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The Bulk Purchase of Pharmaceuticals:

The Experiences of the United States, Europe, and New Zealand

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Executive summary

Pharmaceutical costs are escalating at a rate that outpaces inflation, forcing government providers to balance consumer needs against budgetary realities.

Several strategies for better managing drug expenditures are attracting significant attention, including bulk purchase agreements. Bulk purchasing agreements seek to reduce per unit costs by increasing the volume of product purchased. In pharmaceutical markets this is done by combining multiple purchasing entities, such as employers, states, provinces or municipalities, and the drugs they buy to secure lower prices for their medicines, usually directly from the manufacturer. Bulk purchasing is frequently used in combination with other strategies such as sole tendering, therapeutic substitution, reference-based pricing, restricted formularies, and preferred drug lists.

The reality of pharmaceutical markets is such that discounts and pricing are extremely nuanced, making a straightforward calculation of bulk purchasing and the associated savings impossible. Specifically, bulk purchase agreements are always employed in combination with multiple other cost-saving strategies, making it virtually impossible to tease out the singular impact or cost savings accruing to the bulk purchase agreement alone.

While a systematic analysis of bulk purchase agreements is impossible, this study gathers ample anecdotal evidence to establish that these agreements consistently generate cost savings, ranging from modest to quite impressive. Admittedly, the estimates are very sensitive to the specifics of the strategies in use, the sophistication of the plan, the size of the program, as well as historic purchasing patterns. This study identifies three sources of direct savings:

- provider pharmacies will accept lower reimbursement and dispensing fees in exchange for a larger volume of prescriptions;
- administrative expenses are reduced when spread over a larger number of units, essentially lowering the per-unit cost through economies of scale;
- there is an enhanced opportunity to influence market share from increased volumes and concentrations in a given region, which will result in increased rebates negotiated with pharmaceutical companies.

While bulk purchasing agreements are beneficial to coverage and for taxpayers, they may have an adverse impact on the disability burden and not be good for patients' health. In addition, these policies have angered many physicians who were unable to prescribe the drug of their choosing since the patient would have to pay out of pocket for it. Bulk purchase agreements may result in a situation in which the insured receive

optimal brands in some areas, but less optimal brands in others. Frequent renegotiation (annually in some cases) can lead to abrupt changes in treatment for insured patients, leading to patient dissatisfaction and a potential for adverse outcomes, including lack of adherence, which in turn can lead to a requirement for more expensive treatment options, such as hospital admission.

There are other potential problems with bulk purchasing agreements, too. One consequence may be drug monopolies or limited numbers of drug suppliers. This reduction in competition may lead some manufacturers to leave the market, further restricting opportunities for substitution. At the extreme, drug shortages may occur, which would harm patients. Additionally, these policies lead to both restricted access to medicines due to the preferred drug list, as well as delayed introduction of new innovative medicines, potentially leading to poorer health outcomes and additional expenditures on non-pharmaceutical forms of care. Bulk purchasing agreements also have the potential to limit access to other medications that are not included in the agreements. As a result, prescription costs may shift to patients if the necessary medications are not part of such agreements, thereby requiring higher co-payments, or forcing patients to cover the entire cost of these drugs—or even go without. Finally, there can be an impact on innovation. Price pressure on the innovative pharmaceutical industry will reduce the incentives for pharmaceutical research and development, stifling innovation and reducing the number of breakthrough therapies in the pipeline.

Introduction

Pharmaceutical costs are escalating at a rate that outpaces general inflation, several times over, leaving government providers with the difficult task of balancing consumer needs against budgetary realities. The challenges of reigning in drug expenditures are complicated by a combination of factors that drive escalating drug costs. According to a 2005 report, the drivers of escalating drug costs include:

- changes in the size and demography of the population,
- increases in the unit price of drugs,
- changes in the prescribing patterns of physicians,
- increases in the number of drugs dispensed per patient,
- changes in the number of drug options available for specific health conditions,
- increasing use of newer, more expensive and/or more effective drugs,
- increasing reliance on drug therapy instead of other medical treatments, and
- emerging conditions and diseases requiring drug therapy. (Canadian Pharmacists Association, 2005: 2)

In response, policymakers are focusing their efforts on finding strategies for better managing drug expenditures. They are placing specific emphasis on reducing drug costs, getting value for money, patient compliance, and effective, appropriate, and safe drug use (WHO, 2007; Canadian Pharmacists Association, 2005; European Commission and the Economic Policy Committee, 2010).

In this context, several strategies are attracting particular attention, including bulk purchase agreements. Bulk purchasing agreements seek to reduce per unit costs by increasing the volume of product purchased. In pharmaceutical markets this is done by combining multiple purchasing entities, such as employers, states, provinces or municipalities, and the drugs they buy in order to secure lower prices for their medicines, usually directly from the manufacturer. Bulk purchasing agreements are also known as aggregate purchasing, consolidated purchasing, pooled purchasing, and price volume contracts. Bulk purchasing allows plan sponsors (purchasing entities) to coordinate with other plan sponsors in order to increase the total number of covered lives, to leverage more favourable financial arrangements. According to the Commonwealth Fund, potential savings from bulk purchase agreements commonly increase with expanded participation since drug prices and rebates are tied to volume. Aggre-

gate purchasing of pharmaceuticals encompasses not only the purchase of medications, but also includes the services associated with administering the pharmacy benefit, such as management of drug use, claims administration, and management of the insurance network (Lewis, 2001: 4). Specifically, bulk purchase agreements may result in more favourable pricing and in discounted pharmacy dispensing fees. Both reduce costs for the purchasing entity. Bulk purchasing is most frequently used as a cost containment strategy, frequently in combination with other strategies such as sole tendering, therapeutic substitution, reference-based pricing, restricted formularies, and preferred drug lists.

This study was envisioned as an examination of bulk pharmaceutical purchase agreements in New Zealand, the United States, and Europe, specifically considering how such agreements are used in each jurisdiction, quantifying the savings, and exploring the consequences of employing such agreements. However, the reality of pharmaceutical markets is such that discounts and pricing are extremely nuanced, making a straightforward calculation of bulk purchasing and the associated savings impossible. Specifically, bulk purchase agreements are always combined with multiple other cost-saving strategies, making it virtually impossible to tease out the singular impact or cost savings accruing to the bulk purchase agreement alone. These strategies are pursued by both plan sponsors and suppliers. "A supplier will readily offer discounts, rebates, or kickbacks in exchange for contractually binding purchasing agreements" (Kittridge, Rivera, Coyle, and Zucarelli, 2011: 31). The Academy of Managed Care Pharmacy (AMCP) describes how managed care drug benefit coverage programs routinely incorporate numerous strategies, frequently in tandem, to manage pharmaceutical costs. The mechanisms used include formularies or preferred drug lists, volume discounts, negotiating maximum allowable cost, working with prescribers to ensure appropriate drug usage, promotion of generic medications, disease management and medication therapy management programs, prior authorization, drug utilization review, and negotiating bulk discounts and other contracts with pharmaceutical manufacturers to obtain lower prices (AMCP [no date]: 2). This study finds that government, state, provincial, and municipal entities use combinations of these strategies.

For some perspective on the multiplicity of regulations that government policymakers employ to manage pharmaceutical expenditures, table 1 lists the variety of supply-side and demand-side measures available.

Accordingly, this study describes the comprehensive strategies used in New Zealand, the United States and a selection of European countries. The analysis aims to describe the specific strategies in use in each jurisdiction and quantify the impact of those in use. While a systematic analysis of bulk purchase agreements is impossible, this study gathers ample anecdotal evidence to establish that bulk purchase agreements consistently generate cost savings. This is demonstrated with an exploration of

Table 1: Overview of Regulation on the Supply- and Demand-Side

Supply-side	Demand-side
Price Controls	**Physicians**
Based on:	Clinical practice
Clinical performance	Prescription guidelines
Economic performance	Education
Cost of existing treatments	Information
Cost-plus calculations	Monitoring/audit
International prices	Prescription quotas
Controlled price update	Pharmaceutical budgeting
Free Pricing	Overall budgets
Expenditure Control	**Patients**
Discounts	Cost sharing
Rebates	Information
Pay-back	Education
Price-volume agreements	OTC spending
Price freeze/price cuts	
Industrial Regulation	**Pharmacies**
Profit controls/Rate of return	Generic Substitutions
Tax benefits	Monetary Incentives
	Claw-backs
	Margins
	Discounts

Source: von der Schulenburg, Vandorors, and Kanavos, 2011: 3. Reproduced with permission.

the specific strategies used, and under what conditions, in each of the three regions. In order to understand the variety of strategies employed it is necessary to define the mechanisms used and describe the unique characteristics that apply to each. These definitions follow.

Drug formularies have become a principal tool for many policymakers seeking to manage pharmaceutical expenditures. A drug formulary is a list of both branded and generic prescription drugs that the plan sponsor (insurer or government) prefers. Prescription coverage may only extend to medicines that are on this preferred list, effectively steering prescribers and patients to the least costly medications sufficiently effective for treating the particular health condition. Drug formularies may either be

"positive" or "negative." As described by Morgan et al. (2006), positive listings indicate which medicines are covered under a given program and provide information about the subsidy level and the conditions under which it applies. Drugs that are not listed are generally not covered. In contrast, in the case of a "negative" formulary, virtually all drugs are covered unless they are listed. Centralized reviews are used in both cases to determine which drugs will be placed on the formulary, to either receive or be excluded from coverage. For negative formularies, drugs need not be formally reviewed to be eligible for coverage. Morgan et al. (2007) note that numerous studies have established that when a formulary "is national in scope, potential inclusion on a formulary is a very powerful incentive for manufacturers to price their products competitively" (Morgan et al., 2007: 4).

Closely related to formularies are **preferred drug lists** (PDLs), which are implemented to encourage providers to prescribe and dispense the most clinically appropriate and cost-effective medications, requiring prior authorization for any medication not deemed "preferred." A PDL may be voluntary or mandatory. Under a voluntary preferred drug list, a list of preferred medications is developed and provided to prescribers, but reimbursement of non-preferred medications is not restricted. In this case, the purchasing entity (insurer or government) relies on prescribers to voluntarily change their prescribing habits to favour the drugs on the PDL. Given a mandatory preferred drug list, preferred drugs do not require prior authorization. Preferred drugs may be prescribed and dispensed without any additional verification or clinical documentation. Non-preferred products, however, require prior authorization, a process that may be complex and burdensome. Preferred drugs lists have successfully shifted market share to less-costly preferred products. "In the private-payer marketplace, restrictive formularies typically cause an 80 percent to 90 percent market shift to preferred agents" (Kittridge, Rivera, Coyle, and Zucarelli, 2011: 21).

Tendering is a process in which a purchasing entity (insurer or government) negotiates the lowest price for a pharmaceutical product. Frequently the lowest bidder becomes the sole tender and its drug is the only one available from a specific therapeutic class of drugs to patients participating in the drug plan (Better Pharmacare Coalition [BPC], 2010: 2).

Therapeutic reference-based pricing policies are implemented such that insurers or governments reimburse the cost of only one drug, the so-called "reference drug," in an entire class of drugs. This is frequently the least expensive drug within the class (BPC, 2010: 2). Reference-based pricing assumes that drugs within the same therapeutic class are interchangeable, providing the same therapeutic benefits, such that a common level of reimbursement may be established. While drugs within a specific drug class may differ chemically and structurally, they are considered therapeutically equivalent (BPC, 2010: 2). Drug plans employing reference-based pricing may also use therapeutic substitution, which requires patients to start with or switch to the refer-

ence drug, even if it was not the drug within the same therapeutic class prescribed by their doctor. As Ess, Schneeweiss, and Szucs (2003) describe, reference-based pricing systems are characterized by two primary weaknesses: difficulties in applying them to innovative drugs due to a lack of comparable reference drugs, and the establishment of therapeutic equivalence, which is often based on weak data.

It is essential to distinguish therapeutic reference-based pricing policies from **external reference-based pricing**, also known as international reference-based pricing. In the case of the latter, purchasing entities (frequently government health agencies) employ a reimbursement policy under which payers set a maximum reimbursement price based on the comparison of prices across other nations. The selection of countries is frequently based on a criterion of similar purchasing power.

VanLandingham (2009) outlines a complementary mechanism for capturing additional cost savings. Specifically, he describes how Florida in particular, and other states and entities more generally, could save additional costs by consolidating drug repackaging services. VanLandingham notes that each of several state agencies has a separate contract to dispense drugs. Consolidating the unit dose and prescription dispensing fees paid could result in significant cost savings (VanLandingham, 2009: 9). Moreover, state agencies could recognize further cost savings with a coordinated statewide formulary. State agencies frequently establish different formularies, resulting in additional formulary management and prescribing policymaking costs. More closely aligning state formularies would allow for more effective drug use management and more rapid adoption of best practices. This, however, is not without its own complications and risks. As McKesson noted in a 2010 study, "there may be a small economic advantage to buying in bulk and repackaging discretionary oral solid medications when the acquisition cost differential approaches $0.20 or more per dose. However, this advantage may be offset or more than offset by the increased risk inherent in the additional packaging responsibility, since any medication packaging error can affect patient care and safety" (McKesson, 2010: 8).

Negotiated discounts and rebates are applied based on volume, prompt payment, and market share. For example, the pharmaceutical manufacturers who wish to have their drugs covered by Medicaid must provide rebates to state Medicaid programs for medication purchases. Moreover, many states have negotiated additional, supplemental rebates (Kaiser Family Foundation, 2010: 6). Rebates are broadly defined as discounts that are provided following a purchase, based on volume, market share, and other parameters. Rebate discounts is the mechanism pharmaceutical manufacturers use most frequently to provide lower drug prices (AMCP [no date]: 5).

Pharmaceutical manufacturers use **market share rebates**, also known as "incentive formulary rebates," to increase a specific drug's market share relative to a competitor's drugs within a particular drug plan (AMCP [no date]: 7).

Beyond the use of multiple strategies, which complicate the measurement of the direct impact of bulk purchasing, cost savings estimates are difficult to come by. Such calculations are complicated by the different methods of bulk procurement and by the fact that much of the most desirable information is unavailable. For instance, when tasked with conducting a full audit of prescription drug costs, the Office of the Utah Legislative Auditor General encountered numerous obstacles that ultimately prevented the completion of the audit. Table 2 presents the inaccessible information and the reasons for the lack of availability.

Despite the numerous challenges in evaluating bulk purchase agreements, a significant number of informative studies are available, providing evidence of the benefits of such agreements. At the same time, these savings are not accrued without potential

Table 2: Obstacles that Prevented a Full Audit of Prescription Drug Costs
The lack of accessible data among fully-insured state-funded entities prevented a full audit

Information not accessible	Reason information is not accessible	Effect on audit
Actual cost for prescription drug benefits for those fully-insured state-funded entities that are not Public Employees Health Program (PEHP).	Many fully-insured entities contract with the insurance carrier to provide both the prescription drug and medical benefits. The entity does not generally know the cost breakout of the individual benefits.	We cannot accurately determine the cost for prescription drug benefits.
Employee pharmacy cost share and dispensing fee costs per member per month for fully-insured state-funded entities not with PEHP.	Proprietary information between the insurance carrier and pharmacy benefits manager.	We cannot accurately compare prescription drug benefit costs among state-funded entities.
The amount of selected drug discounts applied to the average drug wholesale price for fully-insured entities that are not with PEHP.	Proprietary information between the insurance carrier and pharmacy benefits manager.	We cannot accurately show a difference in the actual cost of specific drugs.
Rebates from drug manufacturers received by the insurance carriers of fully-insured state-funded entities that are not with PEHP.	Proprietary information between the insurance carrier and pharmacy benefits manager.	We cannot verify that rebates received by the insurance carrier are being passed on to the state-funded entities through lower premiums.

Source: Utah, 2006: 7.

costs. Those costs include limited access to medications, reduced medication supplies, risks of shortages, worsening health outcomes, restricted choices, and stifled innovation. The remainder of this study describes the specific strategies in use in New Zealand, the United States, and Europe, and quantifies the impact of those strategies wherever possible. Reforms in New Zealand, dating from the early 1990s, are described first, followed by an exploration of multi-state programs implemented in the United States. The programs in effect in a selection of European countries follow. Finally, the study describes the consequences (both the risks and benefits) stemming from the use of such cost containment strategies.

