic Antitussive & expectorant combos, Non-narcotic antitussive decongestant combos, Non-narcotic antitussive 1st generation antihistamine decongestant combos)*
- Intranasal Antihistamines
- Leukotriene Modifiers and Inhibitors