

medicaid  
and the uninsured

FLORIDA'S MEDICAID  
PRESCRIPTION DRUG BENEFIT:  
A CASE STUDY

*Prepared by*

Cathy Bernasek, Catherine Harrington,  
Rajeev Ramchand, and Dan Mendelson  
The Health Strategies Consultancy

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**The Kaiser Commission on Medicaid and the Uninsured serves as a policy institute and forum for analyzing health care coverage and access for the low-income population and assessing options for reform. The Commission, begun in 1991, strives to bring increased public awareness and expanded analytic effort to the policy debate over health coverage and access, with a special focus on Medicaid and the uninsured. The Commission is a major initiative of The Henry J. Kaiser Family Foundation and is based at the Foundation's Washington, D.C. office.**

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## EXECUTIVE SUMMARY

### Background

In May 2001, Florida Governor Jeb Bush signed a law (S792) authorizing the state's Agency for Health Care Administration (AHCA or the "Agency") to develop a state Medicaid preferred drug list ("the PDL"). A committee was appointed by the governor to develop this list of drugs that Medicaid providers can prescribe to their patients without receiving prior authorization; physicians are required to call the state and request approval for the prescription of any drug not included on the PDL. The law also allows Florida Medicaid to negotiate supplemental rebates from manufacturers that want their products to be included on the list. In lieu of cash rebates, the Agency may accept a manufacturer's plan to provide disease management and other services that guarantee Medicaid program savings – two manufacturers, Pfizer and Bristol-Myers Squibb (BMS), have agreed to sponsor such programs to date.

The passage of S792 was not Florida's first attempt to implement a program intended to generate prescription drug cost savings. In 1997, the state initiated disease management programs for Medicaid patients with chronic conditions such as asthma, diabetes, and HIV/AIDS with limited success. In 2000, the state imposed a four-brand drug limit that restricts the number of brand-name drugs available to Medicaid patients – physicians are required to seek prior authorization from the state before their patients receive a fifth or higher brand-name drug. The PDL is implemented along with these other program changes.

This case study, commissioned by the Kaiser Commission on Medicaid and the Uninsured (KCMU) and based on interviews with 32 individuals involved in or close to the Florida Medicaid pharmaceutical program, focuses on the state's experience with these and other pharmaceutical initiatives designed to curb Medicaid spending on prescription drugs. It provides a description of major program changes included in S792 and other bills signed into Florida law in recent years. It also offers interviewees' perspectives on the factors that influenced the passage of S792, how these various initiatives might impact beneficiaries' health, and how the state plans to evaluate the effectiveness of these program changes.

### Summary Findings

**Most interviewees described two factors key to the state's ability to pass a preferred drug list in 2001, after repeated attempts in previous years.**

- **A growing Medicaid budget deficit forced the legislature to focus on initiatives presenting immediate cost savings.** In FY2000, Florida Medicaid experienced an \$87.2 million deficit that grew to \$640.1 million in FY2001 and was projected to grow to \$1.5 billion in FY2002. Of more than forty Medicaid initiatives considered during the 2001 session to generate cost-savings, including eligibility reductions and program eliminations, legislators perceived a preferred drug list to be a more attractive option when balancing cost and beneficiary

interests. While legislators and Agency representatives expressed interest in monitoring how a preferred drug list might impact Medicaid beneficiaries, most conceded that specific plans to do so were secondary to budget requirements.

- **A history of experimentation with initiatives intended to generate prescription drug cost-savings paved the way for the passage of S792.** Since 1997, Florida has implemented Medicaid disease management programs and a four-brand limit, and commissioned a panel to study the feasibility of developing a formulary. Experiences with these initiatives combined with the projected budget deficit contributed to the consideration and passage of alternative programs in 2001.

**Beneficiary advocates and manufacturers adjusted lobbying strategies based on their perception that a preferred drug list had become “inevitable” in 2001.** With the exception of HIV/AIDS and mental health advocacy groups, whose constituents are particularly dependent on drug treatments, many beneficiary organizations became relatively quiet during the debates surrounding S792, instead focusing efforts on other potential program changes. HIV/AIDS and mental health groups began to pursue their own agendas to ensure that drugs in their therapeutic categories would be exempt from a new preferred drug list. Similarly by the end of the session, some pharmaceutical companies evidently worked to arrange portfolio deals with the Agency whereby their drugs would be protected on the final list.

**Most proponents of the new PDL – primarily interviewees from the legislature and Agency – claimed that the final list of drugs is comparable to formularies widely used to contain costs in the private sector.** Many interviewees contended that commercial health plans would not utilize such formularies if they were harmful to enrollees. Our own analysis indicates that the Agency’s PDL contains 83 of the top 100 branded drugs, similar to Blue Cross Blue Shield of Florida’s three-tier formulary coverage of 84 of these drugs. (See Appendix G for a comparison)

**Opponents of the change – primarily beneficiary and manufacturer representatives – asserted that Medicaid beneficiaries cannot be compared to private sector patients and that formularies result in cost shifting.** Unlike patients in the commercial sector, Medicaid beneficiaries may lack the means to pay for denied drugs and cannot switch plans to gain better access. Moreover, because the Medicaid fee-for-service population includes many elderly and disabled beneficiaries, it is, in general, a “sicker” population compared to patients in the private sector, and therefore uses more prescription drugs. Opponents also asserted that drug formularies only result in cost shifting due to increased hospitalizations, emergency room visits and/or physician office visits. A less vocal group of opponents, Florida physicians, complained that the new PDL levied a heavy administrative burden on the medical community.

**AHCA has not announced plans to evaluate the effect of the state’s new PDL on Medicaid beneficiaries’ quality of care.** Similarly, while savings targets have been established, the specific clinical goals of the Pfizer and BMS disease management programs are still being defined at this time. AHCA’s Medicaid Director explained that

the state plans to commission the University of Florida to evaluate the new PDL from a clinical perspective. The University of Florida currently is completing a study of the impact of the four-brand limit on physician prescribing patterns. In the absence of a state study at this point, beneficiary groups plan to monitor any anecdotal evidence suggesting that patients are being harmed by these new initiatives.

**Beneficiary advocates expressed concern that the state has not yet made beneficiaries aware of the new changes to their pharmaceutical benefit.** While Florida’s website contains information on the new PDL, the state does not have plans to establish a two-way communication channel to disseminate information directly to beneficiaries about and collect feedback on their experiences with these new programs. Rather, the state generally relies on physicians and pharmacists to ease beneficiaries through new program changes. Advocates are concerned that beneficiaries are currently unaware of their right to a 72-hour emergency supply of a drug pending prior authorization and that going forward, the experiences of the most vulnerable patients affected by the change will not be tracked.

### **Summary Implications**

**Florida’s many years of experience and committed leadership facilitated the implementation of a preferred drug list in 2001.** Florida’s history of pursuing numerous initiatives within the Medicaid pharmaceutical program and the Governor’s strong commitment to developing a preferred drug list played a meaningful role in the passage and implementation of S792. States attempting to follow Florida’s lead would confront their own unique set of political circumstances. While there is a chance that current budget pressures provide an incentive to other states to pass similar initiatives, states still may be challenged to design and implement such programs successfully within one or two years.

**Pressing budget environments may change the lobbying activities of beneficiary advocates and disease groups in other states.** As was the case in Florida, beneficiaries may begin to perceive that preferred drug lists and other programs that restrict access to medications are becoming unavoidable, or the “lesser of evils” when compared to other initiatives intended to generate cost-savings such as eligibility reductions and benefit eliminations. As a result, advocates for individuals with conditions managed largely by pharmaceutical therapy may be forced to split from broader beneficiary coalitions to pursue separate agendas focused on protecting specific therapeutic categories on state preferred drug lists.

**Vulnerable Medicaid beneficiaries are not a well-organized constituency, and the state will need to make a concerted effort to ensure that their experiences are understood, and that systems are developed to protect them.** Although beneficiaries can call or write their local Medicaid offices or the Agency to communicate problems, this method of tracking alone cannot be expected to reflect the true experiences of the most vulnerable beneficiaries – individuals in the Medicaid fee-for-service program with chronic diseases taking multiple medications. The current system relies on physicians

and pharmacists to be patient advocates, and it is conceivable that prior authorization requests could “fall through the cracks.” Studies that seek ongoing feedback from beneficiaries and their providers, as suggested below, could help to strengthen the beneficiary voice and ameliorate this situation.

**While time and funding constraints may delay large clinical studies of how a new Medicaid preferred drug list and other initiatives affect beneficiary health, there are steps AHCA and other agencies can take to monitor beneficiaries’ experiences.** In the interim, among other studies, AHCA could: i) analyze prior authorization requests to understand the specific beneficiary populations affected by program changes; ii) track hospitalizations, ER visits and office visits of those patients whose drug regimens have been affected by the changes; iii) survey physicians and pharmacists to understand their experience with the new PDL or brand limit; and iv) solicit feedback from beneficiaries through surveys and/or face-to-face meetings.

## INTRODUCTION

State legislatures and Medicaid programs are increasingly focused on the rise in spending in their Medicaid outpatient prescription drug programs. In federal FY2000, national Medicaid fee-for-service prescription drug costs totaled \$16.6 billion,<sup>1</sup> and the National Association of State Budget Officers projects this amount to reach \$25 billion by states' FY2002, a 22.7% annual increase. These projections coincide with the strong political interest of many governors in reducing the burden of drug costs on low-income seniors, and addressing an unstable economy and severe budget shortfalls in many states. Consequently, states are aggressively seeking strategies to manage both prices and utilization within the constraints of state and federal statutes governing Medicaid operations.

Florida has been on the forefront of such activity in large part due to the state's Medicaid spending trends. In FY2000, Florida Medicaid experienced an \$87.2 million deficit that grew to an estimated \$640.1 million in FY2001 and was projected to grow to \$1.5 billion in FY2002.<sup>2</sup> In his FY2001 proposed budget, Governor Jeb Bush stated "explosive growth in pharmacy costs represents the greatest factor in rising Medicaid expenditures," a statement validated by Exhibit 1, which shows that in FY1999 and FY2000, 54.2% and 35.0% of Medicaid growth respectively was attributable to growth in the pharmacy program. If left unchecked, spending on prescription drugs was projected to account for approximately 20% of total Medicaid spending by FY2002 (versus the 15.4% in Exhibit 1 which assumes the new cost-saving initiatives are successful), surpassing nursing home care and inpatient hospitalization expenditures.

Exhibit 1.

<b>Medicaid Spending in Florida (In Millions)</b>						
	<b>Actual</b>			<b>Projected</b>		
	<b>FY1997-98</b>	<b>FY1998-99</b>	<b>FY1999-00</b>	<b>FY2000-01E*</b>	<b>FY2001-02E*</b>	<b>FY2002-03E**</b>
<b>Prescribed Medicine Services</b>	<b>\$846</b>	<b>\$1,028</b>	<b>\$1,313</b>	<b>\$1,460</b>	<b>\$1,567</b>	<b>\$1,925</b>
Nursing Home Care	\$1,330	\$1,393	\$1,552	\$1,674	\$1,812	\$2,056
Hospital Inpatient Services	\$992	\$961	\$1,042	\$1,470	\$1,776	\$1,925
Other	\$3,444	\$3,565	\$3,856	\$4,376	\$4,997	\$5,341
<b>Total Medicaid</b>	<b>\$6,612</b>	<b>\$6,947</b>	<b>\$7,763</b>	<b>\$8,981</b>	<b>\$10,152</b>	<b>\$11,246</b>
<b>Growth in Medicaid Spending Attributable to</b>						
<b>Prescribed Medicine Services</b>		<b>54.2%</b>	<b>35.0%</b>	<b>12.1%</b>	<b>9.1%</b>	<b>32.7%</b>
Nursing Home Care		18.9%	19.4%	10.0%	11.8%	22.3%
Hospital Inpatient Services		-9.5%	9.9%	35.2%	26.1%	13.6%
Other		36.3%	35.6%	42.7%	53.0%	31.4%
<b>Total Medicaid</b>		<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>
<b>Percentage of Medicaid Spending on</b>						
<b>Prescribed Medicine Services</b>	<b>12.8%</b>	<b>14.8%</b>	<b>16.9%</b>	<b>16.3%</b>	<b>15.4%</b>	<b>17.1%</b>
Nursing Home Care	20.1%	20.1%	20.0%	18.6%	17.8%	18.3%
Hospital Inpatient Services	15.0%	13.8%	13.4%	16.4%	17.5%	17.1%
Other	52.1%	51.3%	49.7%	48.7%	49.2%	47.5%
<b>Total Medicaid</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

Data from the Social Service Estimating Conference, Sept. 2001

\* Includes savings anticipated from new pharmaceutical cost containment initiatives

\*\* Assumes a reduction in Medicaid appropriations

<sup>1</sup> Office of the Actuary, Centers for Medicare and Medicaid Services, Compilation of HCFA-64 Medicaid expenditure data for federal FY 2000.

<sup>2</sup> "Growth in Medicaid Prescription Drug Costs Indicates Additional Prudent Purchasing Practices Are Needed," Office of Program Policy Analysis and Government Accountability, February 2001.

Compared to other states, Florida does not have a disproportionately higher percentage of elderly and blind and disabled Medicaid enrollees, who generally account for the majority of Medicaid prescription drug spending. However, the state historically has maintained higher than average drug costs per Medicaid drug recipient. Exhibit 2 shows that the state consistently ranked among the highest in the nation for this type of spending, averaging \$920.55 per Medicaid drug recipient in 1997-98. The national average in 1997-98 was \$761.00.<sup>3</sup>

## Exhibit 2.

### Annual Medicaid Fee-for-Service Drug Costs per Medicaid Prescription Drug Recipient, Selected States

State	FY 1995-96		FY 1996-97		FY 1997-98	
	Costs	Rank	Costs	Rank	Costs	Rank
Connecticut	\$700.79	3	\$1,382.88	1	\$1,722.44	1
New Jersey	\$720.88	2	\$1,065.50	3	\$1,375.11	2
Rhode Island	\$874.44	1	\$1,114.25	2	\$1,368.99	3
Missouri	\$599.59	9	\$810.82	5	\$1,080.84	4
Wisconsin	\$663.57	5	\$772.61	6	\$1,048.84	5
Indiana	\$670.76	4	\$831.37	4	\$1,005.87	6
<b>Florida</b>	<b>\$609.83</b>	<b>7</b>	<b>\$754.26</b>	<b>7</b>	<b>\$920.55</b>	<b>7</b>
Ohio	\$574.86	11	\$738.34	8	\$918.79	8
Pennsylvania	\$625.77	6	\$723.57	10	\$904.45	9
Washington	\$564.61	13	\$700.23	12	\$890.75	10
<b>Natl. Average</b>	<b>\$507.94</b>		<b>\$622.67</b>		<b>\$761.00</b>	

Source: Office of Program Policy Analysis and Government Accountability (OPPGA) analysis of Health Care Financing Administration 2082 Report, Fiscal Years 1995-96, 1996-97, and 1997-98.

In response to these trends, in late May 2001, Gov. Jeb Bush signed an act (S792) authorizing the Agency for Health Care Administration (AHCA, or “the Agency”) to develop a state Medicaid formulary, or preferred drug list (“the PDL”), by establishing a mandatory prior authorization program.<sup>4</sup> The act also allows Florida Medicaid to negotiate supplemental rebates from manufacturers that want their products to be included on the PDL. In lieu of cash rebates, the Agency may accept a manufacturer’s plan to provide services that guarantee Medicaid program savings – two manufacturers, Pfizer and Bristol-Myers Squibb (BMS), have agreed to sponsor such programs to date. The law also requires the Agency to develop programs to manage the drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending.

In August 2001, the Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit in federal court challenging S792, claiming that the law violates federal Medicaid statute. On September 18, the U.S. Department of Health and Human Services approved Florida’s state plan amendment to establish a preferred drug list and negotiate rebate agreements with manufacturers that are in addition to those required by Title XIX of the Social Security Act. A few days later, a federal court magistrate in Florida denied PhRMA’s request for a preliminary injunction, saying: “I don’t see that the federal law prohibits a prior authorization program that furthers other state interests... as long as it

<sup>3</sup> In this analysis, the dollar figure (numerator) is the total amount of Medicaid fee-for-service prescription drug claims adjudicated for each fiscal year. Recipients (denominator) are Medicaid enrollees who utilized prescription drug services in that fiscal year. These figures do not account for Medicaid managed care enrollees, nor do they account for drugs used in treatment in hospitals or institutional settings. For a more detailed explanation of the challenges in determining Medicaid prescription drug costs per recipient, see Brian Bruen’s reports for The Kaiser Commission on Medicaid and the Uninsured: “Medicaid and Prescription Drugs: An Overview,” October 2000 and February 2002 (update).

<sup>4</sup> The Federal Medicaid statute includes stringent requirements that govern how state Medicaid formularies may be implemented. In contrast, there are fewer requirements surrounding a state Medicaid program’s ability to develop a list of drugs that require prior authorization. See Appendix A.

keeps intact the idea of the [federal Medicaid] formulary.’<sup>5</sup> In early January of 2002, a federal judge let S792 stand, finding that “Florida’s list steered doctors and patients towards certain preferred drugs, but didn’t prevent access to non-preferred drugs.”<sup>6</sup> At the time of the publication of this case study, PhRMA planned to appeal the decision, though there had been no official action.

While there has been broad media coverage of Florida’s new Medicaid prescription drug programs, there has been little attention focused on how these initiatives are expected to impact beneficiaries over the coming years. To help fill this void, in the fall of 2001 the Kaiser Commission on Medicaid and the Uninsured (KCMU) commissioned The Health Strategies Consultancy LLC to prepare a case study that (1) describes Florida’s recent Medicaid prescription drug initiatives intended to generate cost-savings, and (2) incorporates the views of people involved in the passage and implementation of these initiatives regarding how the changes might impact the health of Medicaid beneficiaries.

### **Study Methodology**

The case study is based on a combination of primary and secondary data sources. To begin, we conducted an in-depth review of relevant legislation, news articles and state government reports that describe Florida’s Medicaid programs. These sources provided varying degrees of information about the state’s implementation of and savings experience with these programs. A complete bibliography is included in Appendix B.

The majority of information contained in the case study – perspectives on how Florida’s new initiatives might impact beneficiaries and on the beneficiary community’s involvement in the implementation of these programs – is based on 24 interviews that involved 32 representatives from 20 different organizations. To collect a broad mix of perspectives, the study team interviewed representatives of AHCA, the Florida legislature, PhRMA, the Florida Medical Association, beneficiary groups such as the National Association of Mental Illness and Florida Legal Services, and the pharmacy sector. Interviewees were sent portions of the case study before its publication to ensure that their views and opinions were accurately represented. A description of our interview sample is included in Appendix C.

### **Case Study Organization**

The case study is organized into five sections:

- **History of Select Medicaid Prescription Drug Programs in Florida.** Describes key strategies pursued by Florida’s Medicaid prescription drug program in an effort to contain costs, leading up to and including S792, the bill that authorized the creation of the PDL and the negotiation of supplemental rebates.
- **Factors Influencing the Passage of a Preferred Drug List in 2001.** Describes the budget environment and lobbying activities surrounding the passage of S792.

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<sup>5</sup> “PhRMA v. Florida,” The Pink Sheet, Sept. 24, 2001.

<sup>6</sup> Gold, R. “Judge Allows Drug Rebates in Florida Law,” The Wall Street Journal, January 3, 2002.

- **Perspectives on Florida’s Prescription Drug Programs and Beneficiary Health.** Relates interviewees’ perceptions of the impact Florida’s recent Medicaid prescription drug initiatives will have on beneficiaries’ access to prescription medications and overall health.
- **Plans to Evaluate New Initiatives.** Addresses the Agency’s plans to evaluate the impact of Medicaid prescription drug initiatives on overall spending and the clinical health of beneficiaries.
- **Implications for Other States and Medicaid Beneficiaries.** Provides brief commentary on the predicted impact of Florida’s recent experience on beneficiaries and on future Medicaid prescription drug programs in Florida and in other states.

## HISTORY OF SELECT MEDICAID PRESCRIPTION DRUG PROGRAMS IN FLORIDA

Florida has several years of experience pursuing legislative initiatives designed to reduce the state’s Medicaid prescription drug spending. These initiatives have extended beyond traditional measures relied upon by most states, such as reduced pharmacy reimbursement, OBRA ’90 manufacturer rebates, and prospective and retrospective utilization review. The table below and the remainder of this section describe programs authorized between 1997 and 2001 that have attracted national attention and set Florida apart.<sup>7,8</sup> The research for this case study focused on these programs.

Initiative	Brief Description	Anticipated Savings <sup>9</sup>
<b>Disease Management</b>  <i>Enacted in 1997 and 1998</i>	Various programs targeting Medicaid MediPass (primary care case management program) clients with asthma, diabetes, HIV/AIDS, hemophilia, hypertension, cancer, end-stage renal disease, congestive heart failure, and sickle cell anemia. AHCA has contracted with disease management organizations to design and implement these programs with limited success.	<b>\$112.7 million 1997-2001</b>
<b>Four-Brand Drug Limit</b>  <i>Enacted June 2000</i>	All adult Medicaid fee-for-service recipients <sup>10</sup> are limited to four brand-name drugs per month. Generic drugs, insulin, diabetic supplies, contraceptives, mental health drugs, and antiretroviral drugs to treat HIV and AIDS are exempt.	<b>\$120 million / FY 2000-2001</b>

<sup>7</sup> A timeline detailing the passage and implementation of these initiatives is included in Appendix D.

<sup>8</sup> A more extensive list of Florida’s Medicaid prescription drug programs is included in Appendix E.

<sup>9</sup> These savings were determined in Florida’s Consensus Estimating Conferences using historical data and anecdotal evidence from physicians and pharmacists to forecast Medicaid caseload projections and utilization trends. A staff member of the Senate appropriations committee explained: “it’s not a scientific process.” These savings are determined for Florida’s Medicaid program (federal+state).

<sup>10</sup> References to Florida’s Medicaid fee-for-service population throughout this document include beneficiaries enrolled in the state’s primary care case management program, MediPass.

<p><b>Preferred Drug List</b></p> <p><i>Enacted May 2001</i></p>	<p>A Medicaid Pharmaceutical and Therapeutics Committee was established to design a preferred drug list based on clinical efficacy, safety, and cost effectiveness. All drugs covered by Medicaid but not included on the PDL are available to Medicaid fee-for-service beneficiaries<sup>10</sup> via prior authorization. All pharmaceutical manufacturers that agree to provide a supplemental rebate (see below) to the state are given an opportunity to present evidence to support inclusion of a product on the PDL.</p>	<p><b>\$214 million /year, including the supplemental rebates described below</b></p>
<p><b>Supplemental Rebates</b></p> <p><i>Enacted May 2001</i></p>	<p>The Agency is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and are equal to no less than ten percent of the average manufacturer price, unless the federal or supplemental, or both, equals or exceeds 25%. However, a pharmaceutical manufacturer is not guaranteed placement on the PDL by simply paying the minimum supplemental rebate.</p>	<p><b>See above</b></p>
<p><b>Manufacturer Disease Management Programs</b></p> <p><i>Enacted May 2001</i></p>	<p>In lieu of cash supplemental rebates, manufacturers may propose to provide other program benefits including, but not limited to: disease management programs, drug product donation programs, drug utilization control programs, prescriber and beneficiary counseling and education, fraud and abuse initiatives, and other services or administrative investments. These programs must provide guaranteed savings to the Medicaid program.</p>	<p><b>Varies</b></p> <p>According to public press releases, the Pfizer disease management initiative promises \$33 million in savings over two years; the BMS initiative guarantees \$16.3 million over two years.</p>

*Disease Management*

In 1997 and then again in 1998, the Florida state legislature directed AHCA to implement disease management programs in nine therapeutic categories for clients in Florida’s primary care case management program, MediPass. Through a competitive bidding process, the Agency planned to contract with separate vendors for each of the different therapeutic categories, stipulating that contracts must include guaranteed savings estimates. A review of the vendor contracts completed by the legislature’s Office of Program Policy Analysis and Government Accountability (OPPAGA), which audits Medicaid and other state programs, indicated that vendors agreed to offer a variety of services to MediPass clients. These services included, but were not limited to, care management by a RN or LPN, individual patient care plans, and patient risk assessments.

OPPAGA concluded that the state had not yet determined whether the Agency’s programs have met the \$112.7 million savings goal established by the legislature in 1997. OPPAGA reported that as of May 2001, the state had advanced \$24.1 million to its disease management contractors and had not determined whether the initiative had improved health outcomes and saved the amount projected over four years. Further, the

legislative office found that the disease management initiatives have only served six percent (for asthma) to 58 percent (for diabetes) of the clients eligible for the services, and that provider support and participation has been extremely limited. Some physicians and medical office staff who serve MediPass clients regularly even admitted to having no knowledge of the various disease management programs. OPPAGA attributed these challenges to inefficient program design and inadequate contractual agreements with vendors. OPPAGA also noted that the disease management program for asthma was discontinued in 2001 due to disagreements between the Agency and vendor, and that only five of the other therapeutic categories currently have programs. No programs have yet been established for sickle-cell anemia, hypertension, or cancer.<sup>11</sup>

#### *Four-Brand Limit*

In 2000, the legislature passed S2034, which, among other Medicaid pharmacy initiatives, included the four-brand limit. This initiative is not unique to Florida; as of February 2002, 12 states had some sort of drug limit established for their Medicaid programs, ranging from three to ten drugs per month.<sup>12</sup> In Florida's original program, Medicaid recipients over the age of 21 who were not in a nursing home or other institution were limited to a 34-day supply of four brand-name drugs per month, excluding generic drugs, insulin and diabetic supplies, contraceptives, mental health drugs, and antiretroviral drugs used to treat HIV/AIDS. The passage of S792 in 2001 expanded the scope of the initiative to include institutionalized patients.

A Medicaid beneficiary may exceed the four-brand limit only if his or her prescriber requests and receives a prior authorization (see Appendix F for a flowchart detailing the prior authorization process). While prior authorization is pending, federal statute mandates that the patient be provided a 72-hour supply of the drug in emergency situations. There are no grandfather provisions in the state statute for those patients who are severely affected by the program, such as beneficiaries with chronic diseases who regularly take more than four brand prescription drugs per month. The system, however, does allow physicians the opportunity to present clinical evidence to the state of a patient's need to have prior authorization extended for a twelve-month period.

#### *Preferred Drug List, Supplemental Rebates, Manufacturer Disease Management*

In 2001, the legislature passed S792, which authorized the creation of the state's new PDL. The Agency contracted with an independent organization, Provider Synergies, to negotiate rebate agreements with manufacturers and recommend products to be included on the PDL to a Pharmaceutical & Therapeutics (P&T) Committee. The Committee has eleven members appointed by the governor, including both a beneficiary representative and pharmaceutical representative. The Committee meets four times per year and reviews drugs by therapeutic category, assigning products to the list based on clinical efficacy, safety, and cost effectiveness; drugs not selected are available via prior authorization (see

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<sup>11</sup> "Medicaid Disease Management Initiative Sluggish, Cost Savings Not Determined, Design Changes Needed," Office of Program Policy Analysis and Government Accountability, May 2001.

<sup>12</sup> National Pharmaceutical Council. "Pharmaceutical Benefits for State Medical Assistance Programs" National Pharmaceutical Council, Inc; 2000. (National Pharmaceutical Council information was verified and updated through state Medicaid websites and calls to state Medicaid pharmacy directors and staff.)

Appendix F). New products are reviewed at the meeting following the date of their market release, and therapeutic categories and manufacturer rebate proposals are re-evaluated annually. Mental health drugs (defined as antipsychotics, antidepressants, and anticonvulsants) and HIV/AIDS antiretroviral drugs are exempt from the list, and institutionalized patients are not subject to the PDL.

Drugs not included on the PDL are only available to patients via an authorization process similar to the one used for the four-brand limit (as described above). The PDL and four-brand limit are independent programs each requiring separate prior authorizations. For example, if a patient's physician requests a fifth or higher brand-name drug, prior authorization is required regardless of whether or not that drug is included on the PDL. One Agency interviewee, however, did mention that the prior authorization process for a fifth or higher brand-name drug is made easier when the drug(s) is on the PDL.

By Florida law, manufacturers must propose a supplemental cash rebate or alternative cost-saving program (such that the maximum total (existing plus supplemental) rebate equals 25% of the average manufacturer price) to gain *consideration* for the PDL. Information about the prices offered by manufacturers to the state are considered proprietary and protected by state law, though the Wall Street Journal reported that companies are generally offering "rebates averaging around six percent on top of those already-discounted prices."<sup>13</sup> Alternative program proposals, which can include disease management services, product donations and patient education among other elements, must include precise, targeted savings amounts. If anticipated savings are not achieved as determined by a third party, manufacturers must pay the difference between the realized and expected savings.

Despite the challenges posed by the state's existing disease management programs described above, the Agency has accepted alternative program offerings that include disease management components from two manufacturers, Pfizer and BMS. According to one AHCA interviewee, the Agency considered proposals only from manufacturers with disease management experience who offered to design and manage programs targeting a Medicaid patient population with proven, unmet needs. Public press releases indicate that Pfizer will assign case managers to patients with congestive heart failure, diabetes, asthma, and hypertension at hospitals. The company also is establishing a product donation program and health literacy materials to be distributed to patients in Federally Qualified Health Centers in Florida. BMS, which is still in final negotiations with the state and has not yet made program information available, is expected to focus on an early intervention program for cancer and HIV/AIDS, and a peer education campaign concentrating on diabetes among Florida's Hispanic community. The Agency expects that the design of these programs will consider the shortcomings of the state's existing disease management programs.

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<sup>13</sup> Gold, R. et al. "States Take on Drug Firms on Prices," The Wall Street Journal, December 7, 2001.

## **FACTORS INFLUENCING THE PASSAGE OF A PREFERRED DRUG LIST IN 2001**

The recent national attention paid to Florida's Medicaid program has focused predominantly on the state's new PDL. This development led Florida to become only the second state (behind California) to move forward with aggressive plans to reduce the list of drugs immediately accessible to Medicaid beneficiaries and to negotiate supplemental rebates from manufacturers. Because of its importance, a portion of our interviews focused on the political climate that influenced the state legislature's unanimous passage of S792 authorizing a preferred drug list in 2001. We asked:

- What were the most significant hurdles to passing S792?
- How vocal were advocacy organizations and other constituent groups in the legislative process that led to the passage of S792?
- What were some of the solutions (if any) that the state, industry, and beneficiary advocates adopted collaboratively during the legislative process?

### **The state has a history of implementing initiatives intended to generate prescription drug cost-savings; a number of our interviewees perceived the passage of a preferred drug list to be “inevitable.”**

Debates surrounding Florida's Medicaid prescription drug initiatives date back to the 1997-98 legislative session. In many ways this experience paved the way for the state's authorization of a preferred drug list in 2001. AHCA's annual report from January 2001 concluded that the extensive measures passed in 2000 (including the four-brand limit) “represent[ed] the culmination of an extensive two-year debate regarding means to control Medicaid drug spending.”<sup>14</sup> Given the size of the projected deficit and challenges faced in the state's existing disease management programs, many alternatives to a preferred drug list such as new disease management programs were no longer practical. Many interviewees also referenced the Governor's strong support for a preferred drug list in the preceding years as having a major influence on its passage in 2001.

### **The 2001 Florida legislative session was budget-driven, creating an environment favorable to further cuts in prescription drug spending.**

The absence of a state income tax and presence of a balanced budget mandate in Florida force the state to pay strict attention to programs affecting the annual budget. For FY2001, the state faced a \$640.1 million Medicaid budget deficit. Prior to the passage of S792, Florida's OPPAGA projected that if the Medicaid program were to continue unchanged, its deficit would grow to \$1.5 billion in FY2002. Most interviewees acknowledged that the evolving budget crisis was the most significant factor influencing the passage of S792.

In the 2001 legislative session, a preferred drug list was not the only initiative that the legislature considered to reduce its Medicaid spending. An interviewee from the legislature's appropriations staff explained that more than forty initiatives intended to

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<sup>14</sup> AHCA, “Medicaid Prescribed Drug Spending Control Program: Annual Report,” January 15, 2001.

save costs in Medicaid were evaluated during the session. This respondent stated that a preferred drug list presented one of the most attractive options, considering savings requirements and beneficiary interests when compared to reductions in Medicaid eligibility and the elimination of optional programs.

**The recommendation of a Formulary Study Panel convened in 1999 that the state *not* adopt a preferred drug list carried little weight in the legislative process.**

In 1999, the legislature authorized the creation of a Formulary Study Panel to “prepare recommendations on the advisability, feasibility and cost-effectiveness of implementing an appropriate formulary for the Medicaid prescribed medicine program.”<sup>15</sup> The panel consisted of nine members, three members each appointed by the Governor, the Speaker of the House of Representatives, and the President of the Senate. After a series of hearings, including testimony from California representatives who spoke about that state’s experience with a Medicaid formulary, the panel members voted in a six-three count *not* to recommend the adoption of a preferred drug list in the Medicaid program. The six members in the majority, all of whom were appointed to the panel by the legislature, cited concerns about access to newer, more efficacious drugs, the potential for adverse health outcomes, and potential harm to the patient-provider relationship. The three dissenting members, who had been appointed by the Governor and did not believe that a formulary would necessarily harm beneficiaries, expressed concern primarily about cost.

Many interviewees who represented beneficiary groups cited the Formulary Study Panel’s report in support of their position against the PDL. These interviewees acknowledged, however, that the publication received little attention by the legislature, Governor and AHCA. While individual commentary from panel members is included in the report, they were not given the opportunity to testify in front of a legislative audience, and after its release, the report was only available to those who knew about it and made an effort to retrieve it. One interviewee from the legislature who participated on the panel speculated that the report’s lack of visibility was in part due to the fact that many panel members who had voted against a preferred drug list in March 2000 had actually altered their views by 2001.