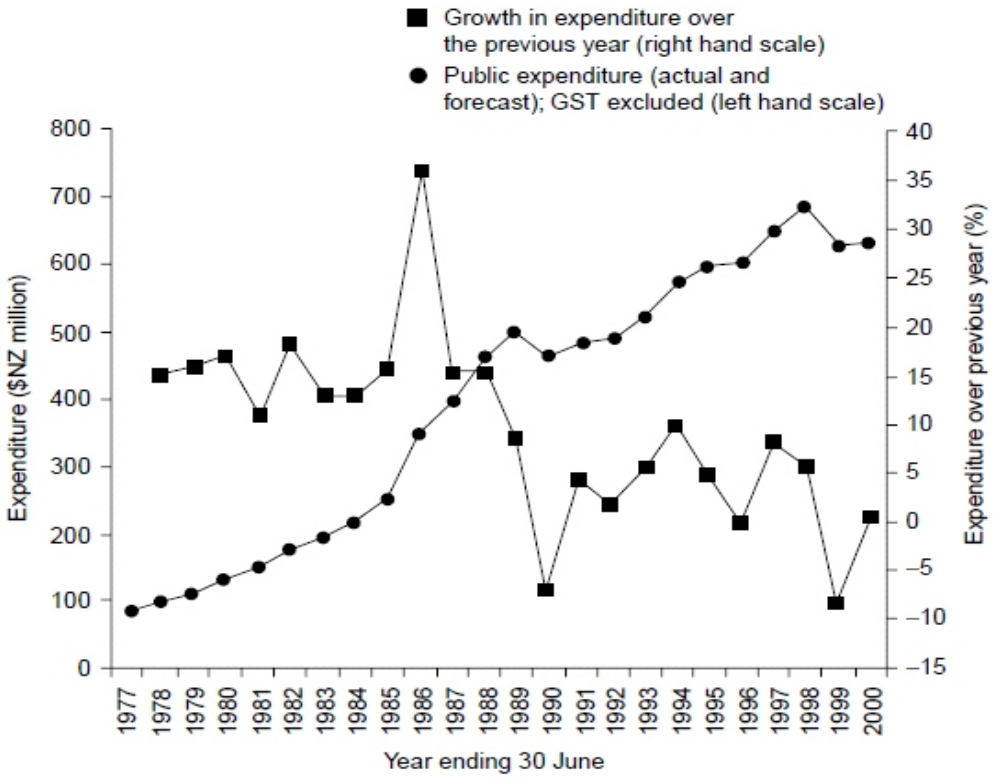
New Zealand

New Zealand provides universal public health insurance through 21 district health boards which also pay for medicines. These district health boards are required to provide the drug subsidies published in the national Pharmaceutical Schedule. Close to 80 percent of all of New Zealand's pharmaceutical expenditures are funded in this way, while the remainder are covered by patient co-payments and charges for drugs outside the Pharmaceutical Schedule (Morgan et al., 2007). Following a period of industry litigation and unsustainable budgetary increases, the Pharmaceutical Management Agency of New Zealand (PHARMAC) was established as a non-profit government agency in 1993 to improve the management of the Pharmaceutical Schedule and stem the growth of pharmaceutical expenditures. PHARMAC itself is governed by the district health boards and has had great success in managing pharmaceutical expenditures while maintaining universal access. The New Zealand experience demonstrates that strong negotiations, under particular circumstances, can reduce pharmaceutical expenditures by up to 90 percent on some drugs (Fayerman, 2007).[1] PHARMAC has successfully controlled pharmaceutical expenditures, "saving the equivalent of its originally allocated budget every year, despite a 50% increase in volumes" (Davis, 2004: 171). The results were apparent almost immediately. Figures 1 and 2 represent the dramatic impact of PHARMAC policies, illustrating public expenditures and growth in expenditures, as well as the changes in price and volume over time. Figure 1 shows that government spending on pharmaceuticals grew at a rate of 20 percent per year through the 1980s, numbers that dropped after the establishment of PHARMAC.

PHARMAC uses a variety of strategies to accomplish its dual objectives: management of pharmaceutical expenditures and maintenance of universal access. Primary among these strategies is PHARMAC's national formulary. PHARMAC makes its listing decisions based on population health needs, safety, efficacy, and cost effectiveness. Beyond this, PHARMAC uses negotiated rebates and discounts, package agreements (also known as cross-product or bundling agreements), tendering sole-supply, therapeutic reference pricing, and contracts. Given the combination of policies in use, it is difficult to tease out the precise impact of bulk purchasing. This is further complicated by the lack of information on the rebates and discounts received by PHARMAC and which thereby distort the pricing information and calculations of cost savings.

1 As noted, New Zealand is a small market with no local manufacturing capacity, both of which weaken its negotiating position.

Figure 1: Nominal Subsidized Pharmaceutical Expenditures, excluding Goods and Services Tax

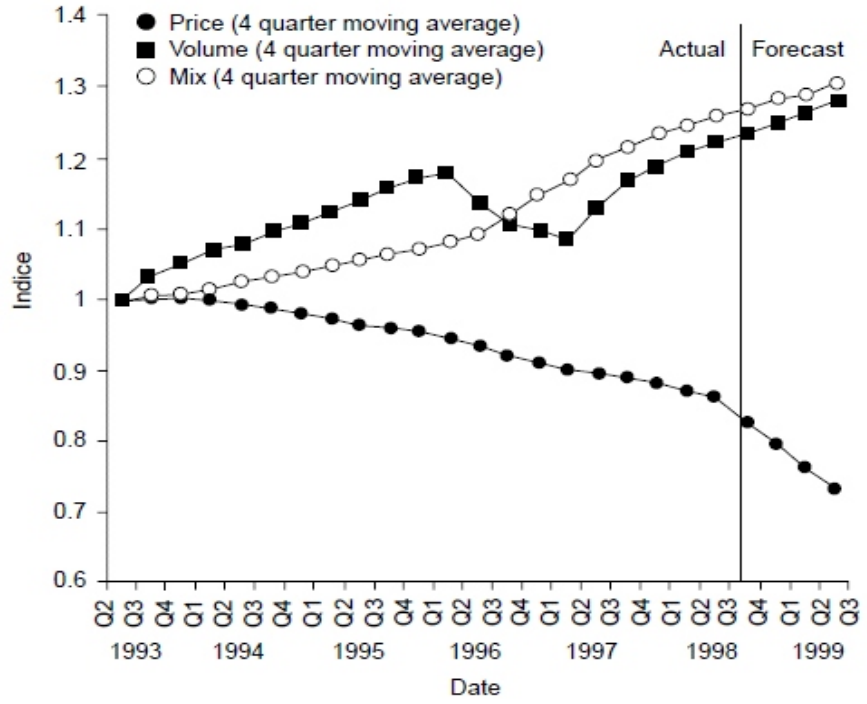


Note: Data for 1999 are estimates and data for 2000 are forecasts. $NZ = New Zealand dollars.
Source: Braae, McNee, and Moore, 1999: 652.

Several important pharmaceutical policies distinguish the New Zealand market. First, whenever possible, New Zealand uses sole tenders to bid down the price of pharmaceutical medications. Through sole tenders, a limited number (or just one) product is procured for each indication. Presumably, the winning bidder provides a lower price in exchange for the opportunity to supply the entire New Zealand market. As Morgan et al. (2007) point out, this auction mechanism for sole-supply can drive prices down to "commodity pricing" levels that characterize perfectly competitive markets and serve as the benchmark of economic efficiency. The first drug put up for tender was paracetamol in 1997. "A price reduction of 44% was achieved ... [and] at a later date for a period of three years, a further price fall of 34% was secured" (Davis, 2004: 176-177).

However, another consequence of this policy is that "patients have no option to pay a premium for their preferred brand; their only choice is to pay the full,

Figure 2: Price, Volume, and Mix Indices for New Zealand Subsidized Pharmaceutical Expenditure



Notes: The price index measures changes in the subsidy level of subsidized pharmaceuticals (weighted by their expenditure). The volume index measures the number of prescription items. The mix index is a residual, derived after calculating the price and volume index, and comparing this with changes in total expenditure. The mix index reflects the composition of drugs being subsidized. Q = quarter.

Source: Braae, McNee, and Moore, 1999: 659.

unsubsidized price for their preferred brand" (Sundakov and Sundakov, 2005: 9). Moreover, reimbursement rates are typically uniform within a therapeutic group since PHARMAC does not increase reimbursements for medicines that have demonstrated greater effectiveness. In addition, the budget for pharmaceuticals managed by PHARMAC is strictly capped. As an autonomous state entity, PHARMAC's mission is to maximize the health impact of prescribed medications by optimizing access subject to their negotiated annual budget.

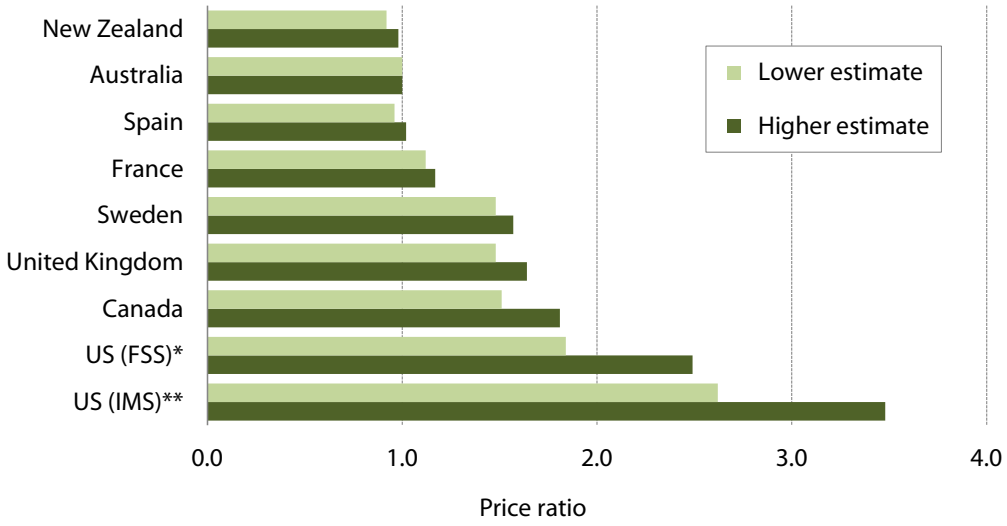
PHARMAC first established a public formulary, the Pharmaceutical Schedule, listing the drugs subject to the government subsidy (either full or partial). New Zealand's "positive" formulary documents the full list of subsidized drugs. As Morgan et al. (2006) describe, positive listings indicate which medicines are covered under a given program, providing information about the subsidy level and the conditions

under which it applies. Drugs that are not listed are generally not covered. Centralized reviews are used to determine which drugs will be placed on the formulary. Braae, McNee, and Moore note that "drugs are assessed for the health gain they provide to patients as well as whether they provide savings in other parts of the system, such as avoided hospitalizations ... the decision criteria exclude the impact on the pharmaceutical industry" (1999: 652-653).

In 1997, New Zealand also adopted therapeutic reference pricing, setting the price for an entire class of drugs by reference to the cheapest drug in the class. PHARMAC is essentially paying for a class or therapeutic effect, encouraging prescribers to use less expensive drugs that are fully subsidized as first-line therapies. Accordingly, PHARMAC endeavors to fully subsidize at least one drug in each reference-priced therapy group (Davis, 2004). The effect is substantial savings, as was seen in 1998 when the reference price for an ACE inhibitor with low market share was reduced 60 percent. The result was an increase in market share from "2% to 47% for the company and a savings of $30 million a year for the drugs budget" (Davis, 2004: 176).

According to Sundakov and Sundakov, "Up to 1997 New Zealand's spending on pharmaceuticals as a proportion of the total health budget was generally in line with the OECD average.... Since 1997, New Zealand has moved dramatically out of line with the OECD. New Zealand's public spending on pharmaceuticals, as a proportion of our total public expenditures on health, is now less than half the OECD average, while our total health spending as a proportion of GDP has remained in line with the OECD trends" (2005: 5). The impact of PHARMAC's strategies is visible in figure 3, which illustrates price differentials for several OECD nations. It is important to note that in 1997 New Zealand prices were between two and five times greater than those in the UK (Braae, McNee & Moore 1999). New Zealand's pharmaceutical expenditure—both as a proportion of total health expenditure and of GDP—decreased significantly in years when these proportions grew in OECD nations in response to innovative treatments and increased reliance on pharmaceutical rather than surgical interventions. While this policy keeps drug prices down, it does risk a single price for a class of drugs that may be so broad as to not be clinically substitutable. As a consequence, New Zealand prescribers and patients face a restricted range and quantity of medications. Not surprisingly, Sundakov and Sundakov report increased costs elsewhere in the health system. This is largely driven by lower health outcomes resulting from limited access to pharmaceuticals, the disruption of established clinical routines, and limited clinical choice, all of which reduce the opportunities for minimizing side effects. Further, non-pharmaceutical treatments and interventions may ultimately cost more than the equivalent medicines-based treatments would have cost. Sundakov and Sundakov cite the case of end-stage renal dialysis in which earlier pharmaceutical interventions alone may save New Zealand tens of millions of dollars in net savings. The fiscal savings from sole tendering and other restrictions on the range of

Figure 3: Price Differences across All Categories of Pharmaceuticals



*FSS = Federal Supply Schedule;

**IMS Health = a leading firm in global pharmaceutical pricing.

Source: Sundakov & Sundakov, 2005: 13. Reproduced with permission.

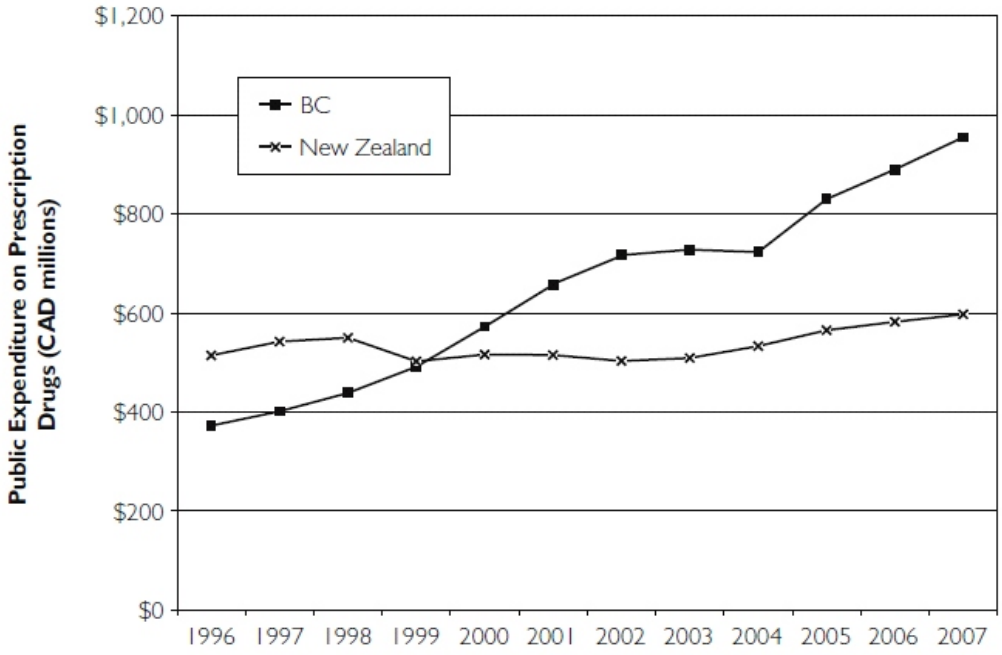
pharmaceuticals available is obvious, but the impact of this policy on patients' health is difficult if not impossible to measure.

New Zealand also takes advantage of negotiated rebates and discounts in order to secure cost-effective prices. These rebates and discounts are not reflected in posted prices and so do not affect the manufacturer's list prices which are used in international reference pricing. PHARMAC also uses expenditure caps to secure rebates. "These act as risk-sharing agreements that ensure that if sales of a listed product exceed an agreed-upon level, the manufacturer is responsible for covering all or part of excess costs" (Morgan et al., 2007: 6).

PHARMAC also uses package agreements (also known as cross-product or bundling agreements) and contracts as formulary-based policies to reduce pharmaceutical costs. Under package agreements, PHARMAC agrees to list a new drug which has been determined to be effective, but not cost-effective, at the posted international price with the concession that the manufacturer discounts another of its currently listed drugs. This process may result in a less effective older drug being funded in one disease area to get a new drug into another disease area.

