Pharmacy Benefits Management in the Veterans Health Administration: 1995 to 2003

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The Department of Veterans Affairs (VA) Pharmacy Benefits Management Strategic Healthcare Group (VA PBM) oversees the formulary for the entire VA system, which serves more than 4 million veterans and provides more than 108 million prescriptions per year. Since its establishment in 1995, the VA PBM has managed pharmaceuticals and pharmaceutical-related policies, including drug safety and efficacy evaluations, pharmacologic management algorithms, and criteria for drug use. These evidence-based practices promote, optimize, and assist VA providers with the safe and appropriate use of pharmaceuticals while allowing for formulary decisions that can result in substantial cost savings. The VA PBM also has utilized various contracting techniques to standardize generic agents as well as specific drugs and drug classes (eg, antihistamines, angiotensin-converting enzyme inhibitors, alpha-blockers, and 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors [statins]). These methods have enabled the VA to save approximately $1.5 billion since 1996 even as drug expenditures continued to rise from roughly $1 billion in fiscal year (FY) 1996 to more than $3 billion in FY 2003. Furthermore, the VA PBM has established an outcomes research section to undertake quality-improvement and safety initiatives that ultimately monitor and determine the clinical impact of formulary decisions on the VA system nationwide. The experiences of this pharmacy benefits program, including clinical and contracting processes/procedures and their impact on the VA healthcare system, are described.

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Prescription drugs constitute a large percentage of the country's overall healthcare spending, as evidenced by double-digit growth rates in the last 6 years.[1] The continued escalation in prescription consumption and spending has gained the attention of policymakers, health plan sponsors, healthcare professionals, and patients. Many US citizens now receive pharmaceuticals through some form of pharmacy benefits management to help achieve cost-effective and high-quality pharmaceutical care. The Department of Veterans Affairs (VA), an organization dedicated to improving the health of our nation's veterans, finds itself at the vanguard of this movement as it has the responsibility to provide all "needed" care to enrolled patients under Public Law 104-262, the *Veterans' Health Care Eligibility Reform Act of 1996.* The term "needed" care refers to "services that will promote, preserve, and restore health…including treatment, procedures, supplies, and services," which encompasses providing and dispensing pharmaceuticals.[2]

As a national healthcare organization, the VA offers a broad array of pharmacy benefits to its patient population (**Table 1**). And, like many other healthcare organizations, the VA has seen its pharmaceutical budget rise dramatically in recent years. For example, drug expenditures in fiscal year (FY) 2003 increased to more than $3 billion from $1.5 billion in 1999 (**Figure 1**), largely driven by rising enrollment of new patients in the VA system. The VA began a national pharmacy benefits management program in 1995 to reduce geographic variability of access to pharmaceuticals across the system, improve the distribution of pharmaceutical agents, promote appropriate drug therapy, and reduce inventory carrying and drug acquisition costs. This article describes the cornerstones of this pharmacy benefits program. We address the question, posed in 1996 by Schulman and colleagues, of how to evaluate pharmacy benefits managers by making explicit the experiences, processes, and procedures that form the core of the VA's Pharmacy Benefits Management Strategic Healthcare Group (VA PBM).[3]

VA PHARMACY BENEFITS MANAGEMENT STRATEGIC HEALTHCARE GROUP

Before 1995, 173 individual VA facilities managed their own pharmaceutical coverage policies via local pharmacy and therapeutics committees. The VA Drug Product and Pharmaceuticals Management division, based in Hines, Illinois, managed and monitored drug usage and purchasing for those facilities, but had no utilization oversight responsibilities. However, in September 1995, Dr. Kenneth Kizer, the VA's former Undersecretary for Health, established the VA PBM,

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Table 1. Department of Veterans Affairs General Pharmacy Utilization Information and Patient Demographics*

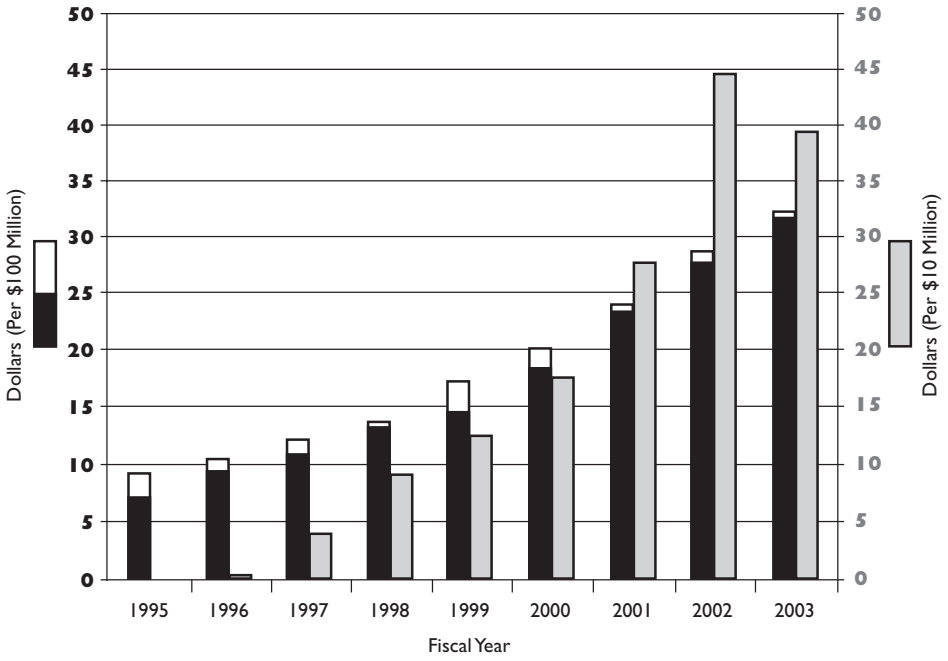
Characteristic	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003
Total enrollees†	4 179 613	4 815 590	6 012 773	6 788 781	7 120 347
Total pharmacy unique patients‡	2 695 241	2 982 676	3 422 751	3 781 286	4 017 776
Total pharmacy unique patients, % change per FY§		10.7%	14.8%	10.5%	6.3%
% Enrollees using the drug benefit‖	64.49%	61.94%	56.92%	55.70%	56.43%
Total actual prescription volume¶	77 877 992	86 045 592	97 971 809	105 499 349	108 349 603
Total actual prescription volume, % change per FY§		10.5%	13.9%	7.7%	2.7%
Thirty-day-equivalent prescription volume	123 963 602	142 184 461	167 483 069	190 836 673	200 021 517
Average prescriptions per pharmacy unique patient#	28.89	28.85	28.62	27.90	26.97
Average cost per actual prescription	$20.74	$21.90	$22.87	$23.79	$26.12
Average cost per pharmacy unique patient per month**	$49.94	$52.64	$54.55	$55.32	$58.70
Patient age††					
<65 y	53.36%	50.97%	48.20%	46.79%	46.72%
≥ 65 y	45.54%	48.09%	50.98%	52.52%	52.59%
Unknown	1.10%	0.94%	0.82%	0.69%	0.69%
Patient sex					
Male	93.77%	93.99%	94.18%	94.51%	94.65%
Female	6.06%	5.89%	5.71%	5.44%	5.34%
Unknown	0.17%	0.12%	0.10%	0.05%	0.01%

*Pharmacy utilization information is from version 3.0 of the Pharmacy Benefit Management Strategic Healthcare Group prescription database (Hines, Ill) from FY 1999 through the present. FY indicates fiscal year.
†Number of eligibles, which includes all veterans enrolled for healthcare benefits, not just pharmacy benefits (ie, readjustment counseling services, prosthetic and sensory aid services, services and aids for blind veterans, home improvements and structural alterations for disabled veterans, alcohol and drug-dependence treatment, mental health psychosocial rehabilitation, outpatient dental services, outpatient pharmacy services, nursing home care, domiciliary care, medical care for dependents and survivors, beneficiary travel to healthcare centers).
‡Any enrolled veteran who is a user of the pharmacy benefit, defined as receiving at least 1 prescription within the system.
§Percent change calculated using prior year data, not a standard reference year.
‖Percentage of eligibles using the drug benefit (user/eligibility ratio), derived by dividing the "total pharmacy unique patients" by the "total enrollees" and multiplying by 100. Pharmacy services comprise only a portion of the healthcare benefits (as listed above) available to enrollees. Veterans enrolled for healthcare benefits in the system may have medical needs not related to pharmacy.
¶Actual prescriptions include those for 30-, 60-, and 90-day supplies. In FY 2003, 40% of total actual prescriptions were for a 90-day supply; 4% were for a 60-day supply; and 56% were for a 30-day supply.
#Derived from dividing "total actual prescription volume" by "total pharmacy unique patients."
**The product of "average cost per actual prescription" and "actual prescriptions per pharmacy unique patient" yields the average cost per pharmacy unique patient. This figure is divided by 12 to give "average cost per pharmacy unique patient per month."
††Age calculations are based on the difference between the date of December 1, 2004, and patients' date of birth. Demographics for veterans who were enrolled for healthcare services but who never got a prescription between October 1, 1998, and December 1, 2004, are not included.

directing it to establish a national formulary; manage pharmaceutical costs, utilization, and related outcomes; and oversee pharmacologic guideline development of common diseases within the VA system. To do so, clinical pharmacists employed at the Drug Product and Pharmaceuticals Management division headquarters collaborated with a newly established consultative body of 11 field-based VA physicians and 1 physician from the Department of Defense. This group became the VA Medical Advisory Panel. This combined entity would later evolve into the VA PBM.

Formulary decisions fall under the purview of 2 groups: the VA PBM and the Veterans Integrated Service Network (VISN) formulary leaders. The VISN formulary leaders manage the pharmacy benefit for VA's 21 regional care systems. Each VISN includes a variety of healthcare centers such as tertiary facilities, ambulatory-care centers, and associated community clinics.

Figure 1. Total Drug Expenditures and Cost Avoidance



Black bars indicate expenditures classified as prime vendor purchases; white bars indicate direct purchases by individual facilities (dollars per $100 million); shaded bars indicate cost avoidance achieved with the contracting initiatives (dollars per $10 million). Total drug expenditures may include pharmaceutical expenditures for state veterans' homes or resulting from state veterans' home purchases, but that portion of the data is not itemized here. These data do not illustrate the influence of the increasing number of users on cost. Expenditure data are from the Pharmacy Benefit Management Strategic Healthcare Group and the VA Total Pharmacy Expenditures for Drugs and Medicine Report, also known as the 887 Report.

Each VISN's formulary committee collaborates with the pharmacy and therapeutics committees of its healthcare centers to allow for integrative, multilevel decision making. Thus, VISNs and local facilities can communicate and provide guidance to the VA PBM, and vice versa, on policies determining drug use within the VA system.

The VA PBM also collaborates with the VA National Acquisition Center for pharmaceutical contracting, establishes clinical guidelines for the VA and Department of Defense, develops criteria for use for new pharmaceutical agents, and maintains a nationwide pharmacy database of patient/provider-specific prescription utilization information for research purposes. We discuss the history and issues in development of each of these below.

NATIONAL FORMULARY DEVELOPMENT

The VA PBM created a VA national formulary to accomplish 2 main goals: to minimize interfacility variation in access to pharmaceuticals and to use VA buying power to leverage contract prices for drugs. These accomplishments occurred in steps. First, in 1996, each VISN established a regional formulary for its facilities, thereby reducing some variation in the pharmacy benefits package. Then, in 1997, the first national formulary was established by assimilating these VISN formularies into a unified list of drugs. This greater uniformity allowed access to the same VA pharmaceutical benefits nationwide. From a system standpoint, this standardization not only defined the core national pharmacy benefits package, but also provided leverage for bulk purchasing, and with that, contracting within drug classes when appropriate. However, to offset concerns about overly centralizing the process and thereby missing opportunities for VISNs to tailor their formularies to local needs, the VA national formulary policy allowed for VISNs to add (but not subtract) pharmaceuticals as needed to match the needs of local patients and resources. In July 2001, the system further evolved to eliminate local drug formularies.

Currently, the VA maintains the VA national formulary and VISN formularies. VISN formularies may list additional drugs and dosage forms not found on the VA national formulary, provided they do not conflict with the VA national formulary (ie, if a mandatory national standardization contract deems an entire VA national formulary drug class as "closed," VISNs may not add noncontracted drugs to the VISN formulary). In addition, a VISN may not add a new molecular entity approved by the Food and Drug Administration (FDA) to its formulary until completion of a national review with specific authorization to do so provided by the VA PBM and VISN formulary leaders. Access to nonformulary drugs occurs locally by either national, VISN, or local criteria.

Standardizing the VA national formulary evoked scrutiny at first, not praise. Veteran, commercial, clinical, and patient advocacy groups expressed concerns about the VA's changes in formulary management. A series of hearings at the congressional level ensued, and in 1999 and 2000, the Senate and House Committees on Veteran Affairs each requested an outside review of the VA national formulary. The House requested an assessment by the US General Accounting Office (GAO), and the Senate by the National Academy of Sciences' Institute of Medicine. These assessments would determine the clinical and economic integrity of the VA national formulary and the formulary management process. Areas of focus included access to formulary and nonformulary drugs, an assessment of the "restrictiveness" of the VA national formulary compared with other government and nongovernment formularies, and the impact of the VA national formulary on the quality of care.

The Institute of Medicine report, released in 2001, concluded that the VA national formulary was not "overly restrictive" with respect to "formulary size and quality, coverage of drugs in different classes, timeliness of new drug additions, fairness and responsiveness of the nonformulary exceptions process, and sensitivity of therapeutic interchange policies and procedures."[4,pp2-3] Per the Institute of Medicine report, from July 1997 through July 1999, only 0.4% (2385 out of 570 937) of all complaints to patient representatives about the VA involved a pharmacy issue.[4]

On the other hand, the Institute of Medicine found inconsistencies in nonformulary use and in guidance for instituting therapeutic interchanges. It also noted the lack of data, both within and external to the VA, measuring the impact of changes in utilization on quality of care and patient satisfaction. Thus, the Institute of Medicine recommended reducing inconsistencies across VISN formularies through more centralized management and by establishing a more timely assessment process for newly approved drugs. They further recommended more research initiatives to generate better data on the safety and efficacy of drug therapy represented on the VA national formulary.[4] The VA largely agreed with the Institute of Medicine recommendations and had already begun to take steps to improve such shortcomings.

The second study, conducted by the GAO, noted that VA national formulary drugs accounted for 90% of outpatient prescriptions dispensed between October 1999 and March 2000 and that the VA national formulary met veterans' needs. However, the GAO reported that local formularies did not always include drugs listed on the VA national formulary, that sites sometimes did not use preferred drugs, and that a wide variation existed in the number of drugs added to VISN formularies (ranging from 5 to 63 over a 3-year period, from June 1997 to March 2000). The GAO also observed variations in nonformulary waiver procedures and in the time needed to process such requests. For example, per prescriber self-reports, the GAO found average approval times ranging from minutes (22%) to a few hours (18%) to more than 1 week (60%). They concluded that the VA national formulary system would benefit by having mechanisms to ensure uniform access to similar drugs across the system, VISN compliance with designated drugs, and improved nonformulary drug approval processes.[5,6]

In response to these reports, the VA PBM instituted several changes. First, the elimination of local facility formularies helped reduce variance within individual VISNs. Thus, no additions or substitutions could occur without VISN approval. Second, to limit variance across VISNs in terms of adding new products, the VA PBM implemented a national review process for all new molecular entities and any other drug deemed important for VA patient care. Third, to ensure a timely review of these new products, the VA PBM removed the 1-year waiting period before consideration of a new product for formulary addition. Fourth, the VA PBM revised its nonformulary policy by requiring quarterly reports of nonformulary approval rates and average review time for such requests (with the goal of a maximum 96-hour turnaround time for nonurgent requests). Last, the VA PBM began to develop an expanded research agenda to measure the effects of the VA national formulary on patient outcomes and safety.

PHARMACEUTICAL CONTRACTING

Standardization of pharmacy benefits through contracting allows for uniformity of generic and branded products as well as price reductions due to bulk purchasing. Other benefits of standardization include ease of access and the ability to provide identical multisource medications from any VA pharmacy or consolidated mail outpatient pharmacy, reducing the risk of patient confusion resulting from different generic or branded products. For instance, in the case of generics, facilities may have dispensed different shapes, colors, and formulations of pharmaceuticals depending on where patients sought care within the VA system. Moreover, pharmaceutical standardization improves drug inventory processes and can reduce inventory management costs.

The most important and most contentious aspect of contracting lies in competitive bidding among branded products within drug classes. Through competitive sourc-

ing, and in collaboration with the National Acquisition Center, the VA PBM estimates that the VA achieved over $1.5 billion in total cost avoidance via national contracting efforts cumulatively from FY 1996 to FY 2003 (Figure 1). This estimate has not been subjected to recent external review, though an earlier assessment by the Institute of Medicine noted an approximate $100 million in savings due to closed and preferred drug classes from 1997 through 1999.[4] The Institute of Medicine also found that contract awards generally reduced pricing by 16% to 41%.[4] As an added benefit, renewable options for up to 4 years have likely led to a reduction in the number of local therapeutic switch programs, which occurred frequently in the past as companies tried to undercut each other's prices in local VA markets.

Contracts have a compelling effect on adherence in the VA. After awarding a national standardization contract, VISNs encourage providers to switch to the contracted agent if clinically appropriate. This, in turn, leads to significant drug acquisition cost savings. As an example, after competitive bidding for proton pump inhibitors in 2001, 95% of patients switched to the contracted agent within 6 months. Patients tolerated this switch well, with only 5% needing another proton pump inhibitor due to suboptimal response or intolerance. This therapeutic interchange generated more than $45 million in cost savings in FY 2001. **Table 2** lists examples of individual drugs/drug classes under contract within the VA from FY 2000 until FY 2003 and corresponding cost avoidances and expenditures (in-house data, the

Table 2. Cost Avoidance and Expenditure History for Contracted Agents From Fiscal Years 2000-2003*

Drug Class or Drug Agent	Cost Avoidance (Cost Expenditures), $				Total Cost Avoidance (Cost Expenditures), $
	FY 2000	FY 2001	FY 2002	FY 2003	
Angiotensin-converting enzyme inhibitors	30 000 591 (32 238 041)	36 881 138 (40 170 004)	44 508 872 (47 482 874)	Contract end	111 390 601 (119 890 919)
Proton pump inhibitors	43 923 966 (95 815 263)	86 241 640 (117 325 949)	153 781 261 (52 223 512)	133 892 545 (114 717 464)	417 839 412 (380 082 188)
Statins	31 310 761 (119 179 917)	51 067 628 (154 377 886)	45 083 526 (179 150 085)	18 455 637 (180 678 069)	145 917 552 (633 385 957)
Diltiazem (short acting)	17 276 288 (11 827 076)	20 921 324 (15 190 816)	22 381 763 (17 224 961)	22 709 812 (18 579 920)	83 289 187 (62 822 773)
Nifedipine (long acting)	3 008 507 (10 707 576)	6 280 481 (15 136 965)	7 358 234 (13 837 616)	2 801 980 (14 057 648)	19 449 202 (53 739 805)
Luteinizing hormone-releasing hormone	21 773 159 (29 947 743)	25 642 779 (34 663 304)	21 356 632 (27 555 473)	7 700 556 (15 745 246)	76 473 126 (107 911 766)
Selective serotonin receptor inhibitors	10 154 420 (not reported)	12 567 399 (not reported)	19 816 312 (141 820 184)	Contract end	42 538 131 (141 820 184)
Dihydropyridine calcium channel blockers (long acting)	12 516 858 (not reported)	9 426 288 (not reported)	21 672 631 (65 430 923)	22 195 235 (65 779 694)	65 811 012 (131 210 617)
Warfarin	1 850 469 (6 121 463)	5 810 141 (8 864 542)	9 116 928 (9 357 380)	9 091 219 (9 778 979)	25 868 757 (34 122 364)
5-HT_3		1 054 122 (3 562 015)	1 435 332 (4 345 970)	1 803 829 (5 379 862)	4 293 283 (13 287 847)
Nonsedating antihistamines		3 628 190 (7 817 291)	15 256 085 (29 356 428)	9 773 269 (26 635 438)	28 657 544) (63 809 157)
Triptans				59 983 (2 210 931)	59 983 (2 210 931)

*Cost avoidance equals the difference between the (1) theoretical cost that would have occurred in a specific FY if a contract had not existed and (2) the actual cost that was incurred in a specific FY for the "market basket" of drugs that pertains to each contract. The theoretical cost for a given FY if a contract had not existed equals the product of (1) the weighted average price per unit that existed during the 3-month period before the contract and the (2) quantity purchased during the FY after the contract took effect. The market basket of drugs includes both the contracted and the noncontracted drugs that pertain to a given contract. The blanket purchase agreements, such as those for selective serotonin receptor inhibitors, dihydropyridine calcium channel blockers (long acting), and warfarin, were not reported until FY 2002. Histamine receptor-2 antagonists and alpha-blockers are not shown in this table as the contract term ended before FY 2000. Cost avoidance due to contracts with generic agents are not shown, but cumulative savings from FY 2000 through FY 2003 reached $324 839 932. FY indicates fiscal year. Data are from Prime Vendor Data, Pharmacy Benefit Management Strategic Healthcare Group and do not include direct purchases.

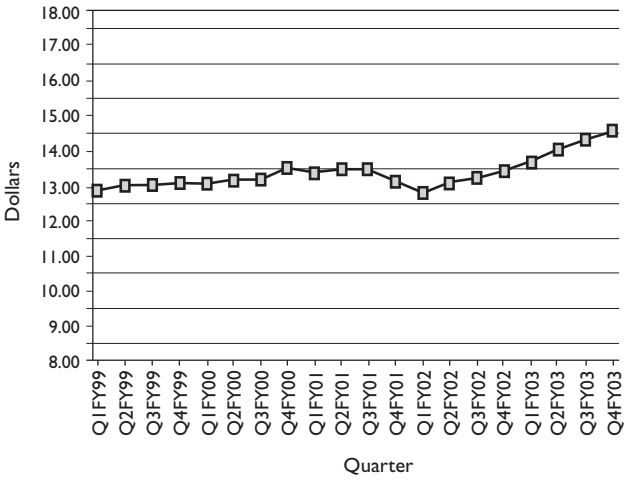
Pharmacy Benefit Management Strategic Healthcare Group).

The VA utilizes contracting techniques other than competitive bidding to reduce prices. First, the federal supply schedule limits by law the price of brand name products to 76% of the nonfederal average manufacturer's price. Secondly, the VA PBM works closely with the National Acquisition Center to negotiate performance-based incentive agreements (where the VA and the manufacturer directly negotiate a price reduction) and to establish generic multisource contracts. This has saved at least $572 million from FY 1996 through FY 2000 when comparing actual expenditures with estimated expenditures.[4]

Through careful competitive bidding, performance-based agreements, and other cost-saving measures (eg, promoting use of generic drugs when possible), the average acquisition cost per 30-day supply of drugs has remained relatively steady (ranging between $13.00 and $14.50 since FY 1999) compared with the average yearly percent increase in VA pharmaceutical expenditures over the past 5 years (Figure 1 and **Figure 2**). Drivers of drug costs in VA include increased numbers of users, drug cost inflation, utilization of new and more expensive drugs, and an increase in the intensity of treatment for certain diseases and conditions (eg, diabetes, hypertension, hyperlipidemia). Despite the presence of these cost-augmenting factors, the VA has demonstrated the ability to stay within its fixed budget and direct savings to local VA medical centers for alternate patient care functions. This opportunity provides incentive for local compliance with national contracting decisions.

Competitive bidding and the subsequent closing of selected drug classes can strain the VA's relationships with pharmaceutical manufacturers, who sometimes only reluctantly accept the "all-or-nothing" concept of doing business across the VA. Indeed, since the competitive bidding program began in 1996, in nearly all of the solicitations VA has attempted, 1 or more manufacturers have invoked their right under the federal acquisition regulations to protest the solicitation, particularly if they have a sizable share of the market basket. The GAO adjudicates these protests and, to date, has ruled in favor of the VA in all cases. As protests can slow the process, the VA PBM takes this into account in the solicitation-planning stages. The VA has observed an increasing number of nuisance protests filed by manufacturers who ultimately choose to submit noncompetitive bids for VA contracts. Additionally, some of these companies attempt to delay or derail the contracting process by lobbying formulary decision makers, patient advocacy groups, and congressional staff. Thus, legal and/or lobbying activity has become an expected occurrence in the VA's formulary management planning.

Figure 2. Department of Veterans Affairs Average Acquisition Cost Per 30-Day-Equivalent Prescriptions



These data are not broken down by the number of unique pharmacy users and therefore do not illustrate the influence of the increasing number of users on cost. Average 30-day drug-ingredient cost is defined as the sum (prescription cost)/sum(day-30 prescriptions), where for each prescription, prescription cost equals quantity multiplied by unit price. Day-30 prescription = 1 for ≤30 days of supply; day-30 prescription = 2 for >30 and ≤60 days of supply; day-30 prescription = 3 for >60 days of supply. Q1FY99 indicates quarter 1 of fiscal year 1999. Data are from the Pharmacy Benefit Management Strategic Healthcare Group.

DISEASE MANAGEMENT AND EVIDENCE-BASED DRUG USE CRITERIA

A primary objective addressed by the VA PBM entailed developing pharmacologic management guidelines for the most prevalent and most costly disease states observed in the VA population.[7] Over time, however, other entities within VA and the Department of Defense have assumed these tasks, with VA PBM clinicians (physicians and pharmacists) taking on either central or peripheral roles in this larger process. Since that transition has occurred, the VA PBM has focused more on evidence-based drug monographs for specific pharmaceuticals or drug classes and on developing appropriate criteria for use for various formulary and nonformulary agents.[7] These clinical documents and algorithms of drug use rely on a consistent evidence-based approach that takes into account published clinical trials and careful cost-effectiveness analyses so that when peer-reviewed by the Medical Advisory Panel, VISN formulary leaders, and field-based experts (thera-

peutic advisory groups), decisions do not depend on drug acquisition costs alone and may even favor use of higher cost pharmaceuticals where evidence supports better patient outcomes. The finalized drug and disease-state policies, together with utilization statistics from its national prescription utilization database, assist the VA in advancing its national purchasing power to contract for quality drug products at competitive prices and to help ensure equal access to specific drugs for specific conditions.

RESEARCH, DATA MANAGEMENT, AND QUALITY-IMPROVEMENT PROJECTS

In 1996, Schulman et al stated that "pharmaceutical benefits managers rarely do original research on the clinical effectiveness of products before considering the products for inclusion in a formulary. These organizations cannot track the effect of their interventions on overall health outcomes…and cannot link patients' medical claims data to prescription drug information."[3,pp3,12] The VA PBM recognized the need for formal assessment of its activities, and dedicated resources and personnel for this purpose. The VA has placed a high degree of importance on computer technology and creating an integrated computerized medical record for each patient. Most outcomes assessment addresses quality-improvement and patient safety initiatives using a pharmacy database developed by the VA PBM. This patient/provider-specific database includes information on all outpatient drugs dispensed from any VA pharmacy and provides a detailed profile of medications, dosing, quantities, and drug costs. Prescription use can be tracked on a macro (national, VISN, or facility) or micro (individual patient and provider) level. Further, when required, merging this data with larger VA administrative and clinical databases can provide further information such as diagnosis, hospitalization, comorbidity, and laboratory data. In addition, the VA PBM utilizes ProClarity®, Professional data management software (version 5.0, ProClarity Corporation, Boise, Idaho) to create views of relational pharmacy databases, allowing quick queries of data on selected pharmaceuticals for questions requiring urgent responses.

Within the VA, the VA PBM has spearheaded nationwide monitoring and management of clinical pharmacy and pharmacy-related patient outcomes. The VA PBM's outcomes research group designs formal research evaluations looking at safety, appropriateness of use, effectiveness, and cost-effectiveness of prescription drugs in the veteran population for retrospective, real-time, and prospective analyses. The VA PBM, along with other VA researchers, have published several efforts in this regard, as the following examples illustrate.[8-20]

First, the VA PBM registry system tracks pharmaceutical agents that have a suspected or identified safety concern. Several features of the VA provide a uniquely powerful and sensitive laboratory environment for conducting postmarketing surveillance activities. The VA essentially mirrors a closed, staff-model health maintenance organization that provides continuous care for a large cohort of patients with significant burden of illness; members stay in the plan for extended periods of time (often decades); medication use is high, reflective of the sicker population; and central tracking of all medications by the VA PBM allows it to follow trends as well as track adverse outcomes.

Furthermore, quality-improvement projects such as database reviews and appropriateness-of-use evaluations capture and quantify the present state of drug interactions, drug switching patterns, inappropriate and indiscriminate use of agents, drug-induced adverse events, treatment diagnoses, related diagnoses, medication compliance, and geographic variation in the utilization of medications.[7] Several of the quality-improvement database reviews began as patient safety initiatives. These and other projects formed the foundation for, