



The Rhode Island 340B Analysis:

Creating an Opportunity

A project of the Heinz Family Philanthropies

Teresa Heinz, Chairman

Report prepared by:

Jeffrey R. Lewis, President
Heinz Family Philanthropies
jlewis@heinzoffice.org

Technical Assistance Provided by:

AmeriChoice Management Services Organization

March 2005

The Honorable Donald L. Carcieri
The Honorable Joseph A. Montalbano
The Honorable M. Teresa Paiva-Weed
The Honorable Dennis L. Algieri
The Honorable William J. Murphy
The Honorable Gordon D. Fox
The Honorable Robert A. Watson
State House
Providence, Rhode Island 02903

Dear Governor Carcieri, Senate President Montalbano, Speaker Murphy, Senator Paiva-Weed, Senator Algieri, Representative Fox, and Representative Watson:

It is my pleasure and privilege to submit the accompanying report, *The Rhode Island 340B Analysis: Creating an Opportunity*, which the Heinz Family Philanthropies have prepared at the request of the Governor and the Rhode Island State Legislature, as part of our ongoing association to find ways to provide Rhode Islanders with safe and affordable prescription drugs.

As you so well know, the exponential increases in the costs of prescription drugs are a cause of concern across the United States, and the State of Rhode Island is no exception. These untoward increases are placing a tremendous burden on state budgets and are threatening the continued viability of critical healthcare programs. In 2003, almost 41.1 percent of Rhode Island's total state budget was linked to the direct or indirect provision of healthcare services.

To control the skyrocketing costs of healthcare services, states are increasingly looking to innovative, and in some cases, radical approaches to cost management in health care. The several states that have had the greatest success in controlling drug costs have chosen to combine multiple strategies in order to generate the greatest returns on investment.

This study was conducted to identify the potential cost savings from implementing a targeted drug discount program; to describe the potential barriers that could postpone ---and might prevent--- such implementation; and to provide a practical blueprint for establishing such a drug discount program.

One avenue of federal funding that is generating a lot of attention nationally is the 340B program, which was established in response to the passage of Section 340B of the Veterans Healthcare Act of 1992. The primary objective of 340B is to provide access to outpatient medications at discounted rates to federal purchasers and certain grantees of federal agencies that provide care to vulnerable populations. The 340B program may well be Rhode Island's secret weapon in the battle to provide affordable access to prescription drugs. There are also other state and federal pharmacy assistance programs that provide opportunities for lower cost prescription drugs to vulnerable populations.

The extensive research, interviews, and data analysis that were performed as part of this feasibility study clearly indicate that dramatic and sustainable cost savings are possible through the implementation of a comprehensive, statewide drug discount program in the State of Rhode Island. For example, based on a comparative analysis of the prices the Department of Corrections (DOC) has paid for drugs by participating in a 340B program and taking advantage of 340B discount prices, it was calculated that, the DOC could save approximately 28 percent of its current annual outpatient drug expenses, or \$900,000 per year.

Our study demonstrates that, despite the one time investments for program design and infrastructure development that would need to occur in year one, the cost savings will exceed

implementation and administrative costs even in that first year. Year one gross savings from the program across multiple agencies are projected to be as high as \$4.23 million, and net savings as high as \$2.77 million. These savings could become even more dramatic in subsequent years. In addition to significant cost savings, a comprehensive 340B program, such as the one described in this study, offers greater coordination of care services, thereby improving outcomes for individuals with complex health needs.

It is the hallmark of our work at the Heinz Family Philanthropies to recognize that solutions, if they are to be of any actual use and not just academic exercises, must be both aware and respectful of the real world in which they will have to be applied. This study, therefore, also analyzes the practical challenges that would be faced in any attempt to implement any (or all) of its recommendations. The work plan underlines the high level collaborative efforts that would be necessary to build support for the program and its goals.

The *Rhode Island Report* represents another first for the Heinz Family Philanthropies and underscores why I believe philanthropy can effectively be used as venture capital before any public dollars are expended.

It is important that I both acknowledge and applaud the efforts of Representative Steven Costantino, Senate Majority Leader Teresa Paiva-Weed, for their unselfish work with our staff and consultants in discussing, debating and evaluating the recommendations contained in this report. Their willingness to help was a great value to all of us. A very special thank you to Marie Ganim, Senate Health Policy Director, for her advice and counsel. Her expertise was invaluable and clearly demonstrated why the state legislature depends on her guidance and knowledge. In addition, I would like to thank Ashish Abraham and Sandra Nienaber of AmeriChoice Management Services Organization for their diligence and contributions to this report.

Finally, I want to thank Jeffrey Lewis, President of the Heinz Family Philanthropies, the architect of this report which continues our cutting edge work.

Sincerely,

A handwritten signature in black ink that reads "Teresa Heinz". The signature is written in a cursive, flowing style with a long, sweeping tail on the letter "z".

Teresa Heinz, Chairman

The Rhode Island 340B Analysis: Achieving Greater Prescription Drug Savings

Introduction

Across the nation, the costs associated with the delivery of and access to healthcare services continue to increase dramatically. Factors contributing to this trend include significant advances in medical technology, a growing elderly population, and an expanding number of patients with chronic illnesses. However, the single most important contributing factor is the rapid and exponential rise in the cost of prescription drugs. The costs of prescription medications are increasing each year because of advancing drug technologies and the introduction of newer drugs in the healthcare marketplace. These costs are placing tremendous burden on state budgets and are threatening the continued viability of critical healthcare programs. A recent study found that the overall cost of prescription drugs increased by 13.4% in 2003, while specialty medications for people with complex, chronic conditions grew a staggering 26.6%.¹

The exorbitant costs of health and welfare services, coupled with declining revenues in a sluggish economy, have severely undermined the stability of state budgets in the last few years. To make matters worse, the economic downturn has resulted in increasing numbers of citizens that are dependant on publicly funded programs to receive needed healthcare services. While the economy is showing some signs of recovery, many states still face the daunting prospect of significant budget shortfalls in fiscal year 2005. To address these shortfalls and control the high costs of healthcare services, states are increasingly looking to innovative, and in some cases, radical approaches to cost management in the health care arena as a whole, but more specifically in the world of high-cost prescription drugs.

Many strategies are being employed to control the rising costs of prescription drugs. Some of these are focused on ensuring clinically appropriate prescription patterns and appropriate utilization of drugs. Others are focused on purchasing strategies that seek to obtain the lowest price for prescription medications through group purchasing initiatives; direct negotiations with pharmaceutical manufacturers, or through the use of state and federal drug discount programs. States that have had the greatest success in controlling drug costs have chosen to combine multiple strategies that generate the greatest return on investment. However, the focus of this report is on the savings that could be generated through drug discount programs that provide states with the opportunity to obtain prescription medications at rates significantly lower than the Medicaid net price.

¹ Medco 2004 Drug Trends Report, Medco Health Solutions, Inc, May 2004

Background

Rhode Island (RI), a small, yet densely populated and highly industrialized state, is renowned for its commitment to freedom of conscience and action. It is this commitment that has made Rhode Island a center of healthcare excellence and innovation. Since healthcare services is the largest and most prominent industry in the State, it is not surprising that the rising cost of healthcare has been the focus of widespread concern and attention for lawmakers, policy experts, and health officials within the State.

Rhode Island is one of the states where the budget crisis has been particularly severe in recent years. The situation continues to be grim with the budget deficit for fiscal year 2005 projected to be \$192 million.² In light of the severe budget shortfalls, Governor Donald Carcieri has implemented a comprehensive “Fiscal Fitness” program that seeks to decrease costs and increase the efficiency of State programs.

Healthcare is one of the high cost drivers for most state governments including the State of Rhode Island. In 2003, the total budget for the State of Rhode Island was \$5.344 billion dollars. Approximately \$2.194 billion, or 41.1% of the total budget, was linked to the direct or in-direct provision of healthcare services.³ Out of the thirteen public departments/programs in the State of Rhode Island, seven are involved in some fashion, either directly or indirectly, in the provision of healthcare services to critical populations within the State. The departments described briefly below are those that not only provide healthcare services to the citizens of Rhode Island, but also are those that would directly benefit from the development and implementation of drug discount programs during this time of fiscal crisis.

- *Department of Elderly Affairs (DEA)*: Provides health services to low and moderate-income seniors 65+ and Social Security Disability Insurance (SSDI) recipients 55-65 who meet income requirements. The RI Pharmaceutical Assistance to the Elderly Program (RIPAE) is a program that provides prescription medications for nine disease conditions to eligible participants within the program.
- *Department of Human Services (DHS)*: Administers the State Medicaid program offering health services to children, pregnant women, aged, blind and disabled individuals and their families within applicable income and resource limits. In 2003, there were approximately 124,000 enrollees in the managed care program (RIte Care) and 54,000 in Medicaid fee-for-service (FFS).⁴
- *Department of Corrections (DOC)*: Through the DOC, healthcare services are provided for adults under correctional supervision. This includes pretrial detention, sentence to incarceration, probation, and home confinement, and release on parole.

² Fiscal Year 2005 Budget, <http://www.budget.state.ri.us/execo5.pdf>

³ Fiscal Year 2003 Budget, <http://www.statebudget2003.pdf>

⁴ Coordinated Contracting of Prescription Drugs: A Fiscal and Policy Strategy for the State of Rhode Island – The Rhode Island Blueprint. Heinz Family Philanthropies. February, 2004.

- *Department of Children, Youth and Families:* Health services for children and adolescents that are in the judicial system are provided through the RI Training School, which is managed by the Department of Children, Youth and Families within the Juvenile Corrections Division.
- *Department of Mental Health, Retardation and Hospitals (MHRH):* Community Medication Assistance Program (CMAP), a program administered under MHRH, provides free psychotropic medications to clients of the eight community mental health centers and three other non-profit providers.
- *Other:* In addition to the departments/programs discussed above, the Department of Administration (State Employees), the RI Veterans Home, and the Department of Health AIDS Drug Assistance Program (ADAP) were also considered during the initial stages of this study.

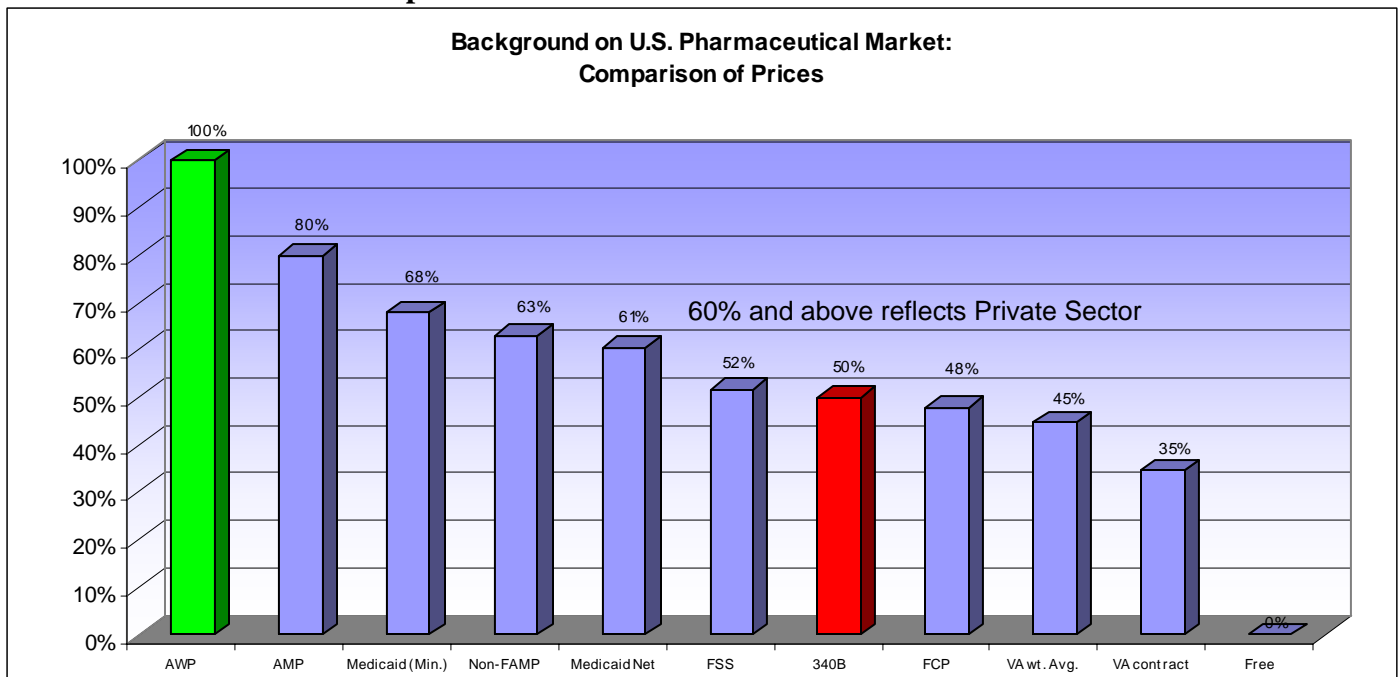
These departments and associated programs play a critical role in the RI health care delivery system by serving vulnerable populations by providing them with much needed, yet expensive health services and prescription drugs. Within each of these State departments, it is clear that the cost of prescription drugs is one of the major contributors to the budget woes. This is also one of the key cost categories that is continuing to increase at an alarming rate. From interviews conducted with key State officials, it was reported that the State currently spends over \$220,000,000 per year for outpatient prescription drugs across some of the largest publicly funded departments/programs that provide healthcare services (RIPAE, Medicaid FFS/Rite Care, DOC, RI Training School, and CMAP). As large contributors to the overall outpatient prescription drug costs borne by the State, an evaluation of these departments/programs was undertaken to identify opportunities to reduce the costs associated with rising outpatient prescription drugs. As a result of this analysis, the above departments/programs were determined to meet the criteria for benefiting from a drug discount program taking into consideration the complexity of implementation. This feasibility study was conducted to quantify the potential cost savings to the State from implementing a targeted drug discount program, the potential barriers associated with such an implementation, and the implementation steps necessary for establishing the drug discount program.

Federal Drug Discount Programs and their Role in Cost Containment

In any exercise that is geared towards decreasing budget deficits within state programs, it is imperative that every effort is made to maximize all sources of available funding. The complexities of federal funding sources, programs, and regulations can be overwhelming to even the most seasoned federal financial policy expert. One avenue of federal funding that is generating a lot of attention nationally is the 340B Program. This program was established in response to the passage of Section 340B of the Veterans Healthcare Act of 1992, with the primary objective of providing access to outpatient medications at

discounted rates to federal purchasers and certain grantees of federal agencies that provide care to vulnerable populations. Discounts through the 340B Program have been estimated to be approximately 50% below Average Wholesale Price (AWP) rates as demonstrated by Exhibit 1 below (published by the National Conference of State Legislatures), which details the percentage of cost savings associated with the various drug-purchasing strategies.

Exhibit 1: Price Comparison of U.S. Pharmaceutical Market



Source: Data derived from Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes, U.S. General Accounting Office GAO/HEHS-00-118, August 2000 and How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Market, Congressional Budget Office Papers, January 1996.

In addition to the 340B Program, there are other state and federal pharmacy assistance programs that provide opportunities for lower cost prescription drugs to vulnerable populations. One powerful avenue is the State Pharmaceutical Assistance Program (SPAP) currently being utilized by the DEA for the RIPAE Program. The pharmaceutical prices under this program can be excluded from best price and Average Manufacturer Price (AMP) calculations. The criteria for a program to qualify as a SPAP, per the Centers for Medicare and Medicaid Services (CMS), include the following:

- Program is a state developed program for disabled, indigent, low-income elderly or other financially vulnerable persons,
- Program receives state funding only,
- Payment for the program is provided directly to providers,
- Program provides either a pharmaceutical benefit or a pharmaceutical benefit with other medical benefits for services, and
- Program does not allow for diversion, the resale or transfer of benefits reimbursed under the SPAP to individuals who are not beneficiaries.

Based on the federal and state drug discount programs available for states to pursue, and faced with significant budget deficits, the State of Rhode Island entered into discussions with the Heinz Family Philanthropies (Heinz) to identify potential strategies for implementing a comprehensive, state-wide drug discount program using 340B and other state and federal discount programs. Based upon these discussions, Heinz, in collaboration with AmeriChoice Management Services Organization, was asked to conduct a feasibility study to evaluate opportunities for the implementation of a discount program and to quantify potential cost savings in total, as well as by individual agency.

Study Objectives

The key objectives of the study, as identified through preliminary discussions with the State of Rhode Island and Heinz, are listed below:

- To identify available sources of pharmacy discounts for the State of Rhode Island with a particular focus on federal programs such as the 340B Program,
- To confirm State programs that would benefit from initial participation in these drug discount programs and to evaluate the feasibility of targeted and expeditious implementation based on current State infrastructure and resources, and
- To quantify potential immediate cost savings that would result from implementation of drug discount strategies for targeted programs/departments within Rhode Island.

Study Methods and Information Sources

In a study of this nature, information from multiple sources is required to obtain a complete and accurate picture of the issues, costs, and consequences of the implementation of a 340B Program. For this reason, the methodology used to complete this study consisted of six key steps:

Step 1: Literature and Web-based Research and Information Review: This step provided an in-depth understanding of the 340B Program, created through the enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The Office of Pharmacy Affairs (OPA), in conjunction with the U.S. Department of Health and Human Services (DHHS), through the Health Services and Resources Administration (HRSA) and Bureau of Primary Health Care (BPHC), administers the 340B Program. The legislation was enacted to provide medically and financially vulnerable populations greater access to medication by offering steep discounts for pharmaceuticals to “covered entities” that serve these populations.

Step 2: Identification of Rhode Island Departments to be Included in the Feasibility Study: In order to identify the initial departments/programs to be included in the study analysis, key State staff were consulted to determine the appropriate departments/programs and associated staff to target for the interviews. Based on feedback from key State staff, one department, the Department of Administration, was removed from the initial focus of this study, at the instruction of State leadership.

Step 3: Interviews with Key Departments/Program Staff and 340 Experts: To conduct a gap analysis of the State infrastructure available to support the development of a 340B Program, several interviews were conducted with State staff. This step was also utilized to gain a perspective on the implementation issues and challenges associated with a 340B Program implementation. Interviews were conducted with each department/program under consideration to identify the current drug expenditures, drug distribution system, and perceived challenges associated with program implementation. External stakeholders, 340B experts, and HRSA's OPA staff were also interviewed for clarification and advice regarding the feasibility of a 340B Program for Rhode Island.

Step 4: Data Collection: Following completion of the face-to-face interviews, data requests were submitted to key departments/programs to obtain cost and utilization data for a 12 month time period at the National Drug Code (NDC) code level. Although initially considered, data was not requested from the RI Veterans Home as they are currently purchasing drugs through the Veterans Administration, which is below 340B pricing.

Step 5: Data Analysis: Data of varying levels of completeness was obtained from the selected departments/programs. Upon receipt, the data was reviewed, formatted, and then analyzed through specific queries to identify total drug costs by department/program at the NDC level when possible. When NDC level data was not available, an attempt was made to match the drugs utilizing the drug name and strength. Based upon the potential for the successful implementation of a 340B Program, the comprehensive data analysis was refocused on four departments/programs: DOC, RIPAE, RI Training School and CMAP. In general, data submitted by each department/program was for calendar year 2003. These data files were then compared to a proprietary file containing 340B drug costs for the first quarter of 2004. Detailed data tables and graphs were created based upon the analysis, and are presented in the Quantitative Analysis section of this report.

Step 6: Report Development: Summary findings and results that emerged through the research and analytical processes have been incorporated into this report, along with recommendations for future steps.

Study Caveats and Limitations

In any study of this nature where cost savings projections are being formulated, there are many factors that impact the interpretations and inferences made as a result of the analysis. The following represent important analytical caveats and limitations that were

encountered during the study.

- The historical data used in this study to determine cost savings may not exactly match the actual unit costs or utilization in future time periods.
- Reasonable extrapolation was performed in instances of incomplete data.
 - When necessary, a manual process was utilized to map the State databases to the 340B database.
 - In instances where less than one year's worth of data was received, a simple ratio was used to annualize the data.
- Cost savings projections have been made based upon current 340B prices, and actual cost savings may vary based on future 340B prices and contractual negotiations with the pharmacy wholesaler(s).

Study Assumptions

Both cost savings, as well as administrative costs, will vary depending on the number of covered entities, the level of support required by each covered entity, and the mechanism for procurement utilized by these entities. Since the implementation options for a 340B Program in Rhode Island are many, certain calculated assumptions were made based upon available information that has allowed the project team to make reasonable projections of potential cost savings by department/program. Key assumptions are presented below:

- Cost savings were calculated based upon all available data as of June 17, 2004.
- Savings estimates assume collaboration with covered entities and active support and involvement of current contracted vendors, including pharmacy wholesalers and drug distribution networks, as well as covered entities.
- Savings estimates assume active involvement of identified State departments/programs with potential changes in some departmental policies.
- A quantifiable shifting of a population segment to covered entities for primary medical services was utilized to calculate cost savings.
- A small trend factor was applied for the drug costs for all cost savings projected beyond the first year.
- A reasonable assumption of additional administrative costs was incorporated in the cost savings projections, such as the inclusion of negotiated dispensing fees.
- Savings estimates depend on timely approval from HRSA for key program components including alternative demonstration projects.

Qualitative Analysis

As states continue to wrestle with budget shortfalls, they are looking at multiple initiatives that would produce cost savings while continuing to provide care services to vulnerable populations. To obtain an accurate understanding of the benefit for the State of Rhode Island in the implementation of a 340B Program, it was important to conduct a

comprehensive review of the best practices that had been utilized thus far by various states. Through research and a series of discussions with 340B experts, it was determined that although no one model fits all programs and populations, it is feasible to create a program that would provide sustained drug cost savings and would promote better access to care for key segments of the population.

It should also be noted that HRSA's interest is in ensuring the viability of safety-net providers and has therefore supported creative initiatives by approving alternative demonstration projects. These alternative demonstration projects allow the creation of programs within certain parameters that enable covered entities such as federally qualified health centers (FQHC's) and their populations to benefit from the reduced cost of outpatient prescription drugs through the expansion of pharmacy networks. Based on the success of these alternative demonstration projects, the guidelines for 340B Programs are continually evolving.

In the development of a 340B Program, a manufacturer agrees to provide discounts on outpatient prescription drugs purchased by covered entities. Once a covered entity is approved by HRSA, they are subject to two restrictions:

- 1. They are prohibited from the resale or transfer of the discounted drugs to anyone other than a patient of the covered entity.** Therefore, key to the development of a 340B initiative is the definition of a patient of a covered entity, as defined by OPA, which must be met.⁵ Although there is some ambiguity about the frequency of patient care visits to a covered entity necessary to ensure the patient definition has been met, HRSA has made it clear that a clear and direct relationship must exist.
- 2. The discounted drugs cannot be subject to any Medicaid rebates.** The drug distribution and inventory management system must ensure that a request for a rebate is not made for any drug purchased under 340B for Medicaid recipients.

In the instances where a covered entity does not have nor want to implement an in-house pharmacy, 340B regulations also allow for a single contract pharmacy option for the purchase and dispensing of drugs. However, several covered entities desire a broader network of pharmacies to ensure wider access for patients. As a result, HRSA has made available the option of alternative demonstration projects. Consideration for an alternative demonstration project involves one or more of the following components:

- The development of a network of covered entities,
- The use of multiple contracted pharmacy services sites, or
- The utilization of a contracted pharmacy to supplement in-house pharmacy services.

National Examples of 340B Initiatives

Although many 340B Programs, including several demonstration projects, have been instituted across the country, the following examples represent some of the program

⁵ 61 Fed Reg 55, 156 (1996)

models that would be most applicable to the environment and program structure in the State of Rhode Island and could be readily adapted to benefit the State.

Massachusetts

The Commonwealth of Massachusetts has implemented a 340B Program utilizing community health centers (CHC's) and disproportionate share hospitals (DSH) for Medicaid. Through a collaborative effort with the Massachusetts' League of Community Health Centers, a pilot project was initiated with one health center. Following a successful implementation, the program was expanded to four additional CHC's, with all but one CHC having an in-house pharmacy. The State provided financial support in the form of start up grants for CHC's in exchange for 'carving in Medicaid'. The State has begun the process of quantifying the cost savings and evaluating next steps for expansion to other departments.

Texas

In a legislative mandate that became effective in 2001, the State of Texas, Department of Corrections, began the implementation of a 340B Program for their corrections population. Through a contractual relationship between the State and two university hospital pharmacy systems that are 340B eligible providers (the University of Texas Medical Branch (UTMB) at Galveston and Texas Tech University) all of the prisons were deemed outpatient clinics of the university systems with medical services being delivered at the prisons. Through this mechanism, the State corrections system has been accessing drugs for inmates at dramatically reduced prices.

Connecticut

In 2003, legislation was passed to provide loans to FQHC's to cover costs related to the establishment of a pharmacy facility or the creation of partnerships with a community pharmacy to serve as a centralized prescription drug distributor for the clinics. This has allowed a large number of FQHC's to participate in the 340B Program and thereby, allowed them the opportunity to provide affordable drugs to their patients.

Alternative Demonstration Projects

There are a number of HRSA-approved demonstration projects currently underway. The projects described below may provide a frame of reference for the feasibility of similar demonstration projects for the State of Rhode Island.