Through this implicit discount the new product becomes cost-effective for New Zealand, while the manufacturer continues to claim the posted international price (Morgan et al., 2007). In addition, PHARMAC contracts for the majority of its listed products to ensure the product is continuously supplied by the manufacturer. The

Figure 4: Public Drug Expenditures for New Zealand and British Columbia, 1996-2007



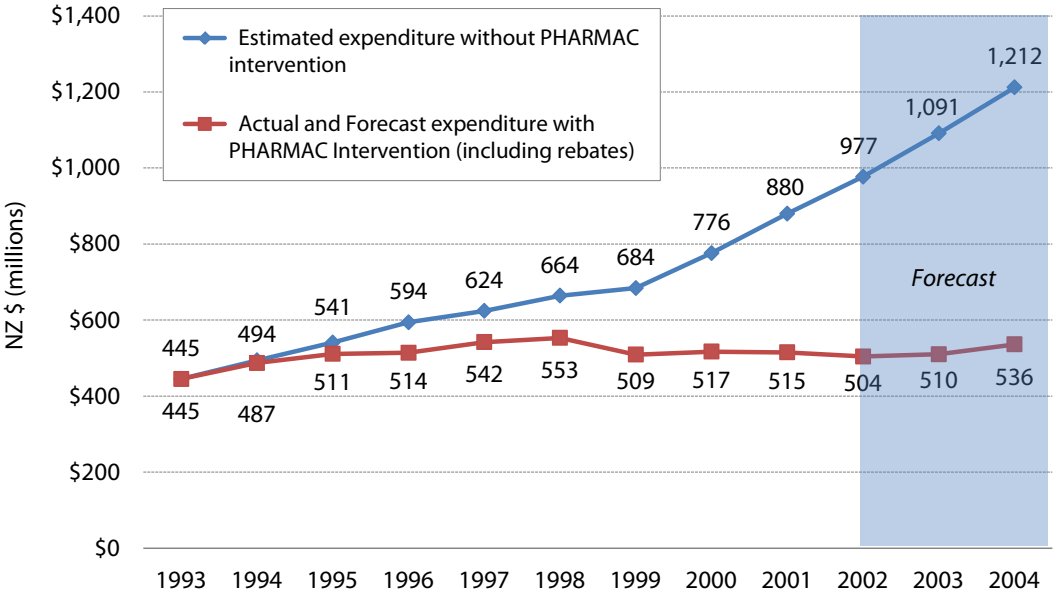
Source: Morgan et al., 2007: 13.

contract may be used to secure a lower price today in exchange for protection against future reference pricing (or other pricing negotiations) for a given period of time into the future (Morgan et al., 2007) .

For perspective on the New Zealand experience, consider a recent study by Morgan, Hanley, McMahon, and Barer (2007). Their analysis examines the potential savings available through formulary-based prices, using Canada as a point of comparison. Relative to British Columbia (a province with a population approximately equal to New Zealand's population), the average price in New Zealand across the four types of drugs was 45 percent lower for branded drugs. For generic products the prices were 58 percent lower, and averaged across both branded and generic versions of the four types of drugs the New Zealand drugs were priced 51 percent lower. Note that PHARMAC funds close to 80 percent of New Zealand drug expenditures, while PharmaCare only funds 43 percent of expenditures in British Columbia. (Morgan et al., 2007: 12).

The growth rate in pharmaceutical expenditures has also been maintained by PHARMAC. "Actual PHARMAC expenditures grew at a rate of 0.5% per year from

Figure 5: Savings Achieved by Price Reductions: Total Subsidized, Non-Hospital-Funded, Drug Cost in Millions of NZ dollars (excluding Goods and Service Tax), Year ending 30 June



Source: Davis, 2004: 178. Reproduced with permission.

1996 to 2004 and are forecast to grow at approximately 3% per annum through 2007" (Morgan et al., 2007: 12). Again, this contrasts dramatically with British Columbia's PharmaCare which experienced growth in provincial drug expenditures of approximately 8.3 percent per year from 1996 to 2004, and which is notably less than the 11 percent Canadian average (Morgan et al., 2007: 12). Annual expenditures are shown in figure 4.

Overall, New Zealand has implemented a highly successful, coherent set of strategies which has enabled the country to simultaneously reign in pharmaceutical expenditures while expanding access. Figure 5 illustrates the savings achieved between 1993 and 2004, contrasting estimated expenditures without PHARMAC intervention to those experienced following the establishment of PHARMAC. These strategies give incentives on both the supply side (manufacturers and retailers) and the demand side (physicians and patients) to adopt policies and behaviours that support PHARMAC objectives. It is, however, important to recognize that these policies did not come without a cost. While they were beneficial to coverage and for taxpayers, they may have had an adverse impact on the disability burden (measured both in terms of disability prevalence and life expectancy with disability) and patient health outcomes. In

addition, these policies angered many physicians who were unable to prescribe the drug of their choosing since the patient would have had to pay out of pocket for the medicine. The following discussion of consequences and risks provides specific examples of negative health outcomes.

Davis (2004) notes that since its inception, PHARMAC has managed pharmaceutical expenditures such that its budget has grown at a rate less than inflation, while expanding the number of available drugs and accommodating approximately a 50% increase in demand. Without these efforts, the pharmaceutical budget would have doubled between 1993 and 2004. The success of New Zealand's policies may also be traced to the limited size of the market and absence of pharmaceutical manufacturing capacity. Small markets are less significant to the industry, both in market sales and in precedent setting. Further, the lack of manufacturing capacity limits the manufacturers' ability to retaliate through domestic industry. While it is impossible to pin down the impact of bulk purchasing exclusively, it is undeniable that the combination of policies employed by PHARMAC secured significant direct savings for New Zealand. At the same time, the nation arguably experienced increases in costs elsewhere in the health care system.

United States

American policymakers are confronted by the increasing costs of pharmaceuticals and the challenges of ensuring access to medicines and quality of care. Escalating drug costs put considerable pressure on state budgets and command the attention of elected officials. As table 3 describes, brand-name pharmaceutical prices in the United States are the highest in the world. While US generic drug prices are among the lowest, overall US drug prices are among the highest in the world. Moreover, they are increasing.[2]

Table 3: Global Prescription Drug Prices

	Prices for 30 most commonly prescribed drugs, 2006-07 (US set at 1.00)*		
	Brand name	**Generic**	**Overall**
Australia	0.40	2.57	0.49
Canada	0.64	1.78	0.77
France	0.32	2.85	0.44
Germany	0.42	3.99	0.76
Netherlands	0.39	1.96	0.45
New Zealand	0.33	0.90	0.34
Switzerland	0.51	3.11	0.63
United Kingdom	0.46	1.75	0.51
United States	1.00	1.00	1.00
Median (countries shown)	0.43	1.96	0.51

*Analysis by G. Anderson of IMS Health Data.
Source: Squires, 2012: 6. Reproduced with permission.

In light of rising costs, bulk purchasing agreements are attracting growing attention. In 1999 the Massachusetts state government authorized a statewide bulk purchase plan, and since that time an increasing number of states and other entities have explored aggregate pharmaceutical purchasing. According to the National Confer-

2 In large part, this stems from the innovation free rider problem. High drug prices in the United States provide the profitability that funds innovation and research, while other nations expend immense effort to purchase drugs nearer to marginal cost.

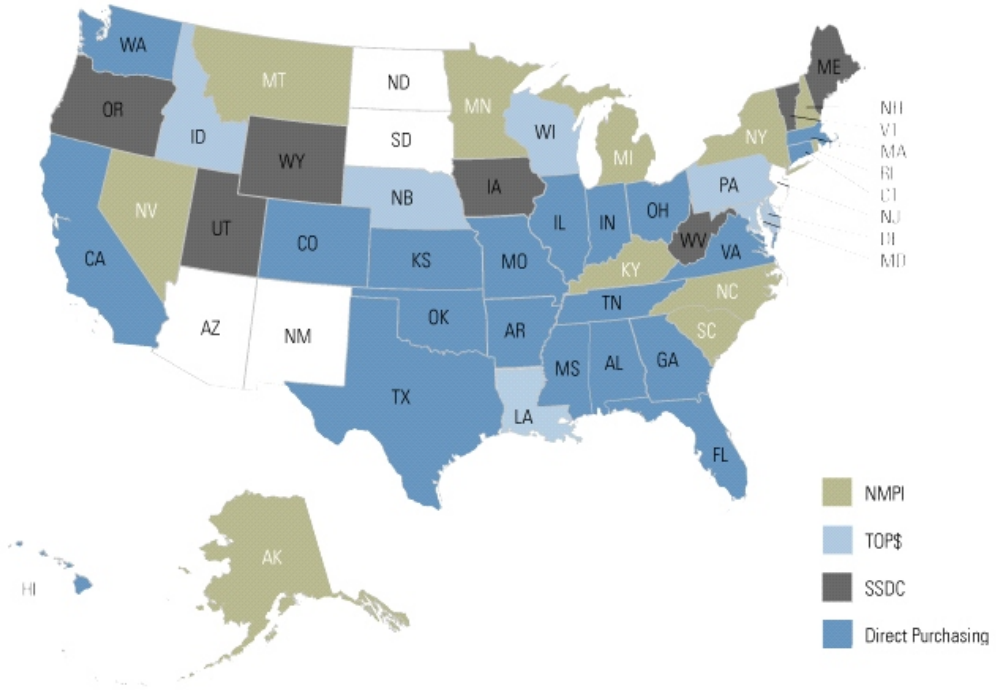
ence of State Legislatures (2012), as of early 2012, five multi-state bulk buying pools are in operation. Numerous single state initiatives are also in effect.

As of early 2012, the programs in operation are:

- The National Medicaid Pooling Initiative (National Medicaid Buying Pool or NMPI or NMBP)
- Top Dollar Program (TOP$)
- The Sovereign States Drug Consortium (SSDC)
- The Northwest Prescription Drug Consortium
- The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)

Kittridge, Rivera, Coyle, and Zucarelli (2011) describe the states that participate in supplemental rebate purchasing pools and direct-purchasing arrangements (see figure 6). The figure includes participation in three programs, as well as direct purchasing arrangements: NMPI (The National Medicaid Pooling Initiative), Top Dollar Program (TOP$), and the Sovereign States Drug Consortium (SSDC).

Figure 6: State Enrollment in Supplemental Rebate Purchasing Pools and Direct-Purchasing Arrangements



Source: Kittridge, Rivera, Coyle, and Zucarelli, 2011: 28.

The National Medicaid Pooling Initiative

The National Medicaid Pooling Initiative began in early 2003 with four states. The total has since increased to ten in addition to the District of Columbia: Alaska, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, North Carolina, Rhode Island, and South Carolina. Six additional states joined but have since withdrawn. The NMPI is a multi-state Medicaid pharmaceutical purchasing pool administered by Magellan Medicaid Administration, Inc./Provider Synergies. As participants in the NMPI, Michigan estimates it will save $8 million on its Medicaid program, Vermont will save $1 million, Alaska estimates $1 million savings in 2004, and Nevada estimates $1.9 million for 2004 and $4.3 million in 2005 (Kasprak, 2005; NCSL, 2012). Upon joining, the New York Department of Health stated, "The preferred drug list could save the state as much as $194 million in fiscal year 2005-06 and $392 million in 2006-07" (NCSL, 2012: 2).

The Top Dollar Program

The Top Dollar Program began in 2005 with Louisiana and Maryland. There are currently eight participating states: Connecticut, Delaware, Idaho, Louisiana, Maryland, Nebraska, Pennsylvania, and Wisconsin. It is administered by Provider Synergies. Louisiana estimates that it will save $27 million in its Medicaid program in 2006, while Maryland reports savings of $19 million in 2006. State Comptroller Kevin Lembo reported that Connecticut can save between $66 million and $80 million by negotiating bulk purchasing and volume-related discounts for the roughly 9 million prescription purchases made by the state's Department of Social Services (Phaneuf, 2011). In 2006, Provider Synergies claimed that a state with an existing preferred drug list typically gains an additional 10% in savings upon joining TOP$ (NCSL, 2012).

The Sovereign States Drug Consortium

The Sovereign States Drug Consortium began in October 2005, founded by the states of Iowa, Maine, and Vermont. There are currently eight participating states: Iowa, Maine, Mississippi, Oregon, Utah, Vermont, West Virginia, and Wyoming. The SSDC is the "first, state-administered multi-state Medicaid supplemental drug rebate pool" (NCSL, 2012: 3). In contrast with vendor-administered pools which are owned by the vender, this program is entirely owned by the participating states. Each participating state has its own preferred drug list. In 2006, Iowa estimates savings of $1.8 million and

Maine calculated savings of $1 million. Utah estimates savings of $1.5 million in 2007 and Vermont received $5.3 million in additional state-negotiated supplemental rebates in 2008 (NCSL, 2012).

The Northwest Prescription Drug Consortium

The Northwest Prescription Drug Consortium began joint purchasing in 2007 with Oregon and Washington. ODS, an Oregon-based pharmacy benefits management company, administers the plan. By the end of August 2008, the Northwest Prescription Drug Consortium enrolled more than 174,000 uninsured or underinsured residents in the discount program and more than 224,000 group members in the pharmacy benefit program. Oregon and Washington residents enrolled in the discount program saved more than $12 million since the inception of the program. (NCSL, 2012).

The Minnesota Multistate Contracting Alliance for Pharmacy

The Minnesota Multistate Contracting Alliance for Pharmacy was founded in 1985 and includes 45 states and the cities of Los Angeles and Chicago. MMCAP is "a voluntary group purchasing organization operated by the State of Minnesota serving government based healthcare facilities. The goal of MMCAP is to provide member organizations the combined purchasing power to receive the best prices available for prescriptions" (Cauchi, 2007: 9). According to Cauchi (2007), MMCAP member facilities purchase more than $800 million in pharmaceuticals per year.

Beyond the cost savings figures, it is important to recognize that bulk purchasing confers indirect savings as well. The concentration of purchases and administrative efficiencies also contribute in important ways to the calculus of bulk purchasing. In the state of Florida, in Fiscal Year 2007-2008, the five state agencies purchasing drugs procured 92 percent of the dollar volume of pharmaceuticals through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) (VanLandingham, 2009: 2).

The MMCAP can claim significant cost savings. Table 4 defines a number of the plethora of relevant US pharmaceutical prices. The most frequently referenced baseline is the "Average Wholesale Price" (AWP), the one referenced by MMCAP in touting the extent of their negotiating power. This table puts other prices in perspective relative to the AWP.

Table 4: National Average Drug Price as a Percentage of Average Wholesale Price

Procurement method	Description	Percentage of average wholesale price
Average wholesale price	National average of list prices charged by wholesalers to pharmacies (i.e., "sticker price")	100%
Average manufacturer price	Average price paid to a manufacturer by a wholesaler for drugs distributed to retail pharmacies	80%
Wholesaler acquisition cost	Price paid by a wholesaler for drugs purchased from manufacturer or other supplier	70%
MMCAP group purchase organization	Price negotiated by MMCAP for drugs purchased from manufacturer or other supplier	60%
Medicaid best price	Lowest price paid to a manufacturer for a brand name drug, taking into account rebates, discounts, and other pricing adjustments, excluding nominal prices	58%
Federal 340B drug pricing program	Prices negotiated by public health service entities	30-50%
Federal Veterans Affairs price	Prices negotiated by the federal Department of Veterans Affairs	45%

Source: VanLandingham, 2009: 4.

According to VanLandingham, "MMCAP reports that it achieves average savings of approximately 23.7% below average wholesale price for brand name pharmaceuticals and 65% below average wholesale price for generic drugs. In addition, participating states achieve administrative savings through lower ordering costs and inventory levels" (2009: 4). In a recent study of MMCAP prices, a consulting firm found its prices to be lower than those achieved by the other four multi-state group-purchasing organizations. "In a market basket of 413 drugs, MMCAP's total prices were 2.8% to 4.4% lower than total prices for the same market basket of drugs from the four other group-purchasing organizations" (VanLandingham, 2009: 4). These numbers are very impressive in light of the prices paid by the US Department of Veterans Affairs, which enjoys the lowest prices available nationally. The US Department of Veterans Affairs

pricing agreements average 45 percent of average wholesale prices (VanLandingham, 2009: 5).[3]

It is important to recognize that there are no direct Medicaid savings to glean from bulk purchasing due to many states' participation in the federal rebate program and legislated pharmacy reimbursement arrangements (Lewis, 2001: 8). Since the states are unable to attain a lower price than that provided through the federal rebate program, or drop their pharmacy rates, participation does not result in additional direct savings. That is, given that states cannot improve upon the federal rebate programs that they already enjoy, or reduce the pharmacy costs, they are unable to capture additional direct savings. However, administrative efficiencies and associated savings are one way in which state Medicaid plans can benefit from aggregate purchasing. Given that administrative costs do not increase linearly with volume, larger pools and greater numbers of participants result in lower per-unit administrative costs.