**There were mixed perspectives on lobbying efforts in the state against a preferred drug list in 2001.**

Although many beneficiary groups banded together to form large coalitions in recent years to protest a Medicaid formulary and other restrictions to the Medicaid benefit, only the mental health and HIV/AIDS groups appeared to be vocal and were successful during the 2001 session. Interviewees from or familiar with the HIV/AIDS and mental health communities explained that they were forced to concentrate their efforts on ensuring that drugs in therapeutic categories relevant to them were exempt from the list. These groups believe that non-compliance is more life threatening to patients with these diseases (i.e., leads to AIDS drug resistance or re-hospitalization/suicides among the mentally ill) and that the mentally ill may lack the cognitive and/or emotional ability to negotiate barriers

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<sup>15</sup> Medicaid Formulary Study Panel, “Florida Medicaid Prescribed Drug Program: A Final Report to the Governor and Legislature,” March 3, 2000.

to access. Also, one interviewee explained that the legislature understands that the cost of hospitalizing or institutionalizing these patients outweighs the medication costs they generate.

Aside from the HIV/AIDS and mental health groups, many interviewees outside of the beneficiary community commented that patient advocates, including advocates for the elderly, were relatively quiet during the development and passage of S792. One AHCA interviewee mentioned that there were some lobbying efforts to include Parkinson's, Alzheimer's, and other types of mental health drugs (e.g. tranquilizers) in the mental health exemption, but these were not included in the final version of the bill. One beneficiary advocate explained that advocates outside of the HIV/AIDS and mental health communities made the decision to establish other priorities, such as saving special interest programs (e.g. tobacco control) or focusing on nursing home quality reforms.

Lobbying efforts against a preferred drug list by the pharmaceutical industry also were not as intense as in previous years. PhRMA representatives noted that key pharmaceutical lobbyists, who were vocal in the past, were “noticeably absent” from the lobbying efforts against S792. This point was supported by a detailed report of the legislative process compiled by the Wall Street Journal:

“[A]t Florida’s statehouse, industry opposition to the proposed drug formulary wasn’t coordinated. Pfizer’s Tallahassee lobbyist, David Nickles, who had led the industry opposition in the past two sessions, uncharacteristically became “very, very quiet,” says Ron Silver, a Democrat and sponsor of the drug-formulary bill. Adds Tara Ryker, an Eli Lilly & Co. Spokeswoman: ‘Nobody knew exactly what Pfizer was doing.’”<sup>16</sup>

According to a Pfizer interviewee, the company also perceived that the passage of a preferred drug list became inevitable in the 2001 session. Given this situation and the company's experience working with the Agency since November 2000 to develop new disease management and quality improvement programs, Pfizer began to pursue a strategy that would help to ensure that all Pfizer drugs would be available to beneficiaries.

## **PERSPECTIVES ON FLORIDA’S PRESCRIPTION DRUG PROGRAMS AND BENEFICIARY HEALTH**

Our interview sample included representatives from each of the key constituent groups involved with and/or affected by the state’s Medicaid prescription drug initiatives. The following chart includes the general impressions interviewees shared about how Florida’s new programs might impact beneficiaries.

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<sup>16</sup> Gold, R et al. “Drug Intervention: Pfizer Ducks Pressure On Prices by Helping State Save on Medicaid,” The Wall Street Journal, July 9, 2001.

**In general, the perspectives shared by interviewees were consistent with the traditional positions of the groups they represent.**

Represented Groups/Organizations	Views Expressed in Interviews
<p align="center"><b>Beneficiary Advocates</b></p>	<ul style="list-style-type: none"> <li>• Beneficiary advocates support maximum access to medications. The PDL and four-brand limit restrict this access, which can harm patients.</li> <li>• Medicaid patients lack the choices that patients in the commercial sector have to obtain drugs not on the PDL. Beneficiaries lack the means to pay for drugs themselves and cannot switch plans to gain better access.</li> <li>• Clinical considerations are secondary to cost savings potential when building the PDL.</li> <li>• The PDL will merely result in cost shifting (i.e., increased hospitalizations, ER visits, office visits).</li> <li>• Advocates lack information on Pfizer’s and BMS’ disease management programs to comment on how beneficiary health might be improved.</li> </ul>
<p align="center"><b>Physicians</b></p>	<ul style="list-style-type: none"> <li>• Although they are accustomed to working with formularies in the private sector, physicians generally do not like restrictions on how they can/cannot prescribe.</li> <li>• Some physicians acknowledged that prior authorization requirements encourage them to think more critically about a patient’s drug regimen.</li> <li>• The prior authorization process places a heavy administrative burden on those who see many Medicaid patients.</li> </ul>
<p align="center"><b>Pharmaceutical Manufacturers</b></p>	<ul style="list-style-type: none"> <li>• PhRMA’s longstanding position is that patients should have maximum access to medications. The PDL limits this access and beneficiaries could be harmed.</li> <li>• The PDL will merely result in cost shifting.</li> <li>• There are alternative cost-saving measures that the state could have adopted.</li> </ul>
<p align="center"><b>Pharmacists</b></p>	<ul style="list-style-type: none"> <li>• Pharmacists are generally supportive of the PDL and four-brand limit as legitimate means of reducing state expenditures (and protecting themselves from further cuts in pharmacy services reimbursement).</li> <li>• Pharmacists do face an additional administrative burden in handling claims rejections for prior authorization.</li> </ul>
<p align="center"><b>Agency for Health Care Administration</b></p>	<ul style="list-style-type: none"> <li>• AHCA believes that implementing a preferred drug list merely mimics what the private sector has done for years.</li> <li>• Florida’s final PDL will be less restrictive than most commercial formularies.</li> <li>• The Agency has developed a prior authorization process that provides a built-in protection that ensures beneficiaries have access to all medications.</li> <li>• Internal Agency analyses conclude that the four-brand limit has resulted in significant medical savings since implementation, without harm to beneficiaries.</li> </ul>

<p><b>Legislature</b></p>	<ul style="list-style-type: none"> <li>• Legislature members and staff acknowledged that the savings opportunity presented by the PDL and four-brand limit dominated legislative discussions. In this budget environment, extensive consideration of how these initiatives would be evaluated to determine their impact on beneficiary health was difficult to initiate.</li> <li>• There is some concern that manufacturer sponsored disease management programs will not be coordinated with existing disease management initiatives and will not result in savings equal to supplemental cash rebates.</li> </ul>
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*Beneficiary Advocates*

The beneficiary community is generally concerned about any restrictions on access to medications. Although they acknowledged that most people in the private sector are accustomed to formularies, they claimed that it is unfair to compare Medicaid beneficiaries to these individuals. Consumers with private sector healthcare coverage often have alternative means to attain restricted drugs that are not feasible options for the Medicaid population, such as paying out of pocket for non-formulary drugs or even switching health plans. Although specific studies were not mentioned, beneficiary advocates included in the interview sample contested that the new PDL would result in “cost-shifting” as patients incurred more hospital, emergency room and physician office visits.

The beneficiary community also raised concerns about the design of Florida’s exemptions and composition of the P&T Committee. There were significant complaints that the four-brand limit and PDL mental health and HIV/AIDS exemptions are *drug*, not *patient*, specific.<sup>17</sup> Most exempt drugs affect patients that suffer from multiple diseases (e.g. depression plus cardiac disease) and there is a danger in adjusting complex, yet stable, drug regimens. Some interviewees from the beneficiary community also expressed concern that they do not have a relationship with the beneficiary representative on the P&T Committee. They stated that there was no public announcement about this appointment, and that there currently is no interaction between the appointee and the beneficiary community.

Finally, there was concern about the population that will be most affected by the Medicaid prescription drug program changes. The four-brand limit and PDL are implemented in the Medicaid fee-for-service program; a capitated Medicaid managed care organization must seek approval from the Medicaid Managed Care Bureau before applying fee-for service regulations to their Medicaid clients. The Medicaid fee-for-service population includes many elderly and disabled beneficiaries who utilize a higher number of prescription drugs than either those beneficiaries enrolled in capitated Medicaid managed care plans or patients in the private sector.

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<sup>17</sup> For example, drugs to treat diabetes for a patient with a mental health condition, or to treat a viral infection for a person with HIV/ AIDS, are still subject to the PDL.

### *Physicians*

A 2001 study conducted by the University of Florida provides some insight into physicians' perceptions about how prior authorization programs affect beneficiaries. The study sought to examine the changes in process and outcomes (e.g., therapeutic interchanges, patient impacts, physician attitudes) caused by the state's four-brand limit. The study authors interviewed over 300 providers about how the new four-brand limit had impacted their prescribing ability. We received limited information about this unpublished study; however the study's findings that were relayed to us by one of the authors include the following:

- 60% of physicians reported that people did not get all of the drugs that the physician felt they needed;
- 84% of physicians had to change drug therapy due to the four-brand limit; half of those said that this change in therapy had a detrimental effect;
- 46% of physicians reported having one or more patients with a measurable change in health due to the four-brand limit.

Although AHCA funded the work, interviewees from the Agency familiar with the study raised questions about its validity. Agency officials mentioned that the next step in the study is for the University of Florida to examine individual patient charts to substantiate any potential negative outcomes resulting from the four-brand limit.

Physician interviewees presented different perceptions about prior authorization requirements, stating that these requirements would not cause physicians to alter their prescribing practices in a way that directly harmed beneficiaries. Their concerns related more to the confusion the prior authorization process may create for beneficiaries. They explained that when a patient's prescription is denied at a pharmacy, there is no guarantee as to when or if the patient or pharmacist will notify the physician that prior authorization is required. If the physician *is* notified and prior authorization is granted, the pharmacist may not notify the patient that the prescription has been approved and filled. In either scenario, the provider is responsible for ensuring that patients do not, as one physician said, "fall through the cracks," creating a significant administrative burden for many physician practices.

Each of the physician interviewees had experience interacting with the Medicaid program outside of the clinical practice setting, through current or past participation on a drug utilization review board, P&T Committee or other affiliation. As a result, these individuals are more likely to push the system to accommodate chronic disease patients requiring multiple, repeated prior authorizations (e.g. to obtain a single, extended prior authorization) and reduce their own administrative burden. A few physician interviewees are concerned, however, for other practitioners and the patients they treat who lack this experience and knowledge of how to work within the system.

While one physician interviewee mentioned hearing complaints about the burden of the prior authorization process, representatives from AHCA and the Florida Medical Association (FMA) both commented on the lack of physician complaints logged thus far.

FMA admitted, however, that its members did not traditionally have a large Medicaid patient base.

### *Pharmaceutical Manufacturers*

Generally aligned with the beneficiary community, the pharmaceutical industry held fast to the position that patients' access to medications should not be limited in any way. Industry interviewees maintained that the four-brand limit in 2000 was a "concession," and that the new PDL became an inevitable development in 2001 due to the growing deficit and strong momentum carried over from previous years. PhRMA will continue to work to develop its case against such restrictions, for instance by tracking anecdotal evidence about harmful patient experiences. It also may push for evaluative studies; according to interviewees, the pharmaceutical industry played a strong role in advocating for the study of the four-brand limit's impact on physicians' prescribing. Industry interviewees stated that they were in the process of developing strategies to evaluate or otherwise work to repeal the state's new PDL going forward.

### *Pharmacists*

Pharmacists were not opposed to Florida's new initiatives to reduce Medicaid pharmaceutical expenditures. Although the prior authorization process does create an additional administrative burden for pharmacists with no corresponding compensation, interviewees stated that these solutions are necessary to help reduce waste in the Medicaid program. Because of the prior authorization provisions and specific exemptions, they expressed little concern that these changes will result in harm to beneficiaries.

Some interviewees shed light on another reason why pharmacists are not vocal opponents of Medicaid preferred drug lists and other utilization restrictions. When states look to reduce Medicaid spending, the National Association of Chain Drug Stores (NACDS) contended, they often seek to reduce the dispensing fee and ingredient reimbursement paid to pharmacists. Given Florida's \$4.23 dispensing fee and already low ingredient cost (AWP-13.25% in February, 2001) reimbursement rates as compared to other state Medicaid programs,<sup>18</sup> the association generally favored a preferred drug list versus other initiatives that could reduce margins of their members.

### *Agency for Health Care Administration*

As articulated throughout this case study, the Agency's impetus for pursuing the PDL and other cost-focused initiatives was a Medicaid budget deficit due, in large part, to the Medicaid pharmacy program. Staff, however, emphasized that quality improvements can result from the PDL and four-brand limit alongside these initiatives' anticipated cost savings. AHCA stressed that a pharmacist at Affiliated Computer Services, Inc. (ACS, formerly Consultec), the organization contracted by Florida to handle prior authorization requests, reviews a beneficiary's complete drug regimen if prior authorization is requested for a drug not on the PDL or for a fifth (or higher) brand-name drug. Although approximately 80% of these prior authorization requests for drugs over the four-brand

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<sup>18</sup> "An update on Medicaid reimbursement by state," Drug Topics, February 25, 2001.

limit are approved, the majority of those denied are typically due to a pharmacist's evaluation of a potential negative interaction or therapeutically equivalent interchange.

The Agency maintained that patients would not be harmed by the new initiatives, and that the controls resemble limitations imposed on private sector consumers. To support this contention, Agency representatives cited the lack of complaints logged by physicians and beneficiary advocates to date, as well as studies showing that aggregate hospitalizations, emergency room visits and physician office visits have not escalated since the implementation of the four-brand limit. These studies are discussed in more detail in the following section.

### *Legislature*

Responding primarily to budget constraints, interviewees from the Florida legislature were most concerned about cost when they passed recent Medicaid pharmacy initiatives. Most legislative interviewees were confident, however, that the prior authorization process and HIV/AIDS and mental health exemptions provide adequate safeguards against harm to beneficiaries caused by these new programs.

Other perspectives offered by various interviewees include the following:

**Most supporters of the PDL as a cost-savings tool believed that it will not have a negative impact on beneficiaries' health and indicated that the state is just mimicking what is common practice in the private sector.**

"If it wasn't a good idea, the Blues wouldn't have been doing it for the past twenty years," stated a representative from the Agency in support of the new PDL. Other interviewees who favored the recent change repeatedly echoed this perception. Despite the Agency's contention that it performed an extensive literature review to understand the impact of formularies on patients, and the general perception that formularies in the private sector are innocuous, it is important to note that there is no peer-reviewed, conclusive evidence that confirms these points.<sup>19</sup>

Many interviewees also commented that the final PDL looks less restrictive than some commercial formularies in place today. Our analysis of the PDL published after the October 25, 2001 meeting, included in Appendix G, shows that Florida's PDL is comparable to private sector formularies. Of the 100 most frequently prescribed brand-name drugs nationally in 2000, the Florida PDL covers 83 of them. This compares to BCBS of Florida's three-tier formulary, which covers 84 of the top 100 branded drugs, and the Aetna closed formulary (with prior authorization), which covers 78. Our primary review indicated that none of the popular thyroid replacement agents (Synthroid,

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<sup>19</sup> For example, the National Pharmaceutical Council's (NPC) 1999 literature review, *Component Management Fails to Save Health Care System Costs: The Case of Restrictive Formularies*, reviews 20 research studies on the association between restrictions on pharmaceuticals and overall treatment costs and quality of care. Thirteen of these studies show an increase in overall costs due to increased utilization of other healthcare services, three show a decrease in overall costs, and four show mixed results. In addition, a 1997 article in "Clinical Pharmacology & Therapeutics" states that in general, formulary systems are "poorly researched and controversial," citing five of the studies reviewed by the NPC (the NPC did review four studies published after the Clinical Pharmacology & Therapeutics report).

Levoxyl, or Levothyroid) are on the list and none of the available generic equivalents for these products is “A” rated (all are rated BX in the Orange Book, meaning that there is inadequate clinical data to establish the highest level of brand-generic equivalency), thus causing potential dosage changes. Also, Humulin insulins are not on the list, which will force the majority of diabetics to change to Novolin insulins. Dosage adjustments probably will not be needed, however the change may prove disruptive to patients who have been using Humulin for years.

The private sector’s process for developing a formulary is very similar to the process used by Florida Medicaid. Private health plans create P&T Committees consisting of practicing physicians and pharmacists who meet on a regular basis to consider changes to the health plan formulary. Typically, a pharmacist will prepare a report on the new drugs to be considered that takes into account the available clinical information as well as relative costs for all the drugs in the class being considered. The committee meets and discusses this information and votes to add, delete, or restrict drugs. Generally, most “A” or “AB” rated generics are included in the formulary. Branded drugs are added if they represent either a significant clinical benefit or if a drug has relative cost-effectiveness as compared to the alternatives.

Several interviewees went on to add that in addition to being less restrictive, the PDL is more generous than some formularies in the private sector given that: a) there are no caps on the number of drugs a beneficiary can receive or on beneficiary drug expenses; b) mental health and HIV/AIDS drugs are exempt; and c) all medications by law are available through the prior authorization process.

Referencing categories in which the PDL does restrict access, one physician interviewee stated that the therapeutic exchanges required by the new PDL thus far (as of November, 2001) were “no big deal.” For example, exchanges between allergy relievers (Claritin for Allegra) are straightforward substitutions where the replacements are equally effective, safe, and with a dosing frequency the same as the displaced agent. Other specialists, however, such as endocrinologists confronting interchanges in the thyroid replacement agent and insulin categories described above, may not share this opinion.

Some challenged the comparison between private sector formularies and a Medicaid preferred drug list due to the demographic differences between the groups to which they apply. The Medicaid population is “economically disadvantaged” and has “more complex health and social needs than do higher-income Americans.”<sup>20</sup> This situation is amplified in fee-for-service Medicaid because it covers a greater proportion of the sickest and poorest beneficiaries – the elderly and disabled. Strategies to control costs or utilization that may be appropriate in the private sector can negatively affect access to care for this vulnerable population.

**Some interviewees expressed concern that cost is the primary factor dictating the PDL, and that beneficiary interests are secondary.**

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<sup>20</sup> Kaiser Commission on Medicaid and the Uninsured. “Medicaid and Managed Care,” December 2001.

This perception about the process the P&T Committee is following to develop the PDL was offered by a handful of interviewees across many constituent groups. To support this claim, individuals most often pointed to the cost-focused statutory requirement mandating that manufacturers provide an additional supplemental rebate to even be considered for the PDL.

To further test this perception, we obtained the transcripts from the first three meetings of the new P&T Committee. Committee members are not given the actual drug prices offered to the state by manufacturers, though Committee members may vote to close the meeting to the public and review this information should it become important to the discussion. Instead, members receive symbolic representations (\$, \$\$, \$\$\$, etc.) of a drug's relative cost. At the first meeting of the committee, it was evident that the members themselves were not sure how to interpret these symbols, nor were they clear as to the role cost should play in their decisions.

Further analysis of these transcripts reveals that cost *and* quality and access have played a significant role in the Committee's and the Agency's placement of drugs on the PDL. The following scenarios from the second P&T Committee meeting held on September 26 highlight two such incidents:

*Scenario One (Cost Issue):* Provider Synergies recommended that the antiviral drug Cytovene (ganciclovir) not be included on the PDL. When asked why, the company stated that the product did not meet the minimum rebate required. A member of the committee stated: “[B]ut you do realize that it probably will be used since I know patients, Medicaid patients are HIV patients. It is going to be used, though,” to which Provider Synergies replied: “That is correct. It is available through the prior auth process.”<sup>21</sup>

*Scenario Two (Quality/Cost Issue):* The product Tamiflu (oseltamivir) also did not meet the minimum rebate requirements. One committee member, however, questioned its exclusion from the list, stating that he “would hate to be somebody out there waiting for a prior auth on Tamiflu” and proceeded to recommend that it be added to the list. His motion, which was approved by the Committee, stipulated that Tamiflu be added to the list “assuming that AHCA is successfully negotiating an appropriate price.”<sup>22</sup>

**Interviewees also expressed concern that beneficiaries do not have knowledge of the new initiatives, and are therefore unaware of their right to appeal.**

The Agency does not have plans to communicate directly with all beneficiaries about the new PDL. One Agency representative did state that by the P&T Committee's recommendation, AHCA sent notices by mail to affected Medicaid recipients and their providers about the exclusion of Humulin insulins, and inclusion of Novolin insulins, on

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<sup>21</sup> “Meeting of the Pharmaceutical and Therapeutics Committee,” September 26, 2001, as reported by Peggy Huffman, p 61.

<sup>22</sup> Ibid, p 62.

the new PDL. The Agency expects to handle other “major” restrictions similarly. Given the challenge to “track down” Medicaid beneficiaries and the expense and perceived ineffectiveness of direct mailings, the Agency will rely on physicians and pharmacists to communicate with beneficiaries about the newest initiative. Agency representatives believed that existing programs, such as the chart review process that occurs when prior authorization is required, and academic intervention programs, will alert providers to those patients who may require detailed program information.

Some patient advocates have attempted to fill this void. Florida Legal Services (FLS) has made efforts to ensure that beneficiaries are given notice of the reason their prescription was not filled at the point at which this occurs, and that they are aware of the 72-hour supply of the medication in emergency situations to which they are entitled and their right to appeal such denials. FLS sent a letter to AHCA in June 2001 to persuade them to provide beneficiaries with this information, but still awaited a response as of November 29, 2001. The organization also filed a public records request, again with no response, along with criticisms that some pharmacies were not providing beneficiaries with their emergency supply, that mental health medications were being counted against the four-brand limit, and that the prescribed drug limits were being incorrectly applied to Medicaid HMO enrollees.<sup>23</sup> Independently, FLS produced a brochure with some pharmaceutical industry funding to explain beneficiary rights. While the goal is for pharmacists to distribute this brochure to the patient when a drug is denied, some pharmacists have been reluctant to provide this information to patients, expressing concerns about the administrative hassle of providing this information to consumers and the remote possibility of being included in lawsuits.

**The details of the disease management initiatives led by Pfizer and BMS have not been made available to the public.**

Manufacturers were given the opportunity to propose other program benefits, including disease management programs, in lieu of a supplemental rebate. To date, Pfizer and BMS have entered into ‘portfolio deals’ with the Agency. A collection of their products is included on the PDL in return for guaranteed savings from proposed disease management programs. The primary focus of Pfizer’s program will be to assign case managers to patients with congestive heart failure, diabetes, asthma, and hypertension at hospitals. The BMS initiative is expected to include both an early intervention program for cancer and HIV/AIDS, and a peer-education campaign concentrating on diabetes in Florida’s Hispanic community.

While manufacturer representatives explained that the disease management programs are “all about quality” and health improvement, specific clinical expectations for these initiatives are unclear to the public. Some beneficiary groups expressed concern that AHCA’s process to approve and establish these programs focused predominantly on savings targets versus clinical outcomes. The Agency and Pfizer, however, claimed that they currently are working to identify clinical endpoints, and hope that these will be

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<sup>23</sup>Medicaid HMOs must seek approval from the Medicaid Managed Care Bureau to use the fee-for-service prescribed drug restrictions. According to an interviewee from Florida Legal Services, no plan had received approval as of October 2001.

established by the time the programs are fully operational. One AHCA interviewee also conceded that “this is new for everyone,” implying that these are new programs and that the manufacturers do not have extensive experience with the Medicaid population.

Some interviewees also expressed concern that AHCA lacks a vision to guide its Medicaid disease management initiatives. There are questions about how these new manufacturer-led programs will overlap with AHCA’s existing disease management programs, which have undergone change and some disruption over the years. One Agency representative explained that beneficiaries already enrolled in a disease management organization’s program would not be eligible to participate in the new programs. It is unclear what will happen to patients in the existing programs if Pfizer’s or BMS’ programs prove more beneficial. One interviewee also raised the potential conflict of interest the Agency may confront: if a competitor’s product is proven to be more effective than that of the manufacturer running the disease management program, will patients receive the most effective product if it drives market share away from the disease management sponsor’s product?

## **PLANS TO EVALUATE NEW INITIATIVES**

In attempting to address the main focus of this case study – the impact of Florida’s new cost-driven initiatives on beneficiaries’ health – the study team sought to learn how the state and other groups plan to evaluate the new programs. It is important to keep a couple of considerations in mind when reviewing the following impressions offered by interviewees on this topic. First, our own literature review did prove that in general, it is difficult to measure the specific clinical impact of formularies and other limitations on beneficiary health. There are a few studies that have attempted to explore such issues in the private sector, but these have yielded conflicting results. Second, the methodology required to conduct an evaluation of the impact of a formulary on beneficiary health is complex and time consuming, and relies upon the availability of clinical data that is often very difficult to obtain. Finally, it is difficult to isolate any one programs’ impact on beneficiary health.

**Florida has some mechanisms in place to evaluate and monitor the state’s Medicaid drug program – OPPAGA, internal Agency offices, and a contract with the University of Florida. Some question the conclusiveness of the Agency’s internal evaluative efforts.**

In 1994, Florida Statutes directed OPPAGA to complete a program evaluation and justification review for every state agency that is operating under a performance-based program budget. In February 2001, OPPAGA released its justification review of Medicaid prescription drug costs, recommending that the state adopt a mandatory preferred drug list to help curtail escalating expenses. Furthermore, OPPAGA is required to perform an 18-month follow-up evaluation to review if, and how, the Office’s recommendations were implemented. Representatives interviewed from OPPAGA noted that they would include the status of the implementation of the PDL in their follow-up

report, but that they likely would lack the resources necessary to perform a clinical evaluation of the PDL's impact on beneficiary health.

In 2000, the legislature passed S2034, which contained the following mandate: “[AHCA] shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 15 of each year. The report must include, but need not be limited to, the progress made in implementing Medicaid cost-containment measures and their effect on Medicaid prescribed-drug expenditures.” In January 2001, AHCA released the first such annual report on the Medicaid Prescribed Drug Spending Control Program, which included the implementation status of various initiatives and provided data on aggregate Medicaid drug spending. In addition, the Agency has begun producing quarterly reports, the latest of which was produced in September 2001 and included graphic depictions of the rates of ER visits, hospitalizations and office visits for Medicaid recipients between January and November of 2000. Most AHCA interviewees cited these reports, specifically the level trend in hospitalizations and ER and physician office visits, in support of both the Agency's efforts to evaluate the impact of the new programs as well as its satisfaction that beneficiaries are not being harmed.

Many interviewees, including one within AHCA, however, questioned the conclusiveness of these reports. One Agency representative called the reports “basic” and noted that there is no mandate, nor specific funding, for a more detailed analysis of the Agency's programs. Outside of the Agency, there also is a reluctance to assert that these reports serve as final evidence that programs are achieving cost savings without harming beneficiaries. One academic pharmacist familiar with the reports noted that they present a “snapshot from the universe.” The interviewee stated that a true evaluation should analyze the hospital, ER, and physician visit trends among those beneficiary groups directly affected by the new policies (for example, the disabled, elderly, those rejected due to the four-brand limit, patients with chronic illnesses). Using all beneficiaries as the denominator dilutes the analysis, making it difficult to see any differences in smaller subgroups.

In addition, this interviewee pointed to “time lags” in the brand limit's implementation, implying that the full impact of the brand limit to Medicaid beneficiaries is not likely to be visible over the time interval depicted in the graph, January to November of 2000. The brand limit was implemented in South Florida on August 1, 2000 and across the rest of the state on September 1, 2000. Given that patients would have an existing supply of medicines, changes in therapy would be implemented gradually over a month's time or longer. Assuming that not all patients suffered immediate ill effects, there is a time lag that could be expected before effects are observed. There is also lag time between a patient's office visit and/or hospital discharge before physicians and hospitals submit their claims.

Finally, AHCA has established a relationship with the University of Florida's Florida Center for Medicaid Issues to study various aspects of the Medicaid program. Four state-funded studies currently are underway, including one focused on the four-brand limit.

The Agency is monitoring this study with some concern about the University's survey instrument.

**The state has not announced plans to evaluate the specific impact of the PDL on the quality of care delivered to Medicaid beneficiaries.**

AHCA's Medicaid Director, however, did explain that the state plans to commission the University of Florida to conduct such a study. Other AHCA representatives noted that the state also will continue to monitor the prior authorization process and track aggregate hospitalizations, and ER and physician office visits to flag potential problems.

**The Agency's contracts with Pfizer and BMS require an outside evaluation of cost-savings; however, the Agency has no formal plans as of yet to evaluate the overall impact of the programs on beneficiary care and outcomes.**

While the Agency does plan to have Pfizer and BMS collect and submit some data about program participants' experiences in the respective programs, it is unclear at this point exactly what type of data will be tracked. Agency representatives explained that they are working on a daily basis with Pfizer representatives to define the clinical improvements that must be achieved for the manufacturer to claim savings success. We also learned that Pfizer will provide funds to evaluate the impact of the company's health literacy project. In addition to its case management program, Pfizer will develop materials to improve the health literacy of patients at nine Federally Qualified Health Centers throughout the state. The University of South Florida will conduct a two-year study of the impact of these materials using a three-center control group.

**Patient advocates and manufacturer representatives have no clear agenda to lead an evaluation, and cite access to data and funds as their primary obstacles in conducting such a study.**

Neither beneficiary groups nor manufacturers currently have plans to conduct or sponsor clinical evaluations of the PDL and manufacturer disease management programs. These groups mentioned being dissuaded by issues of funding or access to necessary clinical data. Additionally, manufacturer representatives cited concern that a pharmaceutical industry-sponsored study would be discounted in the marketplace.

Beneficiary representatives did note separately, however, that they plan to track anecdotal evidence that indicate how the four-brand limit and the PDL impact beneficiaries' health. For example, although there is no clinical evidence to support the claim, the Orlando Sentinel reported in July 2001 that there has been a death associated with Florida's four-brand limit. A close associate of the dead beneficiary's stated that the beneficiary, who took seven brand-name medications per month, often skipped doses as he waited for Medicaid to approve his physicians' prior authorization request.<sup>24</sup> Interviewees stated that they will attempt to seek out similar stories over time.

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<sup>24</sup> Groeller, G. "New Medicaid Drug Policy Stirs Up Fears," Orlando Sentinel, July 1, 2001.

## **IMPLICATIONS FOR OTHER STATES AND MEDICAID BENEFICIARIES**

As states confront slowing economies in conjunction with rapidly rising Medicaid pharmaceutical costs, many are paying close attention to Florida's new Medicaid PDL. Michigan, Illinois, Oregon, Louisiana, and Georgia already have established or are moving toward establishing Medicaid preferred drug lists, and AHCA interviewees mentioned receiving inquiries from a handful of other states, including Washington, Texas, Indiana, Maine, New York, and Connecticut. As more states begin to address similar economic challenges, we expect the number interested in Florida's recent initiatives to grow.

The design and execution of Florida's PDL raised concern among many beneficiary advocates. While cost considerations ultimately are crucial to maintaining the integrity of the Medicaid program, at the time of this report Florida had not announced specific plans to evaluate the impact of its new programs on beneficiaries' health. Also, input from beneficiaries was noticeably absent from the legislative process. It is important that other states consider these beneficiary issues when they design their own programs.

States' Medicaid programs, however, vary significantly across the country, from cost allocations to dispensing fees and eligibility requirements. States also differ with respect to their political environments, processes for implementing Medicaid program changes, and strength of beneficiary and other advocacy groups. Because of this variation, other states looking to follow Florida's lead will likely confront their own unique experiences and face challenges that differ completely from Florida's.

### **Florida's previous experience and committed leadership facilitated the implementation of a preferred drug list in 2001.**

While there were numerous forces that influenced the legislature's passage of a preferred drug list in 2001, the importance of the state's several year history of pursuing initiatives focused on cost-savings cannot be overstated. Florida attempted to reduce Medicaid costs by implementing disease management programs, creating a Medicaid Formulary Review Panel, and establishing a four-brand limit. While many lobbyists had succeeded in staving off a preferred drug list during previous years, they concluded it had become the "inevitable" next step in 2001.

Florida leadership was also committed to working with the Medicaid agency and legislature to promote politically controversial measures such as a preferred drug list. The governor's strong support of a preferred drug list over the years, many interviewees indicated, played a crucial role in the act's final passage. In addition, many interviewees pointed to key figures within the Agency, such as the Medicaid Director, as personnel dedicated to the onerous task of creating and implementing a preferred drug list.

While increased budget pressures on states may expedite the passage of initiatives expected to achieve cost savings, states that lack experience comparable to Florida may

be challenged to design and implement a preferred drug list in one or two years. However, if Florida is successful with this initiative (i.e., the PDL withstands additional legal challenges and succeeds in attaining significant cost savings without harming beneficiaries), it may ease the burden of the political process in other states.

**Interest group lobbies may be fracturing as individual interests seek to protect their own highest priorities.**

Florida is not alone in facing a major Medicaid budget deficit: in November 2001, eight states called special legislative sessions to deal with Medicaid budget issues,<sup>25</sup> and according to the National Conference of State Legislatures, 28 states are considering new cuts to their budgets that are likely to target Medicaid. In addition, a declining national economy and rising unemployment rate could increase Medicaid ranks. When evaluating potential cost-saving initiatives in the Medicaid program, some beneficiary advocates have conceded that a preferred drug list may become the “lesser of evils” when compared to reductions in Medicaid eligibility or the elimination of optional program benefits and other cost saving alternatives.

**Political interests appear to be shifting in response to this new environment.**

Traditionally, beneficiary advocates and the pharmaceutical industry have presented a strong, unified lobbying force against preferred drug lists and other initiatives that restrict beneficiary access to medications. In Florida, however, possibly foreshadowing activity in other states, HIV/AIDS and mental health groups felt forced to pursue their own exemption-focused agendas, which were separate from the broader beneficiary community. Similarly, by the end of the session, the pharmaceutical bloc broke ranks as companies began to promote their individual interests.

**The absence of a strong beneficiary voice in the legislative and executive branch processes to pass and implement new pharmaceutical programs poses the risk that the concerns of the most vulnerable populations will not be heard, and that systems to protect these populations will not be developed.**

In Florida, the state implemented the new PDL with relatively little communication with the beneficiary community. With the exception of mental health and HIV/AIDS advocates, beneficiary groups carried minimal weight in the legislative process. Similarly, while a single beneficiary representative participates in the P&T Committee, no one in the beneficiary community to whom we spoke knew who this person was. It also is unclear if and when the Agency will establish a more dynamic relationship with beneficiaries to incorporate their feedback while changes are being made.

The absence of a strong communication channel presents a greater chance that the state will fail to gain an understanding of the experiences of the most vulnerable beneficiaries who tend to populate the state’s Medicaid fee-for-service program— individuals with chronic diseases taking multiple medications. Although individuals can call or write their local Medicaid offices or the Agency to communicate problems, this method of tracking alone will not necessarily reflect the true experiences of the majority of beneficiaries.

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<sup>25</sup> Ornstein, C. and Bernstein, S. “The Nation Spiraling Medicaid Costs Putting States in a Bind,” Los Angeles Times, November 24, 2001.

Moreover, the system relies on physicians and pharmacists to be patient advocates. When a patient needs a fifth or higher brand-name prescription drug or a medication not included on the PDL, he or she must rely on either (a) the pharmacist to notify the physician about the prior authorization requirement or (b) the physician to initiate the prior authorization request from the onset. Patients also rely on physicians to present clinical evidence to the state of a patient's need to have prior authorizations extended for a twelve-month period. As many physician interviewees warned, it is conceivable that such prior authorization requests could fall through the cracks in a busy medical practice.

Studies that seek ongoing feedback from beneficiaries and providers, as noted below, could help to strengthen the beneficiary voice and help to ameliorate this situation. The state also needs to consider systems that will protect patients whose access to medications may be restricted due to the possible unintended effects of these programs.

**While the challenge of designing and executing a comprehensive clinical evaluation of a preferred drug list's impact on beneficiary health is not disputed, smaller steps could be taken to gain needed insight into how beneficiaries are affected by the state's new policies.**

Clinical evaluations that attempt to measure the impact of formularies on patients' health are both difficult and expensive to conduct; previous studies that have attempted to address this issue in the private sector have yielded inconclusive results. Florida's numerous prescription drug initiatives make it even more complicated to parse out changes in beneficiaries' health caused by the PDL versus the four-brand limit or other program changes.

In the absence of a comprehensive effort to evaluate the clinical impact of the prescription drug initiatives, AHCA still has access to meaningful, clinical data that could promote an understanding of the initiatives' impacts on beneficiaries' health. An analysis of prior authorization requests, which are tracked by ACS, and appeals claims to the Agency, could provide an understanding of the populations and/or disease states most affected by the policies. Hospitalizations, lengths of stay, ER visits, and office visits for those patients who have made prior authorization requests or appeals, or whose drug regimens have been altered in the process, could also be tracked, which would be more effective than the current aggregate tracking process. The Agency could also perform in-depth investigations of any deaths that occurred within a year of a patient's request or appeal to determine if access to medications was a contributing factor in any way.

The Agency also could conduct smaller-scale evaluations to help gather qualitative evidence about initiatives' success. For example, AHCA could survey physicians and pharmacists' satisfaction with the new PDL or four-brand limit, and ask providers for specific case information to document problems. The Agency could also solicit feedback on a continuing basis from beneficiaries through both surveys and face-to-face meetings. Finally, the state could integrate and involve pre-existing quality assurance committees to evaluate patients' and physicians' experiences with the new programs. Such committees include the Drug Utilization Review (DUR) Board, currently mandated by OBRA '90 to review and approve drug use criteria and standards for both prospective and retrospective

drug use reviews, and the Prescribing Pattern Review Panel, which studies the prescribing profiles of Medicaid practitioners and communicates suggestions for cost-effective, efficacious alternatives to providers.

## **Appendix A: Statutory Requirements for Medicaid Formularies and Prior Authorization Programs**

Social Security Act, Title XIX, Section 1927  
Payment for Covered Outpatient Drugs

(d) Limitations on Coverage of Drugs

(4) Requirements for Formularies—A State may establish a formulary if the formulary meets the following requirements:

- (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).
- (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).
- (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.
- (D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).
- (E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of Prior Authorization Programs. — A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system provided for such approval—

- (a) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
- (b) except with respect to drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other Permissible Restrictions. — A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

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## **Appendix C: Interview List**

6 representatives from the Agency for Health Care Administration

1 representative from Provider Synergies

4 representatives from the Office of Program Policy Analysis and Government Accountability

1 member of the Florida State Senate

2 staff members of the Florida Senate Appropriations Committee

6 beneficiary representatives (Mental Health Association of Central Florida, Florida Legal Services, Moore Consulting, National Alliance for the Mentally Ill- Florida Chapter, AARP, and an independent lobbyist)

3 Medicaid Providers

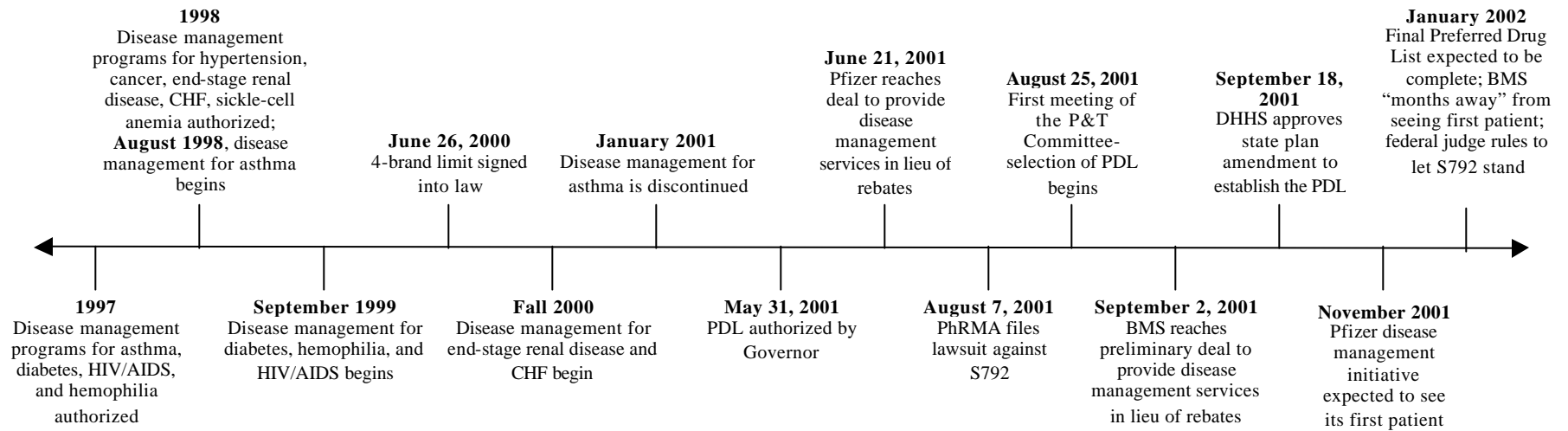
2 staff members of the Florida Medical Association

2 pharmacy representatives (National Association of Chain Drug Stores staff member and a practicing pharmacist in Florida)

3 PhRMA representatives

1 Pfizer representative

## Appendix D: A Timeline of Select Initiatives in Florida's Medicaid Pharmacy Program



## **Appendix E: Select Pharmaceutical Programs in Florida<sup>26</sup>**

### **2001 Session (SB 792 Initiatives)**

- Preferred Drug List (PDL)
- State Supplemental Rebate (Cash or Value-Added Programs)
- Nursing Home Four-Brand Limit
- Drug Therapy Management for HIV/AIDS Patients
- Drug Therapy Management for Patients with 20 or More Unique Prescriptions within 180 Days
- Secure Prescription Blanks
- Long Term Care Formulary Study Panel

### **2000 Session (SB 2034 Initiatives)**

- Four Brand Drug Monthly Limit
- 34 Day Supply Limit
- Ingredient Cost Reimbursement Reduction
- Generic Drug Rebates
- Drug Plan Management Program
- Drug Therapy Limits
- FDA Drug Use Guidelines
- Fraud and Abuse Initiatives (direct mail, on-site, and in-depth pharmacy audits)

### **1999 Session**

- Prescribing Pattern Review Panel and Drug Utilization Review Board

### **Other Program Policies**

Dispensing Fee: \$4.23

Ingredient Reimbursement: AWP-13.25%

Maximum Allowable Cost (MAC): Federal Upper Limits and State Specific Limits on generic drugs.

Patient Cost Sharing: No copayment

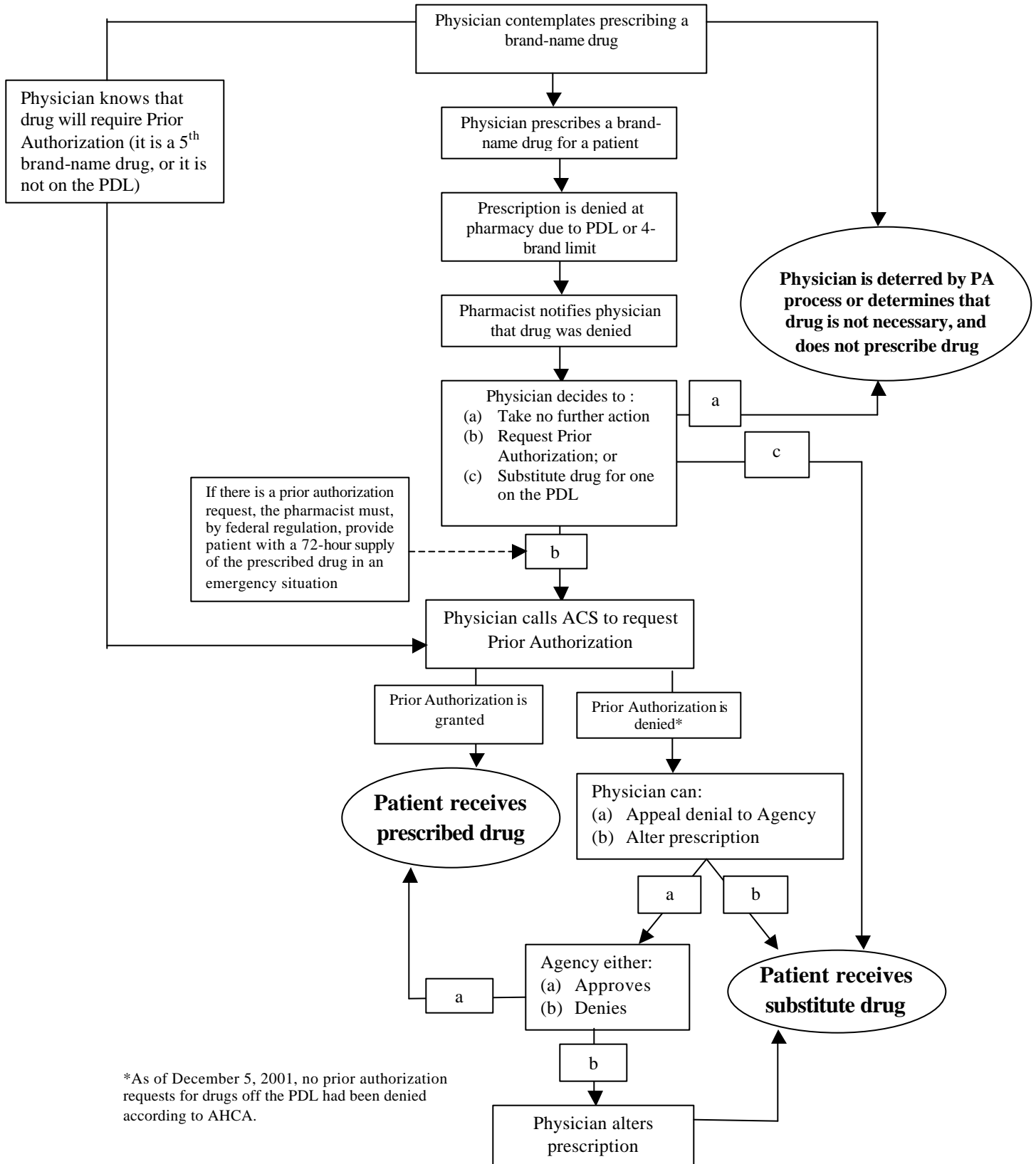
Cognitive Services: Does not pay for cognitive services

Mandatory Generic Substitution: Yes

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<sup>26</sup> Information from AHCA's Quarterly Report, "Medicaid Prescribed Drug Spending Control Program Initiatives for Quarter Ended 9/30/2001" and National Pharmaceutical Council's "Pharmaceutical Benefits Under State Medical Assistance Programs, 2000."

## Appendix F: Navigating Florida's Prior Authorization Process



\*As of December 5, 2001, no prior authorization requests for drugs off the PDL had been denied according to AHCA.

## Appendix G: Florida's PDL Compared to Private Sector and VA Formularies As of October 25, 2001

Generic Name	Brand Name	Top 100 Rank	Florida PDL	BCBS Florida Two Tier*	BCBS Florida Three Tier*	VA National*	Aetna Closed*
<b>1. High Cholesterol Treatments</b>							
atorvastatin	Lipitor	1	Yes	Yes	Yes	No	No
simvastatin	Zocor	17	Yes	Yes	Yes	Yes	Yes
pravastatin	Pravachol	29	Yes	No	No	No	No
fluvastatin	Lescol	84	Yes	Yes	Yes	No	Yes
	Bavcol	98	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn
<b>2. Estrogen Replacement Therapy</b>							
conjugated estrogens	Premarin	2	Yes	Yes	Yes	Yes	Yes
c. est/medroxy	Prempro	16	Yes	Yes	Yes	No	Yes
<b>3. Thyroid Replacement Therapy</b>							
levothyroxine	Synthroid	3	No	Yes	Yes	No	Yes
levothyroxine	Levoxyl	21	No	Yes	Yes	No	Yes
levothyroxine	Levothyroid	89	No	Yes	Yes	No	No
*Generics not bioequivalent (BX)							
<b>4. GI Reflux and Ulcer Therapy</b>							
omeprazole	Prilosec*	4	No	Yes	Yes	No	No
lansoprazole	Prevacid	13	Yes	No	No	Yes	Yes
famotidine	Pepcid*	63	Generic	Generic	Generic	Generic	No
*Pepcid rapid dissolving on 2 tier							
<b>5. Cardiac Drugs: Hypertension, Angina, CHF</b>							
amlodipine	Norvasc	5	Yes	Yes	Yes	Yes	Yes
lisinopril	Zestril*	14	No	No	No	Yes	No
digoxin	Lanoxin	20	Generic	Yes	Yes	Yes	Yes
quinapril	Accupril	28	Yes	Yes	Yes	No	Yes
metoprolol	Toprol XL	31	Yes	Yes	No	Yes	No
lisinopril	Prinivil*	35	Yes	Yes	Yes	Yes	Yes
enalapril	Vasotec	38	Generic	Generic	Generic	Generic	Yes
benazepril	Lotensin	44	No	Yes	Yes	No	No
losartan	Cozaar	55	Yes	Yes	Yes	No	Yes
fosinopril	Monopril	61	Yes	Yes	Yes	Yes	No
bisoprolol/HCTZ	Ziac	69	Yes	Yes	No	No	Yes
nifedipine	Adalat CC	70	Generic	Generic	Generic	Generic	Yes
valsartan	Diovan	72	No	Yes	Yes	No	Yes
amlodipine/benazepril	Lotrel	75	Yes	Yes	Yes	No	Yes
nifedipine	Procardia XL	80	Generic	Generic	Generic	Generic	Yes
losartan/HCTZ	Hyzaar	85	Yes	Yes	Yes	No	Yes
lisinopril/HCTZ	Zestoretic	88	No	No	No	No	No
eiltiazem ER	Cardizem CD	100	Generic	Yes	Yes	Generic	Yes
*Zestril is same drug as Prinivil							
<b>6. Diabetes</b>							
metformin	Glucophage	6	Yes	Yes	Yes	Yes	Yes
glipizide	Glucotrol XL	33	Yes	Yes	Yes	Yes	Yes
insulin	Humulin N*	52	No	Yes	Yes	Yes	No
glimepiride	Amaryl	78	No	Yes	Yes	No	Yes
rosiglitazone	Avandia	79	No	Yes	Yes	No	Yes
insulin	Humulin 70/30*	83	No	Yes	Yes	Yes	No
*Novolin is on PDL = Humulin							

\* A two-tier formulary generally includes a very broad preferred brand drug list; patients pay a different co-pay for (a) generic drugs, and (b) brand-name drugs on the list.

\* A three-tier formulary includes a more restrictive preferred brand drug list; patients pay a different co-pay for (a) generic drugs, (b) brand-name drugs on the preferred drug list, and (c) all other brand-name drugs.

\* The VA National is a totally closed and highly restrictive formulary.

\* A closed formulary is similar to a two-tier formulary except that it includes a highly restrictive preferred drug list; patients pay a different co-pay for (a) generic drugs, and (b) brand-name drugs on the preferred drug list. Patients pay full price for all other brand-name drugs.

## Appendix G: Continued

	Generic	Brand	Top 100 Rank	Florida PDL	BCBS Florida Two Tier	BCBS Florida Three Tier	VA National	Aetna Closed
<b>7. Allergy</b>								
	loratadine	Claritin	7	Yes	Yes	Yes	No	Yes
	fexofenadine	Allegra	22	No	Yes	Yes	Yes	No
	cetirizine	Zyrtec	26	Yes	Yes	Yes	No	Yes
	fluticasone	Flonase	34	Yes	Yes	Yes	No	Yes
	mometasone	Nasonex	53	Yes	Yes	No	No	Yes
	loratadine/psuedo	Claritin D 12 h	56	Yes	Yes	Yes	No	Yes
	loratadine/psuedo	Claritin D 24 h	57	Yes	Yes	Yes	No	Yes
	fexofenadine/psuedo	Allegra D	65	No	Yes	Yes	No	No
	fluticasone	Flovent	45	Yes	Yes	Yes	No	Yes
<b>8. Depression**/Anxiety</b>								
	sertraline	Zoloft	8	Yes	Yes	Yes	Yes	Yes
	fluoxetine	Prozac*	10	Yes	Yes	Yes	Yes	Yes
	paroxetine	Paxil	11	Yes	Yes	Yes	Yes	Yes
	citalopram	Celexa	36	Yes	Yes	Yes	Yes	No
	bupropion	Wellbutrin SR	41	Yes	Yes	Yes	Yes	Yes
	venlafaxine	Effexor XR	47	Yes	Yes	Yes	Yes	Yes
	nefazodone	Serzone	90	Yes	Yes	Yes	Yes	Yes
	zolpidem	Ambien	25	Yes	Yes	No	No	No
	*Generic available soon							
	**All on by exception							
<b>9. Bacterial Infection</b>								
	azithromycin	Zithromax-Z pak	9	Yes	Yes	Yes	Yes	No
	amoxi/clavul	Augmentin	15	Yes	Yes	No	Yes	Yes
	amoxicillin	Amoxil	23	Generic	Generic	Generic	Generic	Yes
	ciprofloxacin	Cipro	24	Yes	Yes	Yes	Yes	Yes
	levofloxacin	Levaquin	43	Yes	Yes	Yes	Yes	Yes
	clarithromycin	Biaxin	49	No	Yes	Yes	Yes	Yes
	azithromycin	Zithromax-Susp	51	Yes	Yes	Yes	Yes	No
	penicillin V	Veetids	54	Generic	Generic	Generic	Generic	Yes
	cefprozil	Cefzil	68	Yes	Yes	Yes	No	No
	cefuroxime	Ceftin	77	Yes	Yes	Yes	Yes	Yes
	nitrofurantoin	Macrobid	95	Yes	Yes	Yes	Yes	Yes
	mupirocin	Bactroban	99	Yes	Yes	Yes	Yes	Yes
<b>10. Arthritis and Pain</b>								
	celecoxib	Celebrex	12	Yes	Yes	No	No	Yes
	rofecoxib	Vioxx	18	Yes	Yes	No	No	Yes
	tramadol	Ultram	32	Yes	Yes	Yes	No	No
	oxycodone	Oxycontin	73	Yes	Yes	Yes	Generic	Yes
	nabumetone	Relafen**	86	Yes	No	No	No	No
	oxycodone/APAP	Roxicet	93	Yes	Yes	Yes	Generic	Yes
	**Generic available soon							
<b>11. Birth Control</b>								
	EEN3	Ortho Tri-Cyclen	19	Yes	Yes	Yes	No	Yes
	EEN3	Triphasil	66	Yes	Yes	Yes	No	Yes
	EEN3	Ortho Novum 7/7/7	67	Yes	Yes	Yes	No	Yes
	EEL	Alesse 28	82	Yes	Yes	Yes	No	Yes
	EENG	Ortho Cyclen	91	Yes	Yes	Yes	No	Yes
	EEN	Necon 1/35	92	Yes	No	No	Yes	No
<b>12. Blood Thinners</b>								
	warfarin	Coumadin	27	Generic	Yes	Yes	Yes	Yes
	clopidogrel	Plavix	64	Yes	Yes	Yes	Yes	Yes
<b>13. Urological</b>								
	sildenafil	Viaqra	30	Yes	No	No	Yes	Yes
	doxazosin	Cardura	48	Generic	Generic	Generic	No	Yes
	tolterodine	Detrol	94	Yes	No	No	No	Yes
	tamulosin	Flomax*	101	Yes	Yes	Yes	No	Yes

## Appendix G: Continued

	Generic	Brand	Top 100 Rank	Florida PDL	BCBS Florida Two Tier	BCBS Florida Three Tier	VA National	Aetna Closed
<b>14. Neurological</b>								
	gabapentin	Neurontin	37	Yes	Yes	Yes	Yes	Yes
	divalproex	Depakote	50	Yes	Yes	Yes	Yes	Yes
	phenytoin	Dilantin	71	Yes	Yes	Yes	Yes	Yes
	dextroamphetamine	Adderall	59	Yes	Yes	Yes	<b>No</b>	Yes
	sumatriptan	Imitrex	97	<b>No</b>	Yes	Yes	Yes	Yes
<b>15. Asthma/COPD</b>								
	montelukast	Singulair	46	Yes	Yes	Yes	<b>No</b>	Yes
	salmeterol	Serevent	60	Yes	Yes	Yes	Yes	Yes
	lpratripium/albuterol	Combivent	87	Yes	Yes	Yes	Yes	Yes
<b>16. Potassium Supplements</b>								
	potassium chloride	K-Dur 20	39	Yes	Yes	Yes	<b>No</b>	Yes
	potassium chloride	Klor-Con	96	<b>Generic</b>	<b>Generic</b>	<b>Generic</b>	<b>Generic</b>	Yes
<b>17. Osteoporosis</b>								
	alendronate	Fosamax	40	Yes	Yes	Yes	<b>No</b>	Yes
	raloxifene	Evista	74	<b>No</b>	Yes	Yes	<b>No</b>	Yes
<b>18. Fungal Infection</b>								
	fluconazole	Diflucan	42	Yes	Yes	Yes	Yes	Yes
	clotrimazole/betame	Lotrisone	76	Yes	Yes	<b>No</b>	<b>No</b>	Yes
<b>19. Glaucoma</b>								
	lantanoprost	Xalatan	58	Yes	Yes	Yes	Yes	Yes
<b>20. Psychosis**</b>								
	risperidone	Risperdal	62	Yes	Yes	Yes	Yes	Yes
	olanzapine	Zyprexa	81	Yes	Yes	Yes	Yes	Yes
	<b>**ALL ON BY EXCEPTION</b>							
	<b>Total number of exemptions:</b>			17 of 100	8 of 100	16 of 100	45 of 100	22 of 100

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