Minnesota

In 2002, Minnesota received approval from HRSA for a demonstration project designed to provide more affordable drugs to the safety-net population through three health centers in Minneapolis-St. Paul who joined forces to create a prescription drug purchasing and distribution system called the Neighborhood Pharmaceutical Care Network. The intent of this alliance was to provide less expensive prescriptions for the centers' more than 13,000 uninsured patients.

Georgia

Simultaneous with the announcement of the Minnesota project, a similar project was approved in Columbus, Georgia where a local safety-net hospital and two health centers formed the Columbus Regional Community Healthcare Network. As in the Minnesota project, the Columbus network will buy and distribute prescription medications to health center patients at lower costs.

Washington

A number of programs are taking advantage of the newest computer technology to dispense drugs at remote sites. One such program received approval from HRSA in 2002 and is located in Spokane, Washington. This program allows pharmacists at a central health center in Spokane to network with other eligible health centers and utilize computer equipment to dispense prescription drugs through machines located at remote health clinics. Video-conferencing is available for patients to receive counseling on proper drug usage.

In addition, there are currently four demonstration projects: two in New York and one each in Mississippi and Massachusetts, where approval has been given for entities to contract with multiple pharmacies to make medications and services more accessible to patients receiving care at covered entities.

Because of the growing number of 340B Programs being implemented across the country, the OPA is closely monitoring new programs to ensure compliance with federal regulations and HRSA guidelines. A number of states that had implemented 340B Programs have had to abandon these programs because of failure to comply with HRSA guidelines. With this in mind, it is prudent for the State of Rhode Island to work very closely with HRSA in the strategic development of 340B Programs, which when executed effectively will provide considerable cost savings to the State while complying with all federal requirements.

State Staff, Stakeholder, and Associated Interviews

Both internal State departmental staff and a targeted set of external stakeholders and 340B experts were interviewed to better understand the current health services and associated pharmaceutical delivery systems for each department/program that potentially could be impacted by a statewide 340B Program and to identify the barriers related to implementing a 340B Program. These stakeholders provided insight into not only the barriers of implementing 340B Programs, but also provided assistance in identifying solutions to overcome such barriers.

Internal State interviews were conducted with each State of Rhode Island department/program under consideration for 340B implementation to identify population eligibility, estimated outpatient drug expenditures, drug distribution and inventory

management system, breadth of provider network, and perceived challenges with implementing a 340B Program.

The Department of Administration was excluded early in the process due to feedback from key State staff that felt that it would be very difficult to implement a 340B strategy for this Department. The following table lists the State staff that was interviewed.

Table 1: Rhode Island State Staff Interview List

Department/Organization	Name	Title
Department of Mental Health, Retardation and Hospitals Primary Focus: CMAP and Eleanor Slater Hospital	Ron Tremper	Administration, Monitoring & Decision Support, Division of Behavioral Health Care Services
	John Murray	Financial Contract Management, Division of Behavioral Health Care Services
	Mike Manosh	Executive Director, Office of Operations
	Richard Garzilli	Administrator of Pharmacy Services
	Richard Freeman	Chief Executive Officer
	Dr. Rick Wagner	Medical Director, CMAP
Department of Human Services Division of Health Care Quality, Financing & Purchasing Primary Focus: Connect CARRE, RItE Care, Medicaid FFS)	Ellen Mauro, RN, MPH	Chief, Family Health Systems (Connect CARRE)
	Frank Spinelli	Administrator, Center for Adult Health
	Tricia Leddy	Administrator, Center for Child and Family Health, RItE Care (Medicaid Managed Care)
	Rick Jacobsen, Bill McQuaid	ACS – Contract support for RItE Care
	Paula Avarista, RPh, MBA	Chief of Pharmacy and Related Services - Medicaid FFS
Department of Corrections Health Service Administration	Joseph Marocco	Associate Director
	Paul Larrat, MBA, PhD	University of Rhode Island, College of Pharmacy, Associate Dean and Professor
	Joanne Hill	State Budget office
Department of Elderly Affairs Primary Focus: RIPAE program	Dennis Costa	Assistant Administrator of Community and Planning Services
	Warren Hurlburt	Superintendent

Department/Organization	Name	Title
RI Training School, Department of Children, Youth & Families, Juvenile Corrections Primary Focus: RI Training School	Warren Hurlburt	Superintendent
	Chuck Golembeski	Clinical Director, RI Training School
State of RI, Department of Health, Office of HIV & AIDS Primary Focus: ADAP	Paul Loberti, Jr., MPH	Chief Administrator
	Annie Silvia	Title II and ADAP Coordinator
D.H.S./Veterans Affairs, Commandant, RI Veterans Home	Daniel Evangelista	Associate Director
	Richard Carbal	Pharmacy Director

The following table lists interviews conducted that were external to State employees or contractors. Advice, clarification, support and feedback were received from each of the individuals listed below.

Table 2: External Interview List

Department/Organization	Name	Title
HRSA	Jimmy Mitchell, RPh, MPH, MS	Director, Office of Pharmacy Affairs
	Kathleen McGee, RPh	Pharmacist, Office of Pharmacy Affairs
	Jeff Mouakket	U.S. Public Health Service, Office of Pharmacy Affairs
Winkelman Management Consulting	Mike Winkelman	President
Massachusetts Department of Medical Assistance	Nancy Schiff	Project Manager
Thundermist Health Center	Maria Montanaro, MSW	Chief Executive Officer
	Martin Killiam	Chief Operating Officer

The interviews served the dual purpose of informing individual State agencies about federal drug discount program options, such as 340B, and gathering critical information on current operations and the challenges that would be encountered in the implementation of a 340B Program. As barriers were identified, the interviews also served as a forum to discuss potential solutions to address these challenges, thereby maximizing the potential for the success of a 340B Program. The following sections provide a brief summary of key operational elements of each department/program and factors that would impact the

success and/or value of cost savings generated through the initial phase of a comprehensive drug discount program.

CMAP: A central pharmacy receives drugs direct from the manufacturers and distributes the drugs to 15 local pharmacies. Eleven community mental health centers (CMHC's are not eligible to be 340B covered entities) send patients to these designated pharmacies. The potential to affiliate the 1,900 people receiving medications under this program with a covered entity within the State is an option that may be considered to allow access to drugs at 340B discount prices. The narrow set of therapeutic classes of medications, small number of current providers, one central distribution system, and limited number of pharmacies, make CMAP a reasonable program to focus on for implementation of a 340B Program. Barriers include limited electronic data monitoring, the lack of an affiliation with a current 340B covered entity, the need to direct patients to a covered entity for primary care, and the potential loss of a "free samples" program currently in place.

Eleanor Slater Hospital (Slater): The initial rationale for interviewing staff at Slater was twofold – to determine the extent of any outpatient drug distribution program as well as to explore the potential of establishing Slater as a covered entity. Although it was quickly determined that Slater does not have an outpatient pharmacy, the possibility of Slater supporting other departments/programs as a covered entity remains. It must be noted that there are a number of other hospitals in the State who are also DSH hospitals and are therefore, eligible to receive 340B discount prices for medications as covered entities, however, they are not owned by, or have an affiliation with the State.

Connect CARRE: The small volume of members (50-150) accessing care through this program reduces the return on investment that a focused 340B initiative would have for this program. All members are in the Medicaid FFS program. However, because it is assumed that some of these members access care through FQHC's, a 340B initiative that supported the FQHC's could impact these specific members and could result in indirect cost savings to Medicaid.

Rite Care: The Medicaid managed care program has both a significant volume of members and a high dollar value for outpatient pharmaceuticals. However, a barrier to the implementation of 340B within this environment is the federal and state regulations that necessitate the presence of a large number of providers and pharmacies to ensure adequate access to care and drug services. These requirements make it difficult to limit the provision of services through designated covered entities, as required by 340B regulations. In addition, the three Managed Care Organizations (MCOs) would need to support this initiative, even if drugs were carved out of their capitation rate. A secondary barrier is the ability of the State to collect any savings that the MCO's, through the covered entities, could attain through a 340B initiative. The "pass-through" of savings to the State would require extensive encounter data reporting and an inclusion of such data in a revolutionary rate setting methodology. The negotiations between the covered entity, MCO, and the State (through the rate setting process) would likely dilute much of the savings to the State.

Medicaid FFS: The Medicaid FFS program has an even larger population and higher outpatient pharmaceutical drug costs than the RIte Care managed care program. However, as with RIte Care, these members access care through many different providers and pharmacies making the implementation of a targeted 340B Program difficult. The application of a limited pharmacy and provider network (under a 340B program) to the Medicaid FFS population would necessitate CMS approval. The loss of Medicaid rebates, which is precluded under 340B statute, also makes the application of a 340B Program to the Medicaid population more complex. It must be clearly stated that if the complexities of the Medicaid environment could be adequately addressed within the framework of 340B Program requirements, the cost savings could potentially be quite high. For this reason, it is recommended that the State continues to pursue strategies for 340B program implementation for the Medicaid program although due to the complexities involved, this should be deferred to the second phase of program implementation.

DOC: The DOC has an isolated population, a limited number of providers, and a central distribution system for almost all pharmaceuticals making this a prime opportunity for 340B implementation. The only barrier that would need to be resolved is the assignment of inmates to a covered entity and making that covered entity responsible for drug purchasing and inventory management for the population. These barriers, while significant, can be overcome, especially given that precedence has been set by other states, such as Texas.

RI Training School: The RI Training School uses an almost identical pharmaceutical provider and central distribution system as the DOC. Therefore, the establishment of a covered entity into a contractual relationship with the RI Training School should facilitate the acquisition of drugs at 340B pricing. Although the cost savings associated with this Department are much less than the DOC, it is likely that the RI Training School would benefit from an adaptation of the program established for the DOC.

RIPAE: The small number of members impacted by this program, about 5000, allows a focused approach to implementing a 340B Program for targeted members of this program. The fact that copays exist for the drugs may encourage some members to transition to a covered entity for medical care and to obtain their medications from an affiliated pharmacy. While significant barriers such as the current large number of providers and pharmacies do exist, the potential savings from transition of even a narrow segment of this population into a 340B Program are considerable. At the time of completion of this study, it is still unclear as to how the changes proposed through the Medicare Modernization Act (MMA) will impact the savings estimates of a 340B Program. It is anticipated that after the year 2006, the state will need to consider wrap-around programs that maximize the value of both Medicare and 340B Programs.

ADAP: The Rhode Island ADAP is one of the few ADAPs in the country that are supported entirely by federal funds and any savings from a State directed drug discount program would not result in immediate cost savings to the State. For this reason, it was determined that further review and analysis should be deferred to a subsequent phase of 340B Program implementation keeping in mind that additional services could be

provided and/or new clients could be served through the ADAP if it were able to generate higher pharmacy discounts through 340B Program participation.

RI Veteran's Home: Interviews revealed that drugs obtained for the Veteran's Home are purchased through the Veteran's Administration (VA). Since the VA pricing vehicle provides drugs at a lower cost than 340B pricing, it was determined that the State should not consider 340B implementation for the Veteran's Home.

Interview Conclusion

The complexity of operationalizing a 340B Program was a factor in decisions made to include departments/programs in the **initial phase** of implementing a drug discount program. In collaboration with the State, a decision was made to exclude the following departments/programs from the initial phase of this drug discount initiative:

1. **Connect CARRE:** due to the limited cost savings yet large provider and pharmacy network.
2. **Rite Care:** due to the current managed care structure, large volume of members and vast provider and pharmacy network.
3. **Medicaid FFS:** due to the large volume of members and vast provider and pharmacy network.
4. **ADAP:** due to the absence of any savings to the State since ADAP is funded entirely through federal grants
5. **Department of Administration:** due to recommendations from key State staff indicating that it would be difficult to implement 340B for State Employees.

Each of the above departments/programs may, in fact, benefit from a 340B Program, but the complexities involved with doing so may make them somewhat cost prohibitive **in the short-term**. However, each of them may greatly benefit, in the long-term, of a more focused analysis regarding the implementation of a comprehensive drug discount program.

The final outcome of the interviews was the identification of four departments/programs that could adapt their current operations based on the federal guidelines associated with a drug discount program with the least amount of disruption while maximizing savings to the State.

In discussing the interview findings with the State, the primary targets for the implementation of a comprehensive drug discount program were narrowed down to:

1. **CMAF** – due to the central pharmacy warehouse and relationship with a limited set of providers and pharmacies.
2. **DOC** – due to the isolated population, limited set of providers, and single source for drug distribution.

3. **Training School** – due to an almost identical situation as the DOC.
4. **RIPAE** – due to the potential savings and the member copays that may encourage member cooperation in a 340B Program.

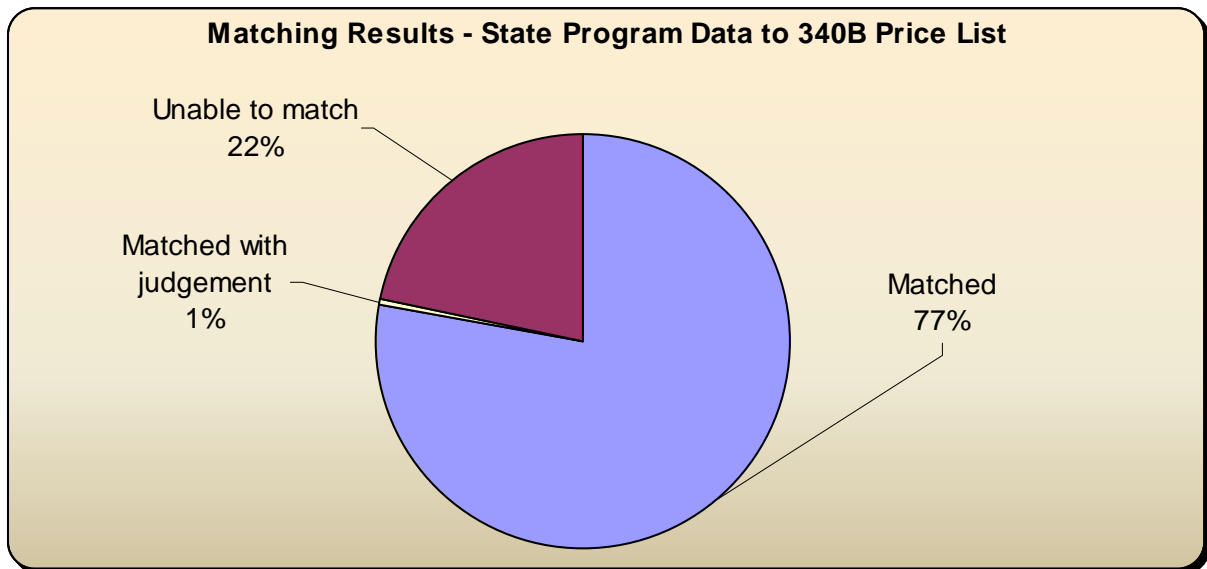
Our quantitative data analysis focused on the data analysis relative to these four departments/programs to determine both the associated cost savings as well as additional short and long-term administrative costs for a drug discount program.

Quantitative Findings and Results

The primary method by which projections of cost savings were made was through a comparison of drug prices in the various State departments/programs with prices of the same drugs at 340B discount rates. The 340B rates were obtained from a recent 340B price list, while each State agency provided department/program specific drug utilization and cost data. As data was obtained from multiple sources, it became clear that each department and/or data source had varying methods to track and quantify drug information with varying levels of detail. For this reason, some drug categories could be matched perfectly (drug name, package type, and dosage).

In other instances, assumptions could be made based on clinical and logic edits that allowed for a manual matching of drugs. However, in approximately 22 percent of the records, it was not possible to match State drug data to the 340B drug pricing data (see Exhibit 2). The savings for these unmatched records were estimated by applying the savings percentage experienced for the matched records to the dollar value of the unmatched volume of drug records.

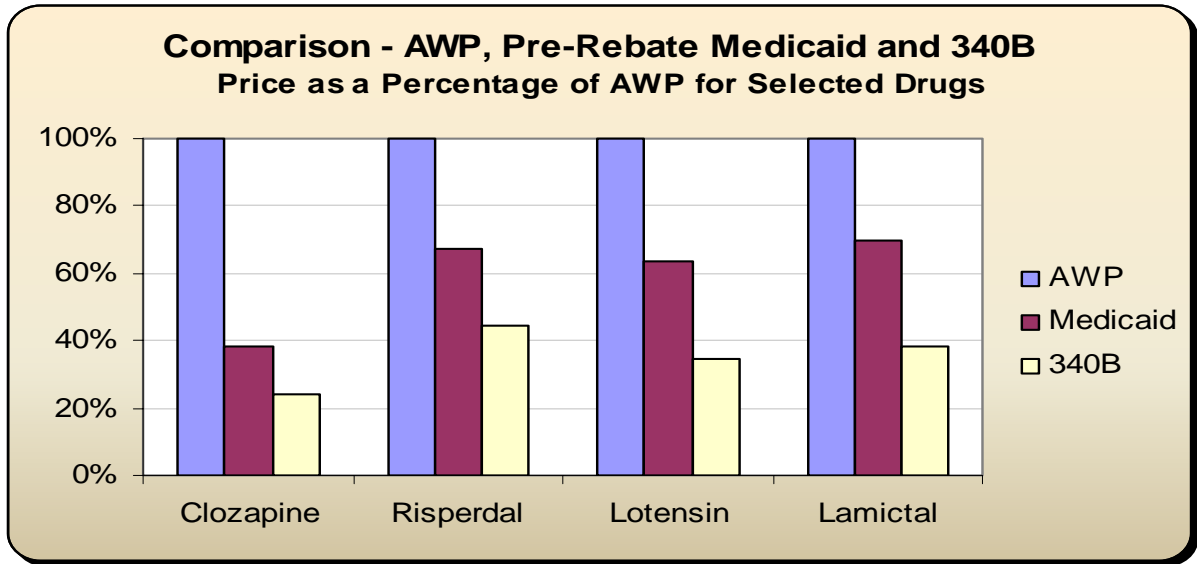
Exhibit 2: Matching Results



Finding 1: Percent Overall Savings

Through a review and analysis of drug cost data obtained from multiple sources, it was determined that in general, the cost of drugs obtained under a 340B Program was estimated to be approximately 43 percent lower than the cost of drugs obtained under Medicaid and approximately 65 percent lower than the AWP for the drugs. It must be noted that the differences in costs across the three pricing levels vary from drug to drug, but the percentage differences presented above reflect an average of all drugs included in the analysis. Exhibit 3 below outlines the variation in costs for some selected drugs.

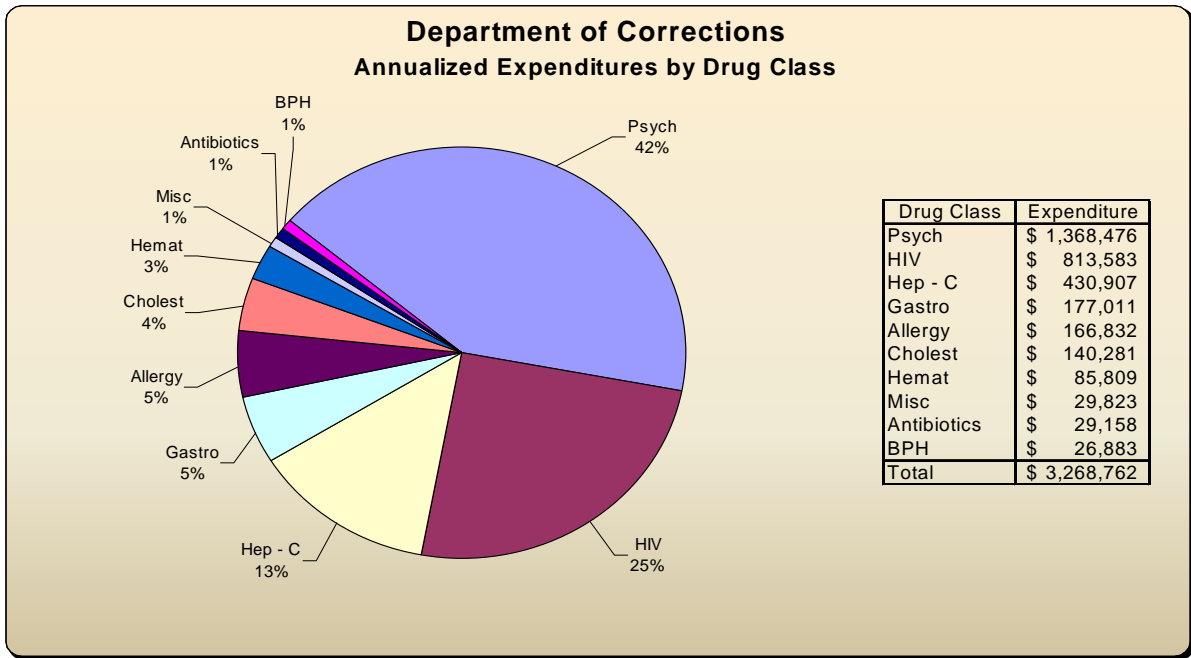
Exhibit 3: Comparison of Selected Drug Prices – AWP, Medicaid Rebate and 340B



Finding 2: DOC

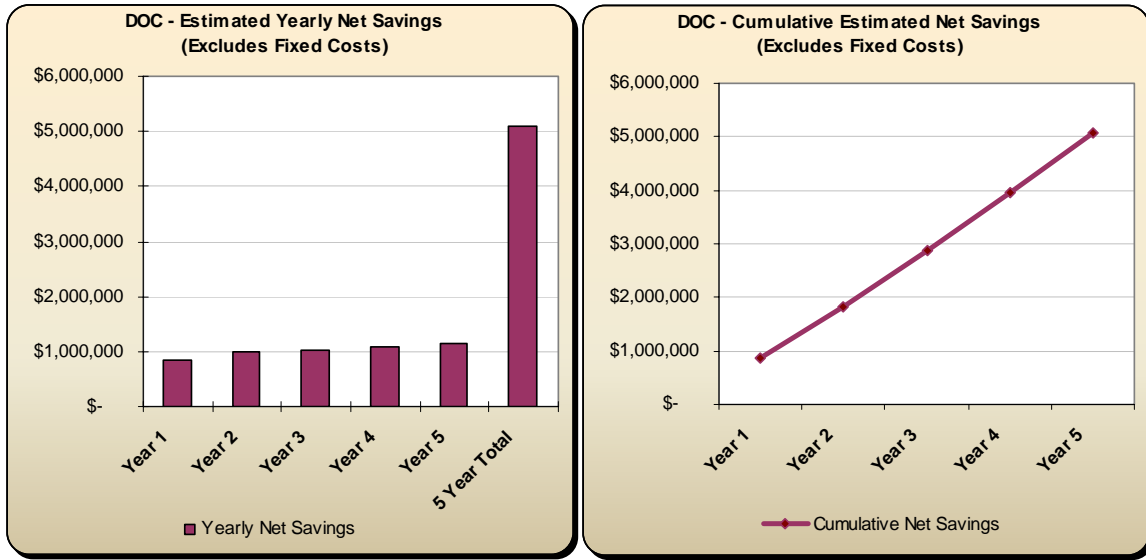
For the DOC, data revealed that the total annual expenditure on prescription medications for 2003 was approximately \$3 million dollars. As mentioned earlier, actual drug data obtained for the DOC included 50 percent of the medications and only covered 3/4th of a year. When current drug costs were evaluated based upon drug class, it was found that 42 percent of current annualized expenditures were for psychiatric drugs. The second highest category of expenditures was for HIV drugs (25 percent). Exhibit 4 presents the annualized expenditures at the DOC categorized by drug class.

Exhibit 4: Current Costs for Outpatient DOC Prescription Medications



Based upon a comparative analysis of DOC drug prices with 340B discount prices, it was calculated that the DOC could save approximately 28 percent of its current annual outpatient drug expenses, or \$900,000 per year, by participating in a 340B Program. Based upon estimated implementation costs, the net annual and cumulative savings for a five-year period are presented in Exhibits 5a and 5b.

Exhibits 5a and 5b: Potential Savings for DOC

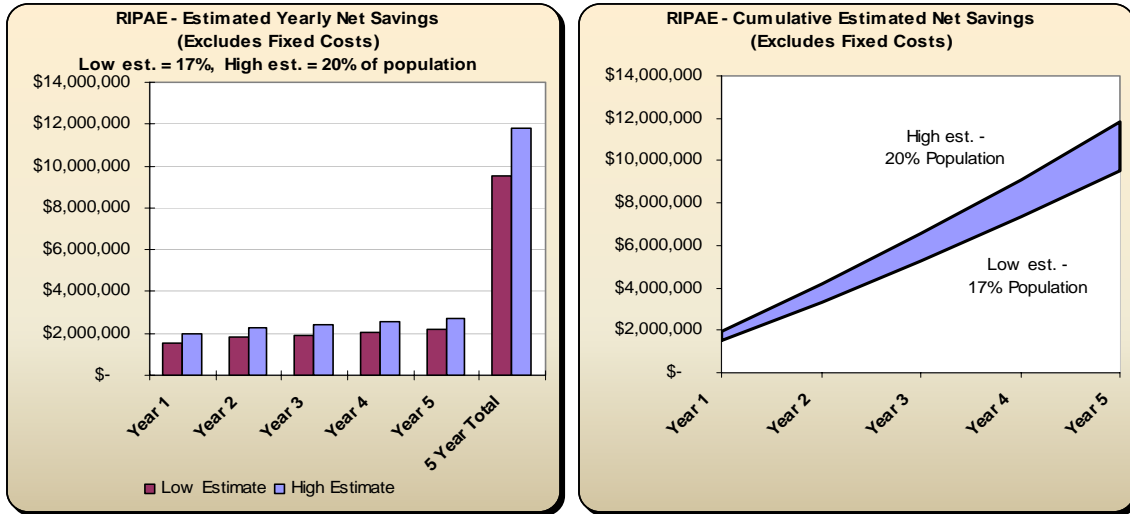


Finding 3: RIPAE Program

Out of all the departments/programs included and evaluated in this study, the RIPAE Program was found to have the largest drug expenditures with total expenditures for the year 2003 amounting to over \$25 million. Through an in-depth analysis of cost saving options and potential drug discount programs, it was determined that additional savings could be obtained by determining whether a segment of this population is receiving care through covered entities or by having a segment of the RIPAE population obtain their primary care from covered entities. By doing so, the patient definition would be met, and all drugs would be obtained through the associated 340B pharmacy (either at the covered entity or a contract pharmacy). This would result in significant savings under the 340B Program. The RIPAE Program currently participates in the SPAP program. An alternative solution would be a closer examination of SPAP to determine if greater savings could be achieved through enhanced wholesaler negotiation, to bring overall prices much closer to those found in 340B Programs.

A second factor that also plays into the level of cost savings is the ability to negotiate discounts with pharmaceutical vendors at 340B sub ceiling pricing. For the purpose of this analysis, a conservative range of 17 to 20 percent of the current drug utilization (population) was estimated to receive discounted 340B drugs. The potential yearly and cumulative savings that the State could attain on an annual basis are presented for a five-year time period in Exhibits 6a and 6b.

Exhibits 6a and 6b: Potential Savings for RIPAE Program

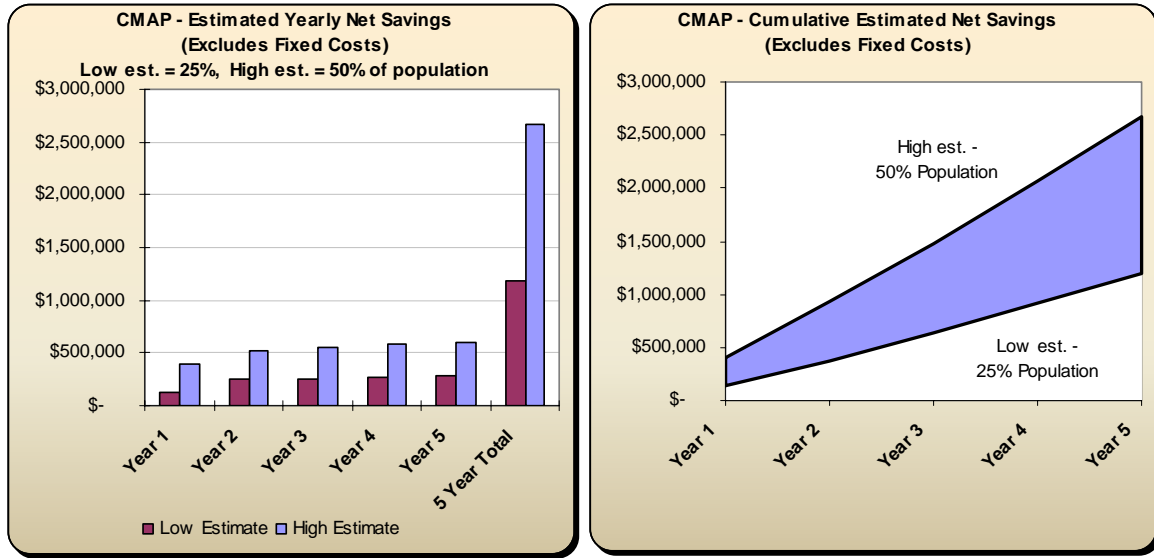


Finding 4: CMAP

Currently, CMAP spends about \$3.4 million per year (net of rebates) for outpatient prescription drugs. Through 340B pricing, the agency may save between \$250,000 (8 percent) and \$525,000 (15 percent) on an annual basis after first year implementation costs, depending upon the percentage of the population eligible for the 340B Program. Cumulative savings over five years may amount to between \$1.1 and \$2.7 million dollars. The exhibits below present the potential annual and cumulative savings for a five-year period. The resultant savings could be obtained by shifting a segment of the CMAP population to covered entities, which would result in dramatic savings for the State. As in the case of the RIPAE Program, the level of cost savings will depend primarily on the number of patients that are willing to receive care and drugs at a covered entity and associated pharmacy. For the purposes of the analysis, a conservative estimate was made that between 25-50 percent of the CMAP population could receive care through a covered entity and would therefore be eligible for 340B discount prices for their outpatient drugs.

Similar to the RIPAE Program, a second factor that plays into the level of cost savings is the ability to negotiate discounts with pharmaceutical vendors at 340B sub ceiling pricing. The potential yearly and cumulative savings that the State could attain on an annual basis are presented for a five-year time period in Exhibits 7a and 7b. Every effort will be made in the implementation phase of this program to increase this number to generate even greater savings, for all targeted departments/programs.

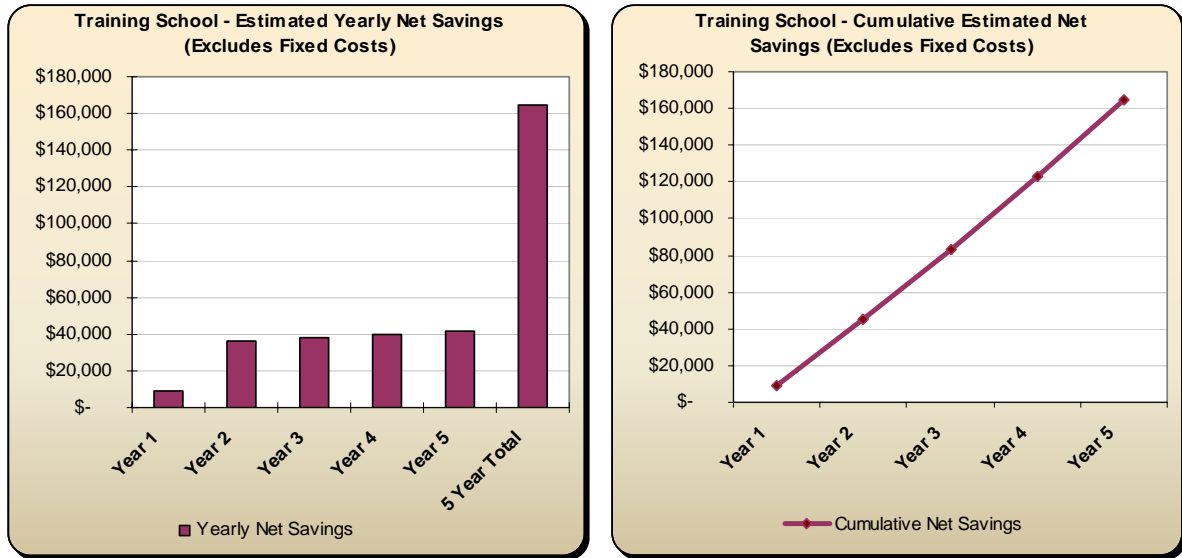
Exhibits 7a and 7b: Potential Savings for CMAP



Finding 5: RI Training School

Drug utilization and cost data were not obtained from the RI Training School. However, since the drug utilization patterns in juvenile detention centers are fairly similar to those in adult prisons, it was assumed that the percent cost savings that could be generated through the implementation of a 340B Program in the RI Training School would be similar to that of the DOC (28 percent). Through interviews with staff at the RI Training School, it was determined that the annual expenditures for outpatients drugs at the Training School was \$120,000 and hence, the projected net savings based upon this expenditure level have been presented in the Exhibits 8a and 8b.

Exhibits 8a and 8b: Potential Savings for the RI Training School



Finding 6: Implementation Costs and Program Wide Net Cost Savings Estimates

Through the research, interviews, and data analysis performed as part of this feasibility study, a combination of strategies is being recommended to the State of Rhode Island in order to generate the greatest cost-savings. A combination strategy is necessary due to variations in administrative structure and program-specific barriers within each department/program. Additionally, the implementation and on-going administrative costs for each department/program are significantly different. Table 3 outlines the expenses associated with both the implementation and ongoing administrative oversight of this comprehensive drug discount initiative.

Table 3: Implementation and On-going Administrative Expenditures

Category	Initial Implementation Costs	Ongoing Administrative Costs	Year 1 Projected Gross Savings		Year 1 Projected Net Savings	
			Low	High	Low	High
<i>Fixed Costs:</i> <ul style="list-style-type: none"> • Legislative analysis and technical support • Targeted research • Meetings with HRSA; 340B application development • Inventory Management System – development, training, and support • Provider outreach and contract development • Clinical staffing 	\$450,000					
CMAP	\$100,000	\$35,140	\$267,955	\$535,909	\$132,815	\$400,769
Department of Corrections (DOC)	\$75,000	\$3,352	\$937,142	\$937,142	\$858,790	\$858,790
Department of Elderly Affairs (DEA – RIPAE)	\$150,000	\$650,110	\$2,342,569	\$2,755,964	\$1,542,459	\$1,955,854
Training School	\$25,000	\$123	\$34,404	\$34,404	\$9,281	\$9,281
TOTAL	\$800,000	\$688,725	\$3,582,070	\$4,263,419	\$2,093,345	\$2,774,694

*Net Savings represent Gross Savings less the sum of the estimated initial implementation and yearly ongoing administrative costs (e.g. \$132,815 = \$267,955 - \$100,000 - \$35,140).

Based upon these implementation and ongoing administrative costs, the following graphs present the overall program-wide net savings that could be generated through the implementation of this comprehensive drug discount program. For each agency, the analytical team created both maximum and minimum estimates of anticipated cost savings. Exhibit 9a presents the most conservative estimate of net savings after costs are subtracted from savings.

Exhibit 9a: Net Program-Wide Cost Savings – Low Estimate

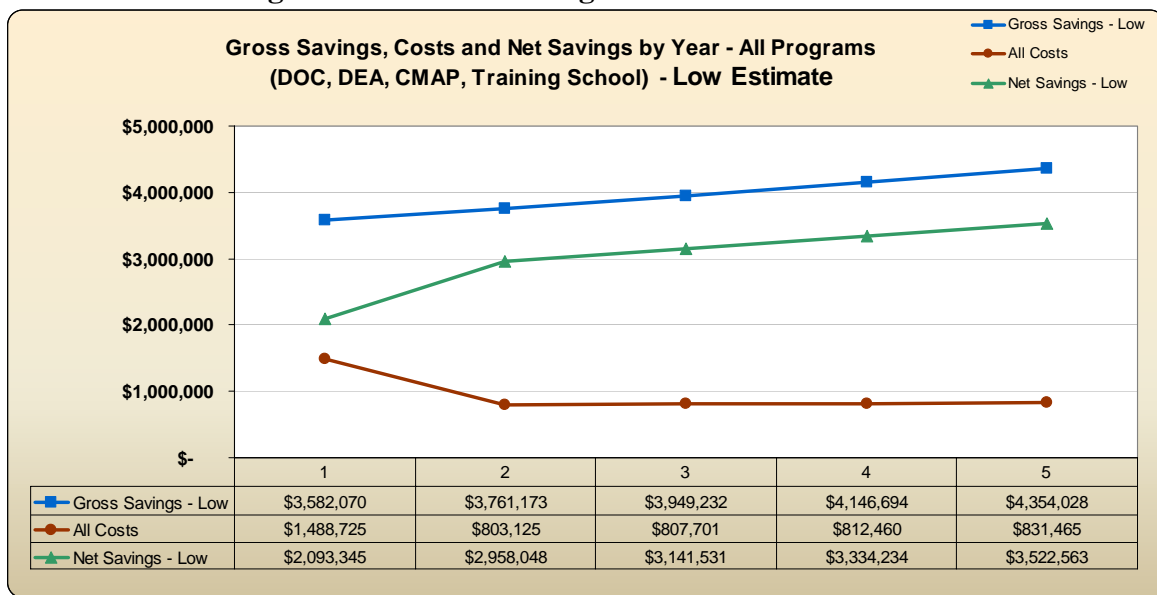
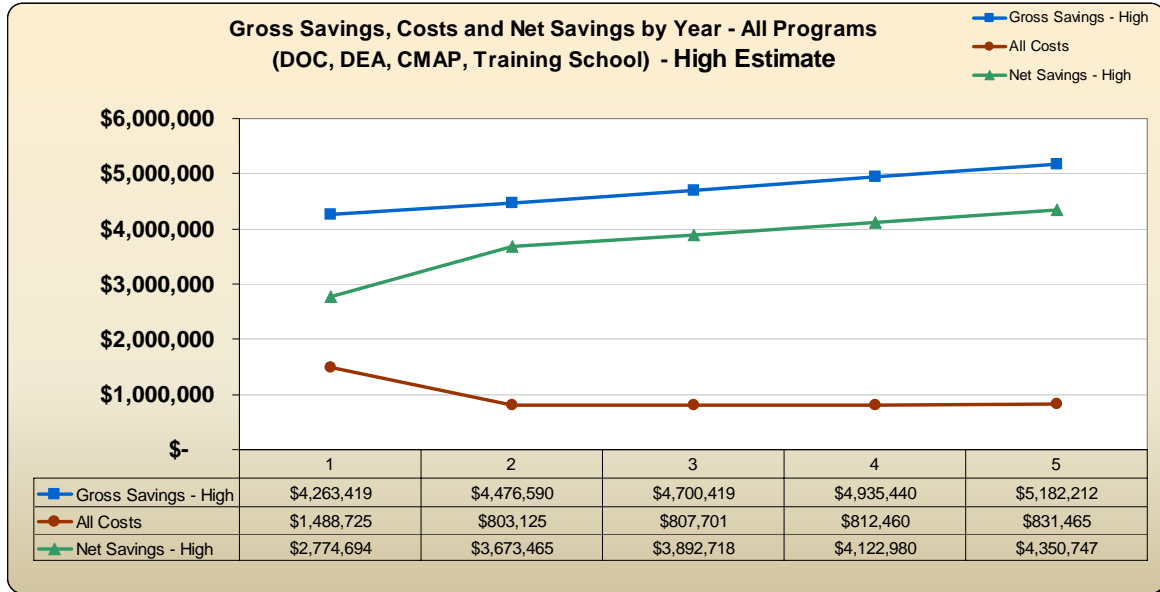


Exhibit 9b presents the less conservative estimate of net savings after costs are subtracted from savings. For this graph, the upper limit of calculated savings were used to determine the net savings estimate.

Exhibit 9b: Net Program-Wide Cost Savings – High Estimate



Conclusions and Next Steps

This feasibility study provides the State and other interested parties a clear demonstration of the dramatic savings that could occur through the implementation of a comprehensive drug discount program and that the savings generated through the implementation of this comprehensive pharmacy discount initiative will exceed implementation and administrative costs even in year one. Since year one implementation is associated with fairly significant one-time investments for program design and infrastructure development, the savings generated through this initiative increase dramatically in year two and beyond.

The exponential rise in prescription drug costs is a cause of tremendous concern across the United States, and the State of Rhode Island is no exception. With the State facing a projected deficit of \$192 million in 2005, drastic steps have to be taken to control rising costs. In this environment, the State must maximize its participation in federal drug discount programs such as 340B, which offer immediate, predictable, and significant savings on prescription drugs.

The research, interviews, and data analysis performed as part of this feasibility study clearly indicate that dramatic and sustainable cost savings are possible through the implementation of a comprehensive, statewide drug discount program in the State of Rhode Island. The study further demonstrates that the cost savings will exceed implementation and administrative costs even in the first year of the program despite the one time investments for program design and infrastructure development that need to occur in year one. Year one gross savings from the program across multiple agencies are projected to be as high as \$4.23 million and net savings are as high as \$2.77 million. These savings become even more dramatic in subsequent years as the costs associated with initial infrastructure development fall off significantly after year one.

As highlighted in this report, the implementation of a state-wide drug discount initiative, whether it be a 340B Program or any other drug discount program, is not without challenges. Fortunately, these challenges are not insurmountable. Experiences in other states have shown that the concerted and coordinated effort of staff and stakeholders from multiple state agencies and organizations can result in the successful establishment of these types of programs that save valuable taxpayer resources and at the same time improve access to life-saving drugs to State residents. The most significant barriers that will need to be addressed are:

- Creation of an environment of collaboration and cooperation among multiple State agencies, stakeholders, and the healthcare community at large.
- Ability to negotiate mutually beneficial arrangements between the State, eligible covered entities, and pharmacy vendors, particularly in relation to the level of discounts and dispensing fees.

- Willingness and support within the State to make programmatic changes within existing regulatory constraints that would facilitate the implementation of the program. This may include making changes to current pharmacy-related purchasing arrangements. Willingness and support from the community and patient advocacy groups to alter some care processes in order to obtain access to a wider range of cost-effective drug and treatment options.