Beyond the five programs described above, several other multi-state programs are in operation, some have ceased to be operational (due in part to consolidating with other plans), and numerous single-state initiatives are operative. For example, the Rx Issuing States (RXIS) project was led by West Virginia and covered public employees in five states: West Virginia, Delaware, Missouri, New Mexico, and Ohio. West Virginia realized $7 million in net savings in the initial year (July 2002-July 2003) and expected $25 million in net savings over the three-year contract period. Ohio estimated savings at $5 million per year, while Missouri expected savings of $1.4 million in the first year. New Mexico expected $2 million in savings. The agreement was terminated in 2005 and the project is no longer operational (Kasprak, 2005; NCSL, 2012). Ultimately, negotiations with other states regarding adequate preferred drug lists for their populations posed the greatest challenges.

In terms of a single state program, Georgia's Department of Community Health uses a single pharmacy benefits manager to negotiate and manage the prescription drug benefit for state health plans, saving $60 million between October 2000 and January 2003 (Krause, 2004: 1). It is worth noting that a portion of overall savings may be attributed to the negotiation of a more competitive financial arrangement with a single plan administrator. In addition, Georgia has reduced pharmacy cost trends for its Medicaid program of 18 to 25 percent during the first six months of the new program (Lewis, 2001: 17).

Washington's State Health Care Authority began the Prescription Drug Program in 2006 for the state's Medicaid, public employee, and workers' compensation

3 While these figures do represent significant savings to the US federal government\rquote s programs, it is important to note that the average price for conventional retail pharmacies, relative to the AWP, is 83 percent, and for mail order pharmacies the average price is no more than 78 percent of the AWP (Congressional Budget Office, 2007: 4). Given that, VanLandingham may have slightly exaggerated the savings.

programs. The program uses an evidence-based preferred drug list and supplemental rebates, generating annual savings of $22 million for Washington. This amounts to almost 5 percent of its Medicaid fee-for-service drug spending and contributes to $38 million savings in combined state-federal spending (Kittridge, Rivera, Coyle, and Zucarelli, 2011; NCSL, 2012).[4]

In addition, health insurers in the US negotiate bundles of products, which may result in a situation in which the insured receive optimal brands in some areas but less optimal brands in others. This mirrors the fluvastatin case in New Zealand described below in the discussion of consequences, benefits, and risks. The contracts are often negotiated yearly, which can lead to abrupt changes in treatment for insured patients, leading to patient dissatisfaction and a potential for adverse outcomes, including lack of adherence, which in turn can lead to a requirement for more expensive treatment options, such as hospital admission.

Finally, it is essential to recognize that the majority of states employ other strategies to manage rising pharmaceutical costs. Kittridge, Rivera, Coyle, and Zucarelli (2011) note that 45 states and the District of Columbia operate mandatory preferred drug list programs and participate in supplemental rebate arrangements. The only states that do not have preferred drug lists and supplemental rebate arrangements are Arizona, New Jersey, New Mexico, North Dakota, and South Dakota. Table 5 describes the details. Appendix 1 describes each of the state bulk purchasing signed laws and executive orders by state, 1999-2008.

Cauchi reports that bulk savings alone are limited but real, accounting for 2 to 5 percent of pharmaceutical spending. He further notes that every operational Medicaid plan uses preferred drug lists, prior authorization, and supplemental rebates (Cauchi, 2007: 17). As further supporting evidence, in a review of inter- and intra-state programs in the United States, the participating entities report substantial savings from bulk purchasing arrangements in the majority of cases (Canadian Pharmacists Association, 2005: 2). As in New Zealand's case, it is virtually impossible to tease out the singular impact of bulk purchasing. Similarly, comprehensive savings calculations, estimated or actual, are unavailable. Despite promises of significant savings from these

4 For additional information on the specifics of how Medicaid is financed and administered, see www.medicaid.gov. In particular, it is important to note that, "States can impose copayments, coinsurance, deductibles, and other similar charges on most Medicaid-covered benefits, both inpatient and outpatient services, and the amounts that can be charged vary with income. All out-of-pocket charges are based on the individual state's payment for that service. States have the option to establish alternative out-of-pocket costs. These charges may be targeted to certain groups of Medicaid enrollees with income above 100 percent of the federal poverty level. Alternative out-of-pocket costs may be higher than nominal charges depending on the type of service, and they are subject to a cap not exceeding 5 percent of family income. In addition, Medicaid enrollees may be denied services for nonpayment of alternative copayments" (http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Cost-Sharing/Cost-Sharing-Out-of-Pocket-Costs.html).

arrangements, states have failed to monitor (or at least report on) their outcomes. Objective evaluations of whether the promised savings were achieved would be incredibly valuable and should be commissioned. A substantial amount of anecdotal evidence is provided here, but definitive conclusions about the impact of bulk purchasing agreements on US pharmaceutical budgets are illusive, both in terms of their benefits and the negative health consequences.

Table 5: Supplemental Rebate Arrangements, by State

State	Single-State (Effective Date)	Multistate (Effective Date)
Alabama	September 1, 2003	NA
Alaska	NA	January 1, 2004
Arizona	NA	NA
Arkansas	October 15, 2004	NA
California	1980s	NA
Colorado	January 1, 2008	NA
Connecticut	August 1, 2004	NA
Delaware	April 1, 2005	October 1, 2005
District of Columbia	NA	February 1, 2007
Florida	January 1, 2001	NA
Georgia	July 1, 2009	NA
hawaii	NA	April 1, 2004
Idaho	April 1, 2003	May 1, 2006
Illinois	January 1, 2002	NA
Indiana	July 1, 2004	NA
Iowa	November 15, 2004	January 1, 2006
Kansas	October 1, 2002	NA
Kentucky	NA	October 1, 2004
Louisiana	April 1, 2002	October 1, 2004
Maine	January 1, 2003	January 1, 2006
Maryland	July 1, 2003	October 1, 2004
Massachusetts	January 1, 2004	NA
Michigan	NA	October 1, 2003
Minnesota	NA	July 1, 2004
Mississippi	February 1, 2006	NA
Misouri	January 1, 2004	NA

Continued next page ...

Table 5: Supplemental Rebate Arrangements, by State

State	Single-State (Effective Date)	Multistate (Effective Date)
Montana	NA	July 1, 2004
Nebraska	NA	October 1, 2009
Nevada	NA	January 1, 2004
New Hampshire	NA	July 1, 2004
New Jersey	NA	NA
New Mexico	NA	NA
New York	NA	January 1, 2006
North Carolina	NA	October 1, 2009
North Dakota	NA	NA
Ohio	January 1, 2003	NA
Oklahoma	October 1, 2003	NA
Oregon	NA	July 1, 2009
Pennsylvania	October 1, 2005	January 1, 2007
Rhode Island	NA	January 1, 2007
South Carolina	NA	January 1, 2007
South Dakota	NA	NA
Tennessee	July 1, 2003	NA
Texas	November 1, 2003	NA
Utah	August 1, 2007	August 1, 2007
Vermont	NA	January 1, 2006
Virginia	January 4, 2004	NA
Washington	January 1, 2002	NA
West Virginia	April 1, 2002	August 1, 2008
Wisconsin	NA	April 1, 2005
Wyoming	NA	January 1, 2008
Total	28	27

Notes: As of March 2010, NA = No agreement.
Source: Kittridge, Rivera, Coyle, and Zucarelli, 2011: 22.

Europe

As in the cases of New Zealand and the United States, European nations also use a variety of strategies to manage escalating pharmaceutical costs. In a joint report on health systems, the European Commission described the policies as follows:

> Recent years have seen a large number of countries implementing policies to control directly and indirectly pharmaceutical expenditure. However, each Member State has its own unique mix of policies and there is significant variation in the number (presence or absence) of policies they implement. Policy areas to control spending include: direct price regulation, direct expenditure control, extent of coverage and cost-sharing, reference pricing for reimbursement, prescription guidelines, monitoring of prescription behavior and other financial incentives related to the prescription of medicines, incentives to pharmacists, policies related to generic medicines, and information to doctors and patients. (European Commission and the Economic Policy Committee, 2010: 155.)

Admittedly, the number of countries and the variety of policies make a summary analysis very difficult. For example, in the Netherlands the government concluded a multi-party pharmaceuticals agreement to secure savings, while in Germany tendering is a relatively novel concept and the government relies more heavily on a rebate system (Kanavos, Seeley, and Vandoros, 2009). Moreover, numerous studies were available for New Zealand and the United States, and they provided significant anecdotal evidence on the effectiveness of bulk purchase agreements. Unfortunately, despite significant effort, the author was unable to find any studies or documentation on the impact of bulk purchase agreement in European nations.[5]

Given this, this section seeks to illustrate the cost control strategies employed in European nations, focusing on bulk purchase agreement whenever possible. Table 6 lists a variety of discounts and rebates provided to public payers and the nations that use each mechanism.

For additional details, please consult the appendices. Appendix 2 provides additional details on supply-side regulations, focusing on product price regulation, control

5 The current system in the UK is focused on value-based pricing, in which negotiated prices reflect the therapeutic value of the treatment. The existence of this policy greatly complicates any analysis of bulk purchase agreements since purchases are not based on negotiating the lowest price based on volume, but rather on therapeutic value. For this reason, an examination of the UK system is not included here.

Table 6: Types of Discounts and Rebates on Medicines Granted to Public Payers in 31 European Countries, 2011

Types	Countries
Reduction of prices (the controlled price type: i.e. ex-factory price or wholesale/retain prices)	Austria (oi), Bulgaria (oi), Croatia (oi), Cyprus (oi), Czech Republic (oi), Denmark (i), Finland (i), France (oi), Germany (oi), Hungary (oi), Ireland (i), Italy (o[1]i), Netherlands (oi), Norway (oi), Portugal (o), Slovakia (oi), Slovenia (o), Spain (oi), Turkey (oi), United Kingdom (o[2]i)
(Global) reductions of payments to pharmaceutical companies	Austria (o), Germany (o), Hungary (o), Slovenia (o)
In-kind support	Austria (i), Croatia (oi), Cyprus (oi), Finland (i), Netherlands (i), Portugal (i), United Kingdom (i)
Bundling (offering several products for sale as one combined product)	Croatia (oi), Finland (i), Portual (i), Slovenia (o)
Refunds by pharamceutical companies back to public payers depending on the sales volume of medicines	Austria (oi), Belgium (oi), Croatia (oi), France (oi), Germany (o), Ireland (oi), Italy (o), Portugal (oi), Slovenia (o), Spain (oi), United Kingdom[1](o)
Other forms:[3]	
Price-volume agreements	France (o), Germany (o), Hungary (oi), Latvia (oi), Lithuania (oi), Slovenia (o)
Risk-sharing agreements	Germany (o), Italy (o), Slovenia (o), United Kingdom[4](i)
Shared risk of potential overspending of a pre-defined target	France (oi), Croatia (oi), Hungary (oi), Italy (o), Slovenia (o)
Cross product schemes[5]	Croatia (oi), Slovenia (o)
Reduction of wholesale mark-ups (if pharmaceutical company provides wholesale as well)	Slovakia (oi)
All types of discounts allowed (not regulated)	Slovenia (o)
Not Specified	Sweden(i)

[1]Companies could choose between a price cut or payback mechanism (based on Law as July 2006).
[2]Companies could choose between price reduction, price modulation and refund.
[3]Open-ended question: information as provided by respondents whose completeness cannot be guaranteed.
[4]Dose cap schemes, single fixed price, response scheme.
[5]Pharmaceutical companies submit binding offers when they apply for inclusion in the reimbursement list. The application can be connected to a parallel proposal for reduction of a price of a medicine already included in the reimbursement list.
Coverage: All 27 European Union Member States except Poland and Romania plus Albania, Croatia, Iceland, Norway, Switzerland, Turkey, Slovenia—only information on the out-patient sector (discounts and rebates also applied in the in-patient sector).
Abbreviations: o = out-patient sector, i = in-patient sector, oi = out- and in-patient sector.
Source: Volgler, Zimmermann, Habl, Piessnegger, and Bucsics 2012, p.41. Reproduced with permission.

Table 7: Range of Discount and Rebates in 31 European Counties, 2011

Types	Range	Countries
Price reductions on specific medicines resulting from individual negotiations	0-50% of the respective price	Austria, Croatia, Cyprus, Czech Republic, France, Germany, Italy, Norway, Portugal, Slovakia, Slovenia
Price reductions on medicines covered by laws/regulations	3-32.5%	Belgium, Germany, Greece, Hungary, Italy, Portugal, Spain and Turkey
Refunds/pay back mechanisms linked to sales volume of pharmaceutical companies	1-8% of the sales	Austria (~1%), Belgium (6.73%), Croatia (confidential), France, Germany, Ireland (4%), Italy, Portugal, Slovenia, Spain (1.5-2%), United Kingdom

Source: Vogler, Zimmermann, Habl, Piessnegger, and Bucsics, 2012: 42. Reproduced with permission.

of expenditure, industry regulation, and product reimbursement. The table in appendix 2 describes 20 types of regulation and identifies which countries use each strategy. Appendix 3 provides additional details on demand-side regulations, focusing on physicians, patients, and pharmacists. The table in appendix 3 describes 14 types of regulation and indicates which countries use each.

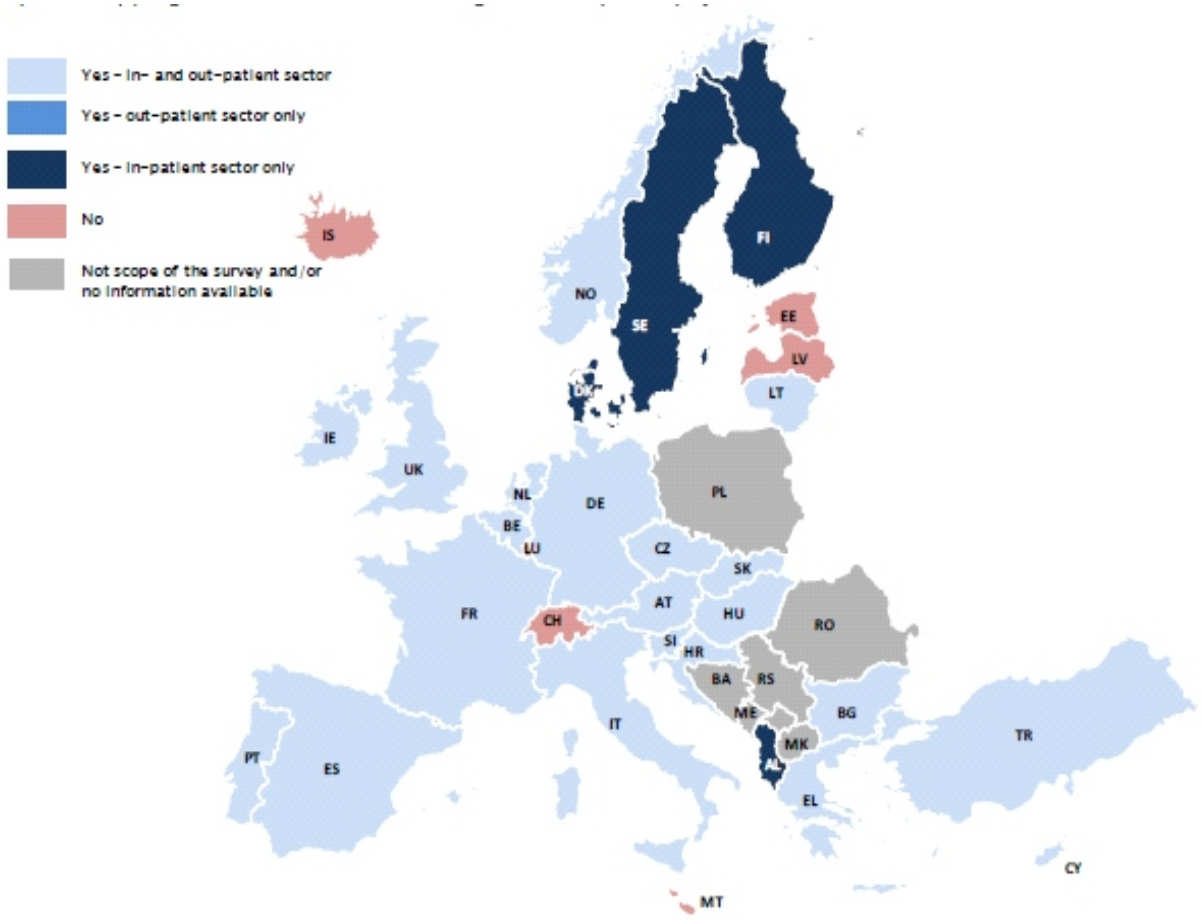
As table 7 describes, European nations achieved the greatest discounts from individual negotiations, ranging from 0 to 50 percent. The savings linked to bulk purchase agreements (sales volume) are limited to 1 to 8 percent. Figure 7 provides a map of the nations that are using these discounts and rebates.

EU member states frequently use external reference pricing. Figure 8 maps the external reference price systems in use by Croatia and Norway and EU member states. Appendix 4 provides an overview of the construction of the national baskets used for external reference pricing in European countries. The number of reference nations varies from one to 26, and the frequency with which a nation is referenced varies from one to 13, with Spain and Germany appearing as the most frequently referenced nations.

Beyond external reference pricing, therapeutic reference-based pricing within drug classes is also widely used in Europe. Table 8 describes the level of equivalence required by each nation, and the year in which therapeutic reference-based pricing regulation began.

The majority of this section describes the tremendous variety of strategies that European nations use, and the combinations of policies that different countries employ. Unfortunately, scant evidence is available on the savings that accrue to these nations from these policies and regulations. Leopold, Habl, and Vogler (2008) describe

Figure 7: European Map Showing the Discounts and Rebates Granted to Public Payers, 2011

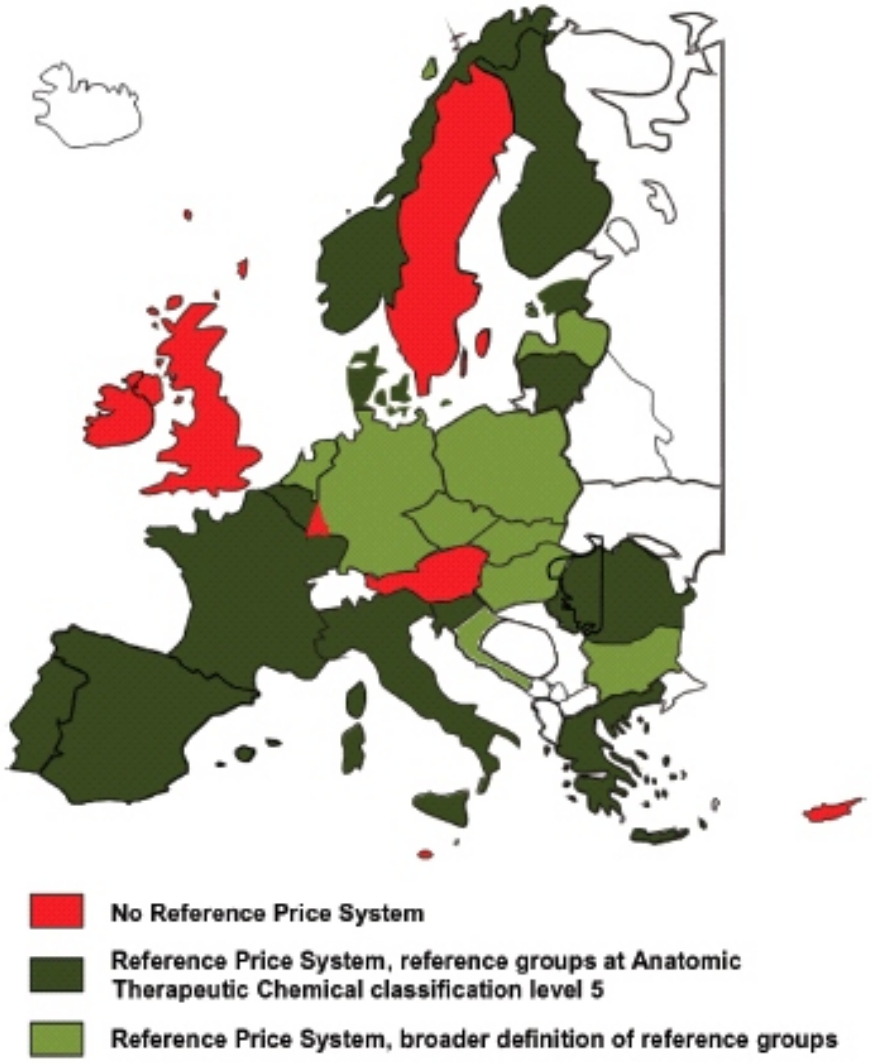


Country abbreviations: AL = Albania, AT = Austria, BA = Bosnia and Herzegovina, BE = Belgium, BG = Bulgario, CH = Switzerland, CY = Cyprus, CZ = Czech Republic, DK = Denmark, DE = Germany, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HR = Croatia, HU = Hungary, IE = Ireland, IS = Iceland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia , ME = Montenegro, MK = Macedonia, MT = Malta, NL = Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, RS = Serbia, SE = Sweden, SI = Slovenia, SK = Slovakia, TR = Turkey, UK = United Kingdom

Discounts and rebates were common in both the out-patient and in-patient sectors. In four, particularly Northern European, countries (Albania, Denmark, Finland, and Sweden), discounts are not applied in the out-patient sector, but only in the in-patient sector. Six countries (Estonia, Iceland, Latvia, Luxembourg, Malta, and Switzerland) reported that no discounts from pharmaceutical companies to public payers existed.

Source: Vogler et al., 2012: 40. Reprinted with permission.

Figure 8: Reference Price Systems in Croatia, Norway, and EU Member States



Note: Data provided and updated by staff and official competent authorities involved in the PPRI/PHIS networks.
Reprinted with permission. Vogler, S (2012). The Impact of pharmaceutical pricing and reimbursement policies on generics uptake: implementation of policy options on generics on 29 European countries – an overview. *Generics and Biosimilars Initiative Journal* (GaBI Journal) 1(2): 93-100. <http://gabi-journal.net/wp-content/uploads/GaBIJ-2012-2-p93-100- SpecialReport-Vogler.pdf>, as of April 26, 2013.

Table 8: Application of Reference Pricing and Generic Price Regulation Systems in the EU

Country	Year reference pricing started	Level of equivalence	Maximum reimbursement rate	Price regulation of generic medicines
Austria		NA	As of third generic, 60% below price of original product	First generic priced 48% lower than original product; second 15% lower than first; third 10% lower than second; fourth and following
Belgium	2001	Chemical	30% below price of original product	Generic priced 30% lower than the original product
Czech Republic	1995	Chemical	pharmacological and therapeutic	Lowest price in group
Denmark	1993	Chemical	Lowest price in reimbursement or substitution group	Generic priced lower than original product
Estonia	2003	Chemical	2nd lowest price in group	NA
Finland	2009	Chemical	Lowest price plus €1.5 (€2 if price > €40)	NA
France	2003	Chemical	Average of generics with one active ingredient	Generic priced 55% lower than original product
Germany	1989	Chemical	pharmacological and therapeutic	Price cap 30% of lowest price in price range of group with chemical equivalence
Greece	2006	Pharmacological	Lowest price in group	Generic priced ≤80% of price or original product
Hungary	1997	Chemical	Price of cheapest product in group	Generic priced 30% lower than original product and no higher than the reference price
Ireland		NA	NA	Generic priced 20% lower than original product
Italy	2001	Chemical	Lowest price in group	Generic priced at least 20% lower than original product
Latvia	2005	Therapeutic	Lowest price in group	NA
Lithuania	2003	Chemical	Lowest price in group	Generic priced 30% lower than original product
Malta		NA	NA	No regulation
Netherlands	1991	Chemical	pharmacological and therapeutic	Lowest price in group

Continued next page ...

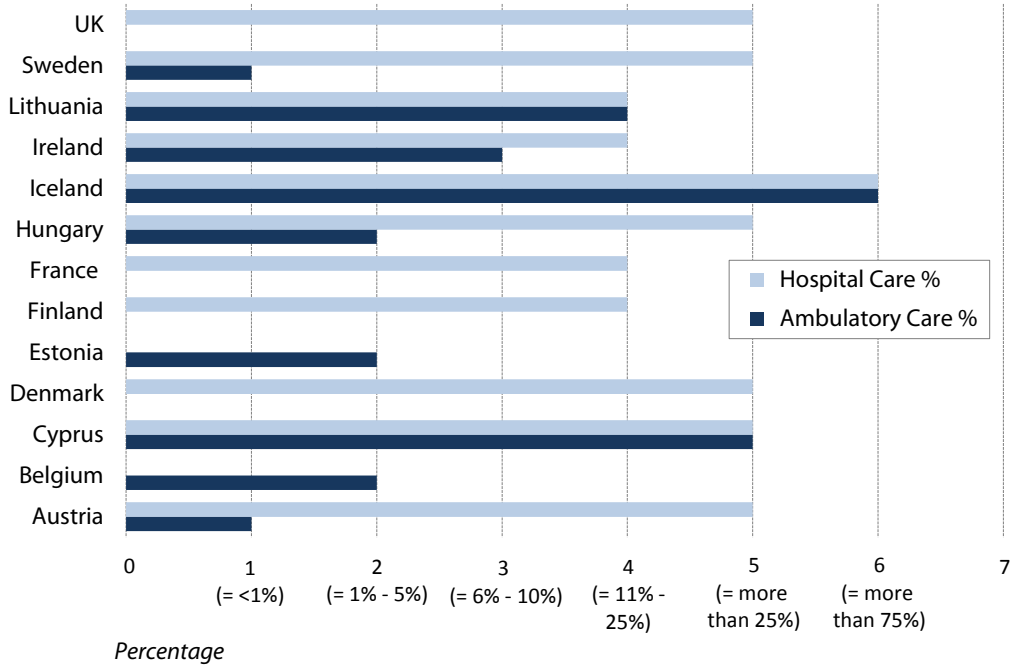
Table 8: Application of Reference Pricing and Generic Price Regulation Systems in the EU

Country	Year reference pricing started	Level of equivalence	Maximum reimbursement rate	Price regulation of generic medicines
Poland	1998	Chemical and pharma-cological	Lowest price in group	NA
Portugal	2003	Chemical	Price of most expensive generic	Generic priced 35% lower than original product
Romania	1997	Chemical	Lowest price in gorup	NA
Slovakia	1995	Chemical and pharmacological	Lowest price (per DDD) in group	NA
Slovenia	2003	Chemical	Price of cheapest generic in group	NA
Spain	2000	Chemical	Average of price of three cheapest products	Generic priced lower than reference price; untransparent criterion before application of reference pricing
Sweden	discontinued in 2002	NA	Compulsory substitution with lowest-priced equivalent product	Free pricing
UK	2005	Drug Tariff Price	Chemical	Weighted average price

Note: No information is available for Cyprus and Luxembourg.
DDD = defined daily dose; NA = not applicable.
Source: Puig-Junoy, 2010: 652. Reproduced with permission.

savings in terms of tendering volume, essentially assuming that the greater the extent of tendering, the more savings are realized. Figure 9 classifies the share of annual total sales for pharmaceuticals that demands tendering. In an effort to understand the quantity of pharmaceuticals that are subject to tendering, nations were asked to classify the share of annual sale of drugs that require tendering. They were given five categories to choose among: smaller than 1 percent of total sales, between 1 and 5 percent of total sales, between 6 and 10 percent of total sales, between 11 and 25 percent of total sales, more than 25 percent of annual sales, and more than 75 percent of annual sales. For example, for eight nations, more than 25 percent of their annual sales of pharmaceuticals for hospital care require tendering. For ambulatory care, the percentage varies much more widely across countries. To put these figures in perspective, the authors note that Hungary, which classifies its annual sales of pharmaceuticals for ambulatory care as 1 to 5 percent, recognized savings of 2 to 3 percent of the total annual pharmaceutical budget.

Figure 9: Overview on the Share of Annual Total Sales for Tendering Pharmaceuticals in Ambulatory and Hospital Care, 2008



Source: Leopold, Habl, and Vogler, 2008: 17. Reproduced with permission.

As do New Zealand and the United States, European nations draw on numerous regulations and strategies, including bulk purchasing, to manage escalating pharmaceutical prices. The number of countries and the details of each nation's policy prescription are beyond the scope of this study. In a study of 31 European nations, Vogler, Zimmermann, Habl, Piessnegger, and Bucsics (2012) do describe the savings linked to bulk purchase agreements (sales volume) as limited to 1 to 8 percent. Greater detail and more transparent calculations are not available, so as a result, we are left with an incomplete picture. However, as Leopold, Habl, and Vogler (2008) describe, European countries seem to have positive experiences with tendering, a strategy frequently used in combination with bulk purchase agreements.

Consequences: Benefits and Risks

The most obvious benefit to bulk purchase agreements is the financial savings that accrue to the plan sponsor. While precise cost savings estimates are difficult to come by, most purchasing entities do report savings. As detailed in a comprehensive report by Silow-Carroll and Alteras, the savings varied across US states, but proved very significant in a number of cases. Michigan experienced savings of $68 million in the first year, while West Virginia estimated savings of $7 million in its first year in the Rx Issuing States program and expected $25 million in net savings over the three-year contract period. Missouri expected savings of $1.4 million in its first year, which amounted to 2 percent of plan cost. New Mexico expected $2 million in savings and Delaware reported $1.9 million in rebates (Silow-Carroll and Alteras, 2004: 2-10). Unfortunately, information is not available on the share of costs savings that these figures represent. In addition, the sources of savings can be both direct and indirect.

As Lewis (2001) described, direct savings result from more competitive discounts, lower dispensing fees from pharmacies, and more competitive administrative fees, while indirect savings stem from the ability to apply consistent and focused pharmacy management strategies across a larger number of participants. Krause (2004) further outlines the benefits realized from bulk purchasing, describing three categories: market power, efficiency, and benefits and care management. Bulk purchasing increases the market clout of purchasing entities and may result in more generous rebates. Administrative costs and fees decrease with the number of covered beneficiaries, increasing the efficiency of the program. Finally, Pharmacy Benefits Managers (PBMs) adopt industry best practices and analyze prescriber habits, both of which enable quality improvements to be implemented.

More theoretical or abstract benefits may also be captured with the adoption of bulk purchasing arrangements. Morgan et al. (2007) argue that since federal, provincial, or territorial drug plans all operate their own formularies, bulk purchase agreements may contribute to greater equity in the medicines available to patients across the covered region. In addition, bulk purchasing may reduce the costs of medicines and consequently help reduce the extent of noncompliance[6] due to cost. *Health Affairs* (2008) reports that relative to patients in seven other countries, chronically ill adults in the United States are far more likely to forego care because of high costs. "More than half (54%) of US chronically ill patients did not get recommended care, fill prescrip-

6 Noncompliance includes prescriptions that are never filled or properly consumed as well as incomplete courses of treatment.

tions, or see a doctor when sick because of the costs, compared to 7 to 36 percent in other countries" (*Health Affairs,* 2008: 1). For the uninsured this percentage increases to 82 percent. In Canada the corresponding percentage is 25 percent. Increased compliance would further reduce health care costs due to the lessened need for hospitalization and physician services that stem from noncompliance.

The numerous benefits of bulk purchasing are widely described in the literature. The World Health Organization and the American Society of Health System Pharmacists (ASHP) both provide excellent, comprehensive descriptions of the advantages of such arrangements. The benefits include:

- Strengthened bargaining position helps ensure that suppliers can no longer exploit inter-country differences; a supplier accepted in one nation is thereby accepted by the other countries and a supplier rejected in one nation is automatically rejected by the others
- Harmonization of drug policies ensure better use of drugs and improved care for patients
- Reduction in costs allows for greater access and more consistent generic substitution
- Standardization of products
- Enhanced information sharing
- Enhanced purchasing experience
- Protracted periods of price protection for purchasers
- Coordinated contracting and budgeting process
- Reduced duplication of purchasing efforts

While the benefits to bulk purchasing agreements are numerous, they do not come without associated medical, financial, and political risks.

A 2005 study by the Canadian Pharmacists Association on bulk purchasing contracts generally reports that such contracts may result in monopolies or limited numbers of drug suppliers. The reduction in competition may lead some manufacturers to exit the market, further restricting opportunities for substitution. When the market is dominated by a single (or a few) manufacturers, the risk is that the supply of a particular drug will be limited. "Experience demonstrates that bulk purchasing contracts often lead to a centralization in manufacturing and distribution, with a market dominated by a very limited number of suppliers of any one drug" (Poston, 2010: 2). Hollis and Grootendorst (2012) observe that sole tendering can lead to the concentration of the domestic generic industry. They describe the situation in New Zealand where almost all tenders are sourced by foreign manufactures and only one domestic generic manufacturer remains in operation.

At the extreme, such concentration may lead to drug shortages when manufacturing problems arise. Indeed, in reality, drug shortages do occur and most commonly result from reliance on a single provider. While this is not uncommon in the global pharmaceutical market, it is more difficult to tease out the factors that lead to a sole supplier. It is virtually impossible to link a specific shortage to the use of bulk purchasing, though logical arguments can be made that one of the consequences of bulk purchasing is a reduction in the number of manufacturers and a greater likelihood of a sole supplier. New Zealand has experienced a number of drug shortages in cases in which the medicine in question was provided by a sole supplier. In 2005, New Zealand's PHARMAC awarded the tender for flu vaccines to Sanofi-Pasteur of France. When all of the vaccines were declared unsuitable, New Zealand was left scrambling to locate an alternative supply. McKay notes that close to one-third of the 2,600 chemicals listed on PHARMAC's Pharmaceutical Schedule were sourced through sole-supply tenders and recounts numerous stories of drug shortages and unavailable pharmaceuticals: "iron tablets, allopurinol for gout prevention, the only stat treatment for chlamydia, certain doses of progesterone, diltiazem" (McKay, 2005: 3). "The numbers of frequently used pharmaceuticals that are unavailable has skyrocketed as sole supply has become more common" (McKay, 2005: 2).

Within the United States numerous drugs are in short supply, and there is increasing evidence that patients are being harmed as a result. A recent study involving Stanford University School of Medicine and Lucile Packard Children's Hospital in Palo Alto, California, indicates that mechlorethamine, a drug given to lymphoma patients as a substitute for a chemotherapy medication (cyclophosphamide) that is in short supply has been linked in a study to an early recurrence of the cancer. US drug shortages stem from various factors, including problems in production, shortages of raw materials, federal recalls, US FDA enforcement actions, and corporate decisions to discontinue certain drugs due to reduced profitability. As Colliver reports, "from 2006 to 2011, the number of pharmaceutical drugs considered in short supply by the US Food and Drug Administration jumped from 70 to 250. Some reports show that the drug shortage rate has slowed, but some drugs that at one point came off the short-supply list are in short supply once again, and many drugs have consistently remained scarce" (2012: 1). Outside of the US, Canada's House of Commons passed a motion concerning drug shortages on March 14, 2012. The motion was prompted by recent events at the Sandoz manufacturing facility, which generated significant drug shortages. The Sandoz plant, based in Quebec, produces 50 percent of the generic injectable medications used in Canada (Smith, 2012). Admittedly, generic injectable medications are a limited, specific case. However, while these cases are not directly linked to bulk purchasing, the risks of pharmaceutical shortages are exacerbated by a sole supplier or single producer.

Beyond drug shortages, sole-supply contracts for therapeutic subgroups, which may be pursued under bulk purchasing to generate further savings, force patients to switch not just from a branded product to a generic version, but frequently to a completely different compound. Maling reports on the ACE inhibitor reference pricing initiative in New Zealand, noting widespread concern for significant health loss. "An evaluation of the brand switch, commissioned by PHARMAC, has recently been released. A disturbing finding was that 30% of the patients did not sustain the initial switch and 11% of those patients with previously controlled blood pressure remained uncontrolled six months after the switch" (Maling, 2002: 12). That is, close to half of all patients either could not tolerate the new medicine or found that it did not control their blood pressure when the previous medication had controlled it.

LeLorier and Rawson (2007) provide preliminary evidence that restricted access to cardiovascular drugs may be associated with markers of declining cardiovascular health in New Zealand.

> As a result of the cost containment system for prescription drugs, fewer new products are available in New Zealand than in Australia and Canada. Eighty-five new drugs were released into the world market between 1994 and 1998, 56 of which were made available for sale in Canada, 43 in Australia, and only 28 in New Zealand... patients in New Zealand are disadvantaged when it comes to access to the newest therapies. In contrast to the evidence that cardiovascular health improved significantly in New Zealand until the early 1990s, our analysis of the OECD health data points to declining cardiovascular health in New Zealand which is supported by other findings. (LeLorier and Rawson, 2007: 717)

Pharmaceutical policies in New Zealand have led to both restricted access to medicines due to the preferred drug list, and to delayed introduction of new innovative medicines, potentially leading to poorer health outcomes and additional expenditures on non-pharmaceutical forms of care.

In a similar incident with statins, in December 1996 fluvastatin became the reference-priced drug and New Zealand and physicians were immediately forced to shift their patients from the drug on which they were stabilized to fluvastatin. The effect was deleterious for many patients.

> Professor Jim Mann from Dunedin published observational data suggesting that the switch to fluvastatin resulted not only in deterioration in control of lipid concentrations in most patients, but also a significant increase in the frequency of thrombotic vascular events compared to the previous six months of simvastatin therapy... This was not surprising because fluvastatin, in its suggested dosage range, operates at a lower part of the dose-response curve than the other statins, and the same lowering of lipids in the same number of people could not be ex-

> pected...The deficiencies of fluvastatin were so marked that they were quickly perceived, not only by practitioners, but presumably also by PHARMAC, who raced to reference price another, more powerful, statin. The statin chosen was atorvastatin—the most potent, and in the doses selected, the most powerful lipid-lowering agent available at the time. The problem with atorvastatin was that, like fluvastatin, its evidence basis was lacking compared with simvastatin and pravastatin. (Begg et al., 2003: 1)

A 2005 Sundakov and Sundakov study adds to the indicative evidence that suggests that restrictions on pharmaceutical availability have had a negative impact on New Zealand's disability burden and health outcomes. Moreover, the authors cite evidence that these restrictions are shifting costs to other, more invasive, costlier treatments: "Non-pharmaceutical treatments and interventions are likely to be costing New Zealand more than the equivalent medicines-based treatments would have cost. For example, reductions in end-stage renal dialysis, which could be achieved with more emphasis on earlier pharmaceutical interventions, may alone generate tens of millions of dollars of net savings" (Sundakov & Sundakov, 2005: 31).

A final concern in the context of prescription choice and availability surrounds patient co-payments. Research from the Better Pharmacare Coalition has shown that bulk purchasing agreements can potentially limit access to other medications that are not included in the purchasing agreements (BPC, 2010). Specifically, prescription costs may shift to patients if the necessary medications are not part of bulk purchasing agreements, thereby requiring higher co-payments, or forcing patients to cover the entire cost of these drugs, or even go without. This cost shift may lead to increased incidents of non-compliance by patients and must be weighed against the potential benefits mentioned earlier. As seen in the cases described above, bulk purchasing agreements may prevent doctors from prescribing the medications that they believe are most effective and beneficial for their patients. Given this, it is essential to account for the cost of *not* providing necessary medications to patients by restricting access and choice. As the Better Pharmacare Coalition notes, "ensuring the right medication at the right time to the right patient ensures better health outcomes, [fewer] doctor visits, [and] less time in emergency, thereby reducing costs to the health system" (BPC, 2010: 4). A primary danger of sole tenders is that patients react differently to different medicines, in terms of both benefits and side effects, leading to the recommendations that multiple medications should be available in each therapeutic class.

Bulk purchase agreements also have the unintended consequence of discouraging pharmaceutical companies from charging lower prices to the uninsured and other marginal users (Cunningham, 2005). A survey by US Public Interest Research Group found that, on average, uninsured Americans pay 60 percent more than what the federal government pays for prescription drugs (Brown, 2006). These prices remain high, in part, due to Medicaid's insistence on the lowest price. While plan participants may

benefit from the lower prices negotiated through bulk purchase agreements, the result may be higher costs for the most vulnerable populations.

Bulk pharmaceutical agreements are frequently accompanied by sole-tendering. A recent study by Hollis and Grootendorst argues that tendering reduces pharmaceutical margins and therefore the advantages to early market entry by generics. Given this, it also exposes potential early generic entrants to additional damages in the event of successful patent infringement litigation. As a consequence, Hollis and Grootendorst predict delayed arrival of low cost generics to markets employing tendering systems. They find supporting evidence in New Zealand, noting that the generic versions of many important drugs arrive much later in New Zealand than other markets, including Canada. For example, Atorvastatin became generically available in New Zealand almost two years later than in Canada, and generic versions of Olanzapine and Venlafaxine became available in New Zealand almost four years later than in Canada (Hollis and Grootendorst, 2012).

While the most significant consequences are medical and financial, bulk purchasing agreements may also generate political consequences. The threat of lower revenues and loss of profits for manufacturers and shareholders may result in increased lobbying efforts. "Firms will thus lobby government, health professionals, patient groups, and the general public to try to muster opposition to any formulary-based policy that requires competitive pricing" (Morgan et al., 2007: 14). The potential for such an industry response is directly correlated with the size and importance of the market. While less in New Zealand due to its small market size and absence of brand name drug manufacturers, nations with larger markets and the presence of brand name drug manufacturers should expect greater industry efforts. Nevertheless, in the early years, New Zealand's PHARMAC was almost constantly plagued by litigation from pharmaceutical companies; defending these efforts accounted for 18 percent of operating costs (Morgan et al., 2006: 177). In the United States, PhRMA, the Pharmaceutical Research and Manufacturers of America, filed lawsuits against Michigan and Florida, challenging the legality of those states' preferred drug lists and imposing significant legal costs on the state plans (Silow-Carroll and Alteras, 2004). The impact of implementing bulk purchase agreements may also extend beyond the adoption of such a policy. Sundakov and Sundakov (2005) describe reservations about the transparency of the New Zealand process for listing new medicines. Specifically, they note growing concern that evaluations of the effectiveness of new medicines is being compromised by judgments about their costs rather than by the relevant clinical considerations.

Finally, there is the question of innovation. On the one side, arguments are made that such price pressure will reduce the incentives for pharmaceutical research and development, stifling innovation and reducing the number of breakthrough therapies in the pipeline. Alternatively, as recently described by the Office of Fair Trade in the United Kingdom, "such value-based pricing and reimbursement policies would

improve innovation by diverting resources from imitative research efforts and related me-too advertising towards the science and product development required to bring break-through drugs for otherwise unmet health needs to market" (Morgan et al., 2007: 14). It is worth noting that duplicative research efforts are not without benefit, to the extent that they change adverse reaction profiles in different population groups. The effect that will dominate is as yet undetermined.

Arguably, the benefits to bulk purchasing and sole tendering can be significant: cost savings, increased patient compliance, information sharing, and organizational and administrative efficiencies. However, it is essential to recognize the risks that may also accompany these benefits. Such agreements may result in limited access to medications, reduced medication supplies, worsening health outcomes, restricted choices, and stifled innovation. Moreover, the limited access to specific drugs may lead to lower quality of life for sick people, as well as reduced productivity. Bulk purchase agreements may also lead to retaliation by innovative pharmaceutical firms that may withdraw investment, with clear political and economic impacts. Accordingly, governments must balance the need to contain costs while maintaining the pharmaceutical industry's investment in plants, equipment, and employees. Clearly any consideration of a bulk purchase agreement requires a thorough, careful analysis of the potential benefits and costs for the specific patient population.

Conclusion

While a great deal of anecdotal evidence is available, a systematic, comprehensive analysis of the benefits of bulk purchasing agreements is impossible. As mentioned repeatedly, while most participants report savings from pharmaceutical bulk purchase agreements, these agreements are rarely used in isolation. As such, the specific combination of strategies employed to control prices must be evaluated in tandem. This study reviewed the experiences of New Zealand, the United States, and Europe, with a focus on reports of actual savings and the consequences of operationalizing bulk purchasing programs. Overall, the reported savings range from modest to quite impressive. Admittedly, the estimates are very sensitive to the specifics of the strategies in use and historic purchasing patterns. Sophisticated existing programs may realize smaller gains, while extensive benefits are available to those programs making more comprehensive reforms. Larger entities may also realize greater benefits. The magnitude of the savings is very sensitive to the extent of changes, the sophistication of the plan, the size of the program, and the starting point. For example, Vogler, Zimmermann, Habl, Piessnegger, and Bucsics (2012) described savings of approximately 1 percent for Austria, while in a 2007 report to the World Health Organization, the Organization of Eastern Caribbean States reported achievements from bulk purchasing including "strong bargaining power, average cost savings of 37 percent for 25 selected items over a five year period, enhanced quality control, sharing of information and experiences and measurable increased access to medicines" (WHO, 2007, p.vii). For industrialized nations, savings are more likely to be in line with the estimates provided by Cauchi (2007), who reports that bulk savings alone are limited but real, accounting for 2 to 5 percent of pharmaceutical spending.

Although this study was unable to quantify the specific impact of bulk purchasing, several unifying themes do emerge from the examination of recent academic articles and government reports on pharmaceutical expenditures. To start, plan sponsors do recognize savings, from both direct and indirect sources. Lewis (2001) describes three sources of direct savings from bulk purchasing agreements. First, provider pharmacies will accept lower reimbursement and dispensing fees in exchange for a larger volume of prescriptions. Second, administrative expenses are reduced when spread over a larger number of units, essentially lowering the per-unit cost through economies of scale. Finally, through increased volume and regional concentration, there is an enhanced opportunity to influence market share, resulting in increased rebates negotiated with pharmaceutical companies. Plan sponsors also benefit from efficiencies in organization, administration, and information sharing. In addition, it appears

that bulk purchase agreements are most effectively, and commonly, used in combination with restricted formularies (either positive or negative) and tendering.

In addition to the benefits, a number of the potential risks to bulk purchasing were echoed time and time again. Monopsony purchasing from a sole supplier may result in limited supplies or shortages. In addition, reduced profitability may result in delayed launch dates for innovative drugs and potentially less research and innovation overall. It is also of utmost importance that policymakers consider the unseen costs of preferred drug lists and the consequences of therapeutic substitution. As the Better Pharmacare Coalition states, "Ensuring the right medication at the right time to the right patient ensures better health outcomes, [fewer] doctor visits, [and] less time in emergency, thereby reducing costs to the health system" (BPC, 2010: 4). Moreover, preferred drug lists may result in drug costs being shifted onto patients—potentially the entire cost of their medications.

Finally, it is worth listing the design factors that most contribute to a successful purchasing pool. As Krause (2004: 3) describes, the elements that are considered important include:

- Volume: greater benefits, lower prices, and larger rebates accrue to larger pools of beneficiaries.
- Technological capacity: sophisticated analysis of beneficiary use and prescriber habits.
- Leadership, cooperation, and political will: necessary for meeting the logistical challenges, especially across state or provincial lines and diverse populations.
- Similar preferred drug lists: savings are maximized when formularies are similar across therapeutic classes.
- Single negotiating entity: one entity to negotiate with pharmaceutical manufacturers to maximize effectiveness.
- Similarity of plans and plan sizes: these commonalities spread the benefits across members of all plans.
- Prioritized savings strategies: savings may come from a variety of sources (lower administrative fees, rebate sharing, disease management, etc.) and pool members must determine what form they will take.

Despite the numerous challenges inherent in an evaluation of bulk purchase agreements, a significant number of informative studies are available, providing evidence of the benefits of such agreements and a glimpse of their potential consequences. This study has described the specific strategies in use in New Zealand, the United States, and Europe, and quantified the impact of those strategies whenever possible. Within the confines of available information this analysis provides perspective on the experiences of several industrialized nations and reveals that in virtually all

cases, bulk purchase agreements provide savings to plan sponsors, but choice and flexibility are often sacrificed. Moreover, important potential but unknown impacts include risks to patient health and well-being, and reductions in pharmaceutical innovation.

Appendix 1: State Bulk Purchasing Signed Laws and Executive Orders by State, 1999-2008

Taken directly from: National Conference of State Legislatures, 2012.

State, Law, Web link	Description / excerpts of bill text
Alabama HB 581 Rep. Beasley (2002)	Authorizes the state to consolidate buying power in pharmaceutical market for price reduction aggregate or negotiate for all state agencies or by "joining a multi-state pooling initiative or both", would authorize the state to negotiate rebates and discounts from pharmaceutical manufacturers. Exempts the Medicaid agency. *(Passed House, 3/19/02, passed Senate 4/11/02; signed into law by governor as* Act No. 2002-494, *4/26/02.)*
Alaska Agency action (2004)	Alaska filed a Medicaid State Plan Amendment to permit coordinated purchasing with the National Medicaid Buying Pool. The application was approved by CMS as of April 2004 and purchasing is operational.
Arkansas HB 2498 Rep. King (2001)	Authorizes the state to join a multi-state or multi-governmental purchasing consortium for the purpose of purchasing pharmaceuticals and other medical supplies; and for other purposes. Also authorizes expanded use, creation or designation of Federally Qualified Health Centers to access "substantially discounted prescription drug prices." *(Passed Senate and House 4/13/01; signed into law by governor as Act 1770)*
Arizona Executive Order (2003)	Gov. Janet Napolitano signed an executive order setting in motion a new program to allow Medicare-eligible seniors to purchase prescription drugs at lower prices through contracts to be administered by Arizona's Health Care Cost Containment System (AHCCCS.) The order "Explore how prescriptions are now purchased through the State and find the most efficient and cost-effective way to buy prescriptions in bulk through one rather than through several State agencies." *(Executive order signed 1/7/03)*

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State, Law, Web link	Description / excerpts of bill text
California SB 1315 Sen. Sher (2002)	Requires the Governor to designate a central purchasing agency for purchasing pharmaceuticals. The bill would require the central purchasing agency to execute prescription drug purchasing agreements with certain state entities that purchase pharmaceuticals, unless the entity can purchase the pharmaceuticals for a lower price than through the central purchasing agency. The bill would authorize the central purchasing agency to include the University of California, local governmental entities, and private entities that choose to participate; also includes authorization to contract with a pharmaceutical benefits manager to negotiate prescription drug contracts. The bill would establish reporting requirements for manufacturers of prescription and wholesale distributors of prescription drugs in the state. *(Passed Senate and House 8/02; signed into law by governor 9/11/02)*
California AB 1959 Assm. Chu (2004)	Requires the State Auditor to conduct audits of the state's prescription drug procurement and reimbursement practices. The audit report shall include: (1) A review of a representative sample of the state's procurement and reimbursement of drugs "to determine whether the state is receiving the best value for the drugs it purchases." (2) A comparison of drug costs to the state with drug costs to other appropriate entities such as the federal government, the Canadian government, and private payers. (3) A determination of whether the state's procurement and reimbursement practices result in savings from strategies such as negotiated discounts, rebates, and contracts with multi-state purchasing organizations, and whether the strategies selected by the state result in the lowest possible costs. A first report is due May 31, 2005. *(Filed 2/12/04; passed Assembly 5/26/04; passed Senate; signed into law by governor as Chapter 938, 9/29/04)*
California AB 76 Assm. Frommer (2005)	Would repeal provisions that authorize the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of drugs, and to obtain discounts, rebates, or refunds. Would create the Office of Pharmaceutical Purchasing within the California Health and Human Services Agency with authority and duties to purchase prescription drugs for state agencies. Would expand the state role to act as purchasing agent for more entities and would authorize the office to "negotiate the lowest prices possible for prescription drugs." Also authorizes establishing "a formulary or formularies for state programs"; Pursuing "all opportunities for the state to achieve savings through the federal 340B program including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving prescription drugs through state programs. It would "develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the program. (Filed 1/3/05; *passed Assembly* 6/2/05; *passed Senate* 9/15/05, *vetoed by governor* 10/7/05)

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State, Law, Web link	Description / excerpts of bill text
California AB 2877 Assm. Frommer	Requires the CA Department of General Services, University of California, and the Public Employees' Retirement System to "regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings." Requires the state to "participate in at least one independent association" that evaluates Rx effectiveness. *(Filed 2/24/06; passed Assembly 5/31/06; passed Senate 22y-14n, 8/31/06; signed into law by governor as Chapter 720 of 2006, 9/29/06)*
Colorado EO 07-04 Gov. Ritter (2007)	Based in part on SB06-01 enacted in 2006, this Executive Order establishes a "preferred drug list for non-Medicare clients receiving drugs through the fee-for-service and primary care physician programs in the Colorado Medical Assistance Program." Requires the Department to "evaluate the various methods by which a PDL is implemented and maintained and shall determine the best option for Colorado's PDL; also requires obtaining supplemental rebates and an evaluation of the feasibility and cost-effectiveness of entering into one of the existing multi-state purchasing pools. *(Signed by governor as Executive Order 1/31/07)*
Delaware HB 300 (2003)	FY '04 budget authorizes the Department of Health and Social Services to contract with a cooperative Multi-State purchasing contract alliance for the procurement of pharmaceutical products, services and allied supplies. *(Passed House and Senate, signed into law by governor, 6/25/03)* *DE was an operational part of the Rx Issuing states* (RXIS) pool for state employees. The program is no longer operational.
District of Columbia B15-569 Councilmember Catania (2004)	Enacts the Rx Access Act of 2003, requiring the Dept. of Health to run an AccessRx subsidy program; also permits negotiations with other states or jurisdictions for bulk purchasing. Also provides that the Department "shall investigate purchases from outside the U.S. (*Filed 11/4/03; Passed City Council 3/24/04; signed by mayor as* Act 15-410)
Georgia Executive action (2000)	Department of Community Health has developed the consolidated drug-purchasing program in Georgia. Combining Medicaid fee-for-service, the public employees and the university teachers, the number of enrollees included in the state drug plan was reported to be 1.2 million as of March 2001. Medicaid is not included in the most recent structure. Express Scripts is the pharmacy benefits manager (PBM) for the program.
Idaho HCR 26 Rep. Henbest (2001)	Resolution encourages the Governor and the Department of Health and Welfare to "develop a compact with our sister states to facilitate purchases of prescription drugs by the most economic method. Sponsors claimed that "this coalition would ease the rising prices of current prescription drugs on Idaho residents, especially Idaho senior citizens." *(Adopted by House, 3/5/01 and Senate, 3/13/01; to Secretary of State, 3/19/01)*

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State, Law, Web link	Description / excerpts of bill text
Illinois SB 3 Sen. Halvorson (2003)	Establishes the Senior Citizens and Disabled Persons Prescription Drug Discount Program Act, requiring the state to "negotiate and enter into rebate agreements with drug manufacturers" to effect prescription drug price discounts, with enrollees receiving the resulting discount. The plan includes multi-agency bulk buying, with details to be finalized by the executive branch. *(Passed House and Senate 5/15/03; signed into law by governor 6/16/03 as Public Act 93-18)*
Indiana HB 1265 Rep. Kersey (2004)	Requires the state personnel department to establish a bulk prescription drug purchasing program to negotiate terms related to the purchase of prescription drugs; requires participation by certain entities and allows participation by other certain entities; authorizes the state to enter into multi-state prescription drug bulk purchasing agreements. *(Passed House 2/5/04; passed Senate 2/24/04; signed into law by governor as Public Law 50, 3/16/04)* *Related News:* Bill proposed to lower drug costs:Democratic leader wants to add small businesses, nonprofits to buying pool. - NW Indiana Times, 9/3/04
Iowa H 619 Health Committee (2003) HF 2192 Committee (2002)	**HF 619** establishes a multi-agency bulk purchasing council, as well as creates a preferred drug list, increased co-pays and other changes in pharmacy reimbursements for Medicaid. *(Filed 3/18; passed House 4/2/03; passed Senate 4/14/03; signed into law by governor 5/2/03)* **HF 2192** creates the Interstate Prescription Drug Purchasing Cooperative Work Group to determine the feasibility of establishing an interstate prescription drug purchasing cooperative with other Midwestern states. Would include "utilizing regional and national entities such as the Council of State Governments, the National Conference of State Legislatures, and others in establishing contact with the governors and legislative leaders of other Midwestern states"; and other states with existing interstate cooperatives, including the states participating in the tri-state coalition and the northeast legislative association on prescription drug prices. *(HF 2192 amended passed House, 2/12/02; passed Senate 3/18/02; signed into law by governor, 5/11/02)* Report on Interstate Prescription Drugs - January 2003 [16 pages]
Maine S1026;Chapter 786 (2000)	§ 2: Purchasing alliances and regional strategies. Authorizes the state to decrease prescription drug prices through purchasing alliances and other regional strategies with other states and private and public entities. *(Passed House and Senate, signed by into law governor, 5/11/2000. Parts of the law were adjudicated by the U.S. Supreme Court in a May 2003 decision, but section two appears not to be affected.)*

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State, Law, Web link	Description / excerpts of bill text
Maine H 343 (2005)	FY06 budget (in §165) establishes the joint purchasing effort of the Pharmaceutical Cost Management Council, to "develop options to maximize cost effectiveness" for all publicly sponsored purchases. *(Filed and approved by House and Senate 3/30/05; signed into law by governor as Chapter 12, 3/31/05)*
Maine H 1591 (2008) Rep. Sharon Treat	Reduces cost of prescription drugs purchased by state and counties by expanding access to discounted prescription drugs; requires that counties and the Dept. of Corrections contract only with entities that are eligible to participate in the purchase of prescription drugs; directs the Dept. of Health and Human Services and Dept. of Corrections to each develop a plan to maximize access to prescription drugs. (*Filed 2/25/08; signed into law by governor as Chapter 43, 4/16.08)*
Maryland HB 1287 Del. Rudolph (2005)	Establishes the Maryland Rx program "to achieve savings on the cost of prescription drugs for the State Employee and Retiree Health Program and local governments, through use of PDLs, manufacturer rebates, negotiated discounts and other cost savings measures. (*Original language deleted*: would have included private businesses and use of evidence-based analysis of products.) (*Filed 2/11/05; passed House 135y-0n, 3/26/05; passed Senate 47y-0n, 4/8/05; signed into law by governor as Chapter 428 of 2005, 5/10/05)*
Massachusetts H. 4900 (1999)	FY 2000 budget section 271 creates a state "aggregate" or bulk purchasing program, to include Senior Pharmacy Assistance enrollees, Medicare and Medicaid, state workers, uninsured and underinsured people. Up to an estimated 1.6 million people would be involved, with eventual total savings for individuals and government as high as $200 million; also creates a temporary Catastrophic Prescription coverage plan and expands Senior Pharmacy program from $30 million to $72 million. *(Enacted and signed into law as Ch. 127 by governor 11/16/99; implementation on hold by executive agencies and two changes in governor, 2000-2004)*
Massachusetts H. 4004 Conference Committee (2003)	The FY04 budget, section 19 requires executive agencies to "develop and implement a coordinated prescription drug procurement plan for all pharmacy benefit plans funded or subsidized, in whole or in part, by the commonwealth. The plan shall maximize cost savings, efficiencies, affordability and be designed to improve health outcomes, benefits and coverage in the pharmacy benefit plans. Also mandates that the state "shall contract with a third party nonprofit pharmacy benefits manager to provide pharmacy benefit management services and negotiate pharmaceutical discounts, rebates and other prescription related cost savings with pharmaceutical manufacturers." *(Finally passed by House and Senate, 6/23/03; signed/vetoed by governor 6/30/03)* *[Became law by veto override 7/06]*

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State, Law, Web link	Description / excerpts of bill text
Massachusetts H. 4850 Conference Comm.	FY05 Budget provides for: (Sec. 15:) Creates a state "coordinated, aggregate prescription drug procurement plan" (bulk purchasing), for all state funded or subsidized pharmaceutical purchases. The plan is to include Medicaid, through a separate managed program. The state shall contract with a PBM, with bidding process to include option of a not-for-profit pharmacy benefit manager. Program is to be operational by November 5, 2004. *(Passed House and Senate, 6/20/04; signed into law by governor 6/26/04)*
Michigan Executive agency (2003)	In February 2003, Michigan's Governor Jennifer Granholm initiated the first multi-state Medicaid purchasing arrangement. The program is run by First Health Services, and is partnered with Vermont and South Carolina as of December 2003. See National Medicaid Pooling Initiative, above.
Minnesota State Plan Amendment Executive Agency (2004)	The Medicaid agency filed and received approval for a State Plan Amendment that authorized joining the National Medicaid Pooling Initiative, termed the Michigan Multi-State Pooling agreement ("SPA). The state notes that its amendment to the supplemental drug Rebate agreement also has been authorized by CMS." *(Filed with CMS 4/30/04; approved by CMS 9/3/04)*
Mississippi HB 528 (2007)	Requires Medicaid to "establish a mandatory preferred drug list (PDL), with drugs not on the list to "be made available by utilizing prior authorization;" also requires mandatory generic substitution and affirms a 5-drug cap or limit per month only two of which may be brand name products. Authorizes establishing relationships with other states for bulk purchasing, as well as negotiations with other countries "if allowed by federal law or regulation." *(Filed; passed House; passed Senate 3/13/07; signed into law by governor, 4/20/07)*
Montana SB 324 Sen. Pres. Tester (2005)	Authorizes negotiation for discount process and rebates among all state-funded programs using Rx including Medicaid and the SPAP; also creates an SPAP, discount program and clearinghouse. *(Filed 1/28/05; passed Senate 39y-10n, 3/7/05; passed House 92y-10n signed into law by governor 4/19/05)*
Nebraska LB 830 Sen. Lathrop (2008)	Requires that the state "shall negotiate discount prices or rebates for prescription drugs from manufacturers and labelers. A manufacturer or labeler that sells prescription drugs in this state may voluntarily elect to negotiate supplemental rebates" for Medicaid, the new Rx Card and any other state program purchasing Rx. Allows use of Medicaid prior authorization if manufacturers fail to negotiate discounts. Requires the department "Enter into a multistate purchasing pool or contract with a pharmacy benefit manager for negotiated discounts or rebates for all prescription drugs under the medical assistance program in order to achieve the lowest available price for such drugs under such program." Includes proposed $1 million for start-up costs, to be effective January 2009. *(Filed 1/10/08; signed into law by governor 4/17/08)*

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State, Law, Web link	Description / excerpts of bill text
Nevada SB 277 Sen. Wiener (2003)	Requires state agencies to purchase prescription drugs, pharmaceutical services, or medical supplies and related services only through Purchasing Division of Department of Administration, unless they can certify to obtaining a lower price from another source. *(Filed 3/13/03; passed Senate and Assembly; signed into law by governor 5/15/03 as Chapter 97)* | *Update:* Nevada has filed a Medicaid State Plan Amendment to permit coordinated purchasing with the National Medicaid Buying Pool. The application is pending at CMS as of February 2004.
New Hampshire Executive agency (2004)	Gov. Craig Benson announced February 17, 2004 that New Hampshire has filed a Medicaid State Plan Amendment to permit coordinated purchasing with the National Medicaid Buying Pool. The State Plan Amendment #04-05 was approved 7/1/04. The Governor noted that "the state could save up to $15 million a year in Medicaid costs starting next year if it joins the pool. New Hampshire now spends $140 million a year." *(Governor's action, 2/17/04; CMS approval 7/1/04)* "(NH) State Still Mulls Drug Options" - Concord Monitor, February 18, 2004
New Mexico SB 91 Sen. Feldman HB 200 Rep. Picraux (2002)	Establishes the Senior Prescription Drug Program. Eligibility covers persons age sixty-five years or older with no other prescription drug benefit. Directs the Retiree Health Care Authority to administer the program in conjunction with the consolidated purchasing process in the Health Care Purchasing Act. No state funds are appropriated to subsidize drug purchases. [fiscal note] *(Passed House and Senate, 2/02; signed into law by governor as Chapters 75 and 80, 3/5/02)* *Update:* A February 2004 journal article notes that "New Mexico is creating a massive drug-buying pool to cover all 635,000 state residents who get health care coverage from any public entity. Later, the pool may also purchase medications for the state's 400,000 Medicaid recipients." *Drug Benefit Trends 16(1):11-12, 2004.*
Ohio HB 66 (2005)	State budget Sec. 5111.0114(B) provides "The director of job and family services may enter into or administer an agreement or cooperative arrangement with other states to create or join a multiple-state prescription drug purchasing program for the purpose of negotiating with manufacturers of dangerous drugs to receive discounts or rebates for dangerous drugs dispensed under the Medicaid program." (*Passed House and Senate; signed into law by governor 6/30/05)*

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State, Law, Web link	Description / excerpts of bill text
Oregon Ballot Measure 44; Full Text	Allows "Any Oregon Resident Without Prescription Drug Coverage to Participate in Oregon Prescription Drug Program." The 2006 program was limited to Oregon residents who are: a) at least 54 years old; b) earn less than 185% of the federal poverty level (currently $18,130 per individual); and c) have not had private prescription drug coverage for the six months preceding application to the program. Ballot Measure 44 expands the Oregon Prescription Drug Program by removing eligibility requirements so that all Oregonians without prescription drug coverage regardless of age or income may participate. Participation in the Oregon Prescription Drug Program is voluntary. Medicare Part D prescription plan enrollees would be eligible to join. Participants would receive a card to use at participating pharmacies to purchase prescription drugs at the discounted price. *(Passed into law by statewide voter initiative, 11/7/06)*
Pennsylvania (2006)	PA Medicaid joined TOP$, the State Medicaid Pharmaceutical Purchasing Pool administered by Provider Synergies.
Rhode Island (Executive action)	RI Medicaid joined the National Medicaid Pooling Initiative in 2006.
South Carolina S 317 Sen. Elliott (2003)	Creates the Interstate Bulk Prescription Drug Program with neighboring states to provide prescription drugs at a reduced cost to senior and disabled residents who do not have prescription drug coverage. The program is not specifically connected with Medicaid. *(Passed House 5/21/03; passed Senate 6/3/03; signed into law by governor 6/17/03)* |
South Carolina HB 3221 Rep. Clemmons (2006)	Requires that the South Carolina Retirees and Individuals Pooling Together For Savings Act (SCRIPTS) and the SILVERxCARD subsidy program must coordinate with Medicare part D to provide to low income senior residents assistance with the cost of prescription drugs, *(Passed House 5/18/05; passed Senate 2/3/06; signed into law by governor as Ch. 233, 2/21/06)*
Texas HB 915 Rep. Gray (2001)	Authorized creation of a system of bulk purchasing of prescription drugs by state agencies, including Dept. of Health, Mental Health, state employees, retirees, teachers, prison system and any other agency that purchases pharmaceuticals. It established the Interagency Council on Pharmaceuticals Bulk Purchasing, and would use existing distribution networks. The Council "shall investigate" options of expanding Medicaid purchasing, and using DSH and FQHC facilities. Final version includes provisions for manufacturer and wholesaler price reporting and enforcement powers for the Attorney General. [fiscal note online estimates savings of $13 million for first two years] *(Passed House, 4/30/01; passed Senate, signed into law by governor, 6/15/01)* Analysis of Multi-state Medicaid Drug Purchasing Pool - June 2006

Continued next page ...

State, Law, Web link	Description / excerpts of bill text
Utah SB 42 Sen. Christensen (2007)	Allows use of a Preferred Prescription Drug List in Medicaid, which "may include placing some drugs on a preferred drug list to the extent determined appropriate by the department" and repeals 2003 language restricting PDLs. Final version provides a blanket exemption for psychotropic or anti-psychotic drugs and allows prescribers to override restrictions in cases of "medical necessity" when documented in the patient's medical file and by handwriting on the prescription. *(Filed 12/26/06; passed Senate 28y-10n, 1/26/07; passed House 70y-1n, 2/6/07; signed into law by governor as Chapter 385, 3/20/07)*
Vermont H.31 Rep. Koch; Sen. Shumlin (2002)	Authorizes participation and financial support for the Northeast Legislative Association on Prescription Drugs; also names the West Virginia multi-state initiative. State departments are directed to aggregate or combine public and private health benefit plans within and outside the states, to achieve better prices for residents. The law also establishes a discount plan via Medicaid waiver, and requires disclosure of pharmaceutical marketing activities. *(Passed by conference committee, 5/28/02; signed into law by governor 6/13/02)* |
Vermont H. 768 (2004)	FY 2005 Appropriations Act provides (in Sec. 128g) that the Department of Prevention, Assistance, Transition, and Health Access (PATH) is required to study the expansion of federal 340B drug programs, including use in managed care, state bulk purchasing and inmate populations. *(Passed House and Senate 5/20/04, signed into law by governor as Act 122, 6/10/04)*
Vermont S 115 S. Finance Comm. (2007)	Authorizes a joint pharmaceuticals purchasing consortium. Also includes a "plan to inform residents of the availability of health services and 340B prescription prices through federally qualified health centers, aimed at Medicaid, state employees, corrections, workers comp and any other public programs; includes restrictions on "prescription information containing prescriber-identifiable data." *(Passed Senate 28y-1n, 4/4/07; passed House 89y-44n, 5/4/07; signed into law by governor as Chapter 80, 6/9/07)* NEWS UPDATE: VT: Companies sue state over prescription drug law *By Rutland Herald, 8/80/07. Three data-collection companies sued the state of Vermont over a provision in the new prescription drug law that would conceal from public view what drugs doctors are prescribing to their patients.*
Washington SJM 8001 Sen. Franklin (2002)	Resolution, calls for cooperation among Washington, Idaho, Oregon, Alaska and Montana to seek "joint pricing and purchasing agreements for prescription" drugs with savings passed on to consumers. *(Passed Senate, 2/5/02; passed House 3/5/02; signed by President & Speaker)*
Washington SB 6088 Sen. Deccio (2003)	Creates a statewide pharmaceutical discount plan for residents with incomes up to 300% of federal poverty, which includes a provision for voluntary negotiated discounts initiated by the Health Care Authority for multiple state agencies. *(Filed 6/5/03 in special session; passed Senate and House; signed into law by governor 6/26/03)* |

State, Law, Web link	Description / excerpts of bill text
Washington HB 1168 Rep. Appleton (2005)	Authorizes the State Board of Pharmacy to regulate nonresident Canadian pharmacies; authorizes state agencies to "undertake bulk purchasing of drugs approved by the federal FDA from Canadian pharmacies and wholesalers." Effective date: July 24, 2005. *(Filed 1/18/05; HB 1168 passed House 54y-41n, 2/25/05; passed Senate 33y-14n, 4/6/05; signed into law by governor as Chapter 275, 5/4/05)*
Washington SB 5471 Sen. Thibaudeau (2005)	Authorizes a prescription drug purchasing consortium, based upon the evidence-based prescription drug program, with all state agencies required to participate. Voluntary participation is authorized for local governments, private entities, labor unions and for individuals who lack or are underinsured for prescription drug coverage. Uses features of the 2003 state bulk purchasing pool, including a preferred drug list. Effective 7/24/05. *(Passed Senate 25y-24n, 3/10/05; passed House 56y-42n, 4/6/05; signed into law by governor as Chapter 129, 4/21/05)* |
West Virginia S 127 Sen. Tomblin, Gov. Wise (2001)	Allows WV Public Employees Insurance Agency to pursue a multi-state buying pool with all state agencies and institutions, as well as "governments of other states and jurisdictions, and "regional or multistate purchasing alliances". Allows "innovative strategies", such as "enacting fair prescription drug pricing policies" and providing discount prices or rebate programs for seniors" and uninsured. The agency may explore "requiring prescription drug manufacturers to disclose to the state expenditures for advertising, marketing and promotion, as well as for provider incentives and research and development efforts." *(Passed House and Senate; signed into law by governor 5/15/01 as Chapter 97)*
West Virginia HB 4084 Del. Michael (2004)	West Virginia Pharmaceutical Availability and Affordability Act establishes a state-sponsored prescription drug discount card program for residents. It also provides that the state shall "explore the feasibility of using or referencing, the federal supply schedule or Canadian pricing. 4) requires the state to "investigate the feasibility of purchasing prescription drugs from Canada," including feasibility of serving as a wholesale distributor of prescription drugs in the state." *(Passed House 1/22/04; passed Senate 3/13/04, signed by into law governor 4/7/04)*
Wisconsin SB 44 | enrolled (2003) Governor Doyle	2003-4 Budget bill:. Prescription drug cost controls and drug purchasing: authorizes joining a multi-state purchasing group or agreement. Also establishes supplemental rebates for Medicaid, Badger Care and others such as senior pharmacy, if feasible; exempts most mental health drugs from prior authorization [§1393] and makes other pharmaceutical policy change. *(Passed Senate and Assembly; signed into law /partial veto by governor 7/24/03 as Act 33)*
Wyoming	WY joined the Sovereign States Drug Consortium (SSDC) in 2008.

Appendix 2: Overview of Supply-Side Regulation

Appendix 2a: Product Price Regulation

Country	Initial price decision based on clinical performance	Initial price decision based on economic evaluation	Initial price decision based on cost of existing treatments	Initial price decision based on cost-plus calculations	Initial price decision based on international prices	Controlled price updates	Other
Austria	X	X	X		X		X
Belgium	X	X	X		X	X	
Cyprus					X		
Germany				O			
Denmark							X
Estonia		X	X		X		
Greece				X O	X	X	
Spain	X		X	X	X	X	
Finland	X	X	X		X	X	X
France	X		X		X		
Hungary			X		X		
Ireland	X	X	X		X		
Italy	X	X	X		O	X	
Lithuania					X	X	
Latvia	X	X	X			X	
Malta							
Netherlands				X			
Norway					X		
Poland	X				X		
Portugal	X	X	X		X	X	X
Romania					X	X	
Sweden	O	X	O		O		X
Slovakia	X	X			X	X	
Slovenia		X			X	X	X
United Kingdom					X	X	

*X = Currently applied, O = Once applied but discontinued.
Espin & Rovira, 2007: 33.

Appendix 2 (continued)

Appendix 2b: Control of Expenditure

Country	Use of discounts/ rebates	Payback	Price-volume agreements	Use of price-freezes and cuts	Other
Austria	X				X
Belgium		X		X	
Cyprus					
Germany	X			O	X
Denmark			O	O	
Estonia			X		
Greece	X			X	
Spain	X	O	O	X	
Finland				X	
France	X	X	X	X	
Hungary	X	X	X	O	
Ireland	X			X	
Italy	X	X		X	
Lithuania					Other
Latvia			X		
Malta					X
Netherlands			X	X	
Norway			X	X	
Poland					
Portugal		X	X	X	
Romania	X	X		O	
Sweden	O		X		
Slovakia		X			X
Slovenia			O	X	
United Kingdom	X		X		X

*X = Currently applied, O = Once applied but discontinued.
Espin & Rovira, 2007: 33.

Appendix 2 (continued)

Appendix 2c: Industry Regulation and Product Reimbursement

Country	Industry Regulation			Product reimbursement				
	Profit control	Tax benefits	Other	Reference Price System	Positive Lists	Negative Lists	Based on economic evaluation	Other
Austria					X		X	
Belgium		X		X	X		X	
Cyprus	O		X		X			
Germany				X		X		
Denmark				X	X		X	
Estonia				X	X		X	
Greece				X	O		O	
Spain		X		X	O	O		
Finland					X	X	X	
France					X			
Hungary		X		X	X	X	X	
Ireland					X		X	
Italy	X			X	X		X	
Lithuania				X	X		X	
Latvia				X	X		X	X
Malta			X		X		X	
Netherlands		X	X	X		X		
Norway				O	X	X	X	
Poland				X	X		X	
Portugal		X		X	X		X	X
Romania	X	X		X	X	O		
Sweden				O	X		X	
Slovakia			X	X		X		
Slovenia			X	X		X	X	
United Kingdom	X				X			

*X = Currently applied, O = Once applied but discontinued.
Espin & Rovira, 2007: 33.

Appendix 3: Overview of Demand-side Regulation

Country	Physicians							Patients			Pharmacists			
	Clinical practices/ prescriptions Guidelines	Educational and information	Monitoring of prescribing patterns	Prescription quotas	Pharmaceutical budgets	Financial incentives	Other	Information education campaigns	Cost sharing	Other	Generic substitution	Financial incentives	Claw-back	Other
Austria	X	X	X			X		X	X				X	
Belgium	X	X	X	X		X		X	X				X	
Cyprus											X			
Germany	X	X	X	X		X		X	X		X			
Denmark	X	X	X					X	X		X			
Estonia	X	X					X	X	X					
Greece			X					O	X					
Spain	X	X	X	X	X	X		X	X		X	O		X
Finland	X	X	X					X	X		X			X
France	X	X	X					X			X	X		
Hungary	X		X						X		X			
Ireland		X	X			O		X	X			X		
Italy	X	X	X					X	X		X	X	X	
Lithuania	X			O		O			X					
Latvia	X	O	X	X	X			O	X		X			
Malta	X	O	O							X	X			X
Netherlands	X	X	X			X		X	X		X	X	X	
Norway	X	X	X	X					X		X	X		
Poland		X						X	X		X		X	
Portugal	X	X	X				X	X	X	X	X			X
Romania		X	X		X			X	X		X			X
Sweden	X	X	X		X	X		X	X		X			
Slovakia	X	X	X	O	O			X	X		X			
Slovenia	X	X	X								X			X
United Kingdom	X	X	X		X	X		X	X			X	X	

*X = Currently applied, O = Once applied but discontinued.
Espin and Rovira, 2007: 33.

Appendix 4: Overview of Country Baskets in Europe, 2010

Country	Countries in the basket																												Additional countries	Number of countries
	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SE	SL	SK	UK		
Austria		X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X		X	X	X	X		24
Belgium	X			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X		X	X	X	X		24
Bulgaria	X				X					X			X									X	X	X			X	Russia	9
Cyprus[a]	X								X			X													X					4
Czech Republic[b]								X	X	X		X	X		X	X							X							8
Germany																														
Denmark																														
Estonia													X			X		X											Country of origin	4
Greece	X	X	X	X	X	X				X	X	X	X	X	X	X	X	X		X		X	X	X		X	X	X		22
Spain																													Countries of Euro zone	
Finland	X	X				X	X		X	X		X		X	X		X			X	X		X		X			X	IS	16
France						X				X					X													X		4
Hungary	X	X			X	X			X	X		X		X	X							X	X			X	X		1 add	c
Ireland	X	X				X	X			X	X	X								X								X		9
Italy																													Not specified	
Lithuania					X			X					X					X				X					X			6
Luxembourg																													Country of origin	1

Continued next page ...

Appendix 4: Overview of Country Baskets in Europe, 2010

	Countries in the basket																													
Country	**AT**	**BE**	**BG**	**CY**	**CZ**	**DE**	**DK**	**EE**	**EL**	**ES**	**FI**	**FR**	**HU**	**IE**	**IT**	**LT**	**LU**	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SE**	**SL**	**SK**	**UK**	**Additional countries**	**Number of countries**
Latvia								X								X														2
Malta				X	X			X	X				X			X		X				X	X			X	X	X		12
Netherlands		X				X						X																X		4
Norway	X	X				X	X				X			X						X					X			X		9
Poland		X			X	X	X		X	X		X	X	X	X	X	X			X			X		X			X	Switzerland	17
Portugal									X	X		X			X															4
Romania	X	X	X		X	X			X	X			X		X	X						X					X			12
Sweden																														
Slovenia	X					X						X																		3
Slovakia	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X		X		26
United Kingdom																														
Reference frequency	11	10	3	5	10	13	7	7	11	13	6	13	11	8	11	10	6	7	3	8	1	9	10	3	8	6	8	12		

Country abbreviations: AT = Austria, BE = Belgium, BG = Bulgario, CY = Cyprus, CZ = Czech Republic, DE = Germany, DK = Denmark, EE = Estonia, EL = Greece, ES = Spain, FI = Finland, FR = France, HU = Hungary, IE = Ireland, IT = Italy, LT = Lithuania, LU = Luxembourg, LV = Latvia , MT = Malta, NL = Netherlands, NO = Norway, PL = Poland, PT = Portugal, RO = Romania, SE = Sweden, SL = Slovenia, SK = Slovakia, UK = United Kingdom.

[a]Alternative countries: Belgium, Germany, Denmark, Spain, Italy, and Portugal.
[b]Czech Republic: This methodology is only applicable for pricing; for reimbursement prices of all other EU member states are checked and the lowest price per basket is taken.

Source: Leopold, Vogler, Mantel-Teeuwisse, de Joncheere, Leufkens, and Laing,, 2011: 56. Reproduced with permission.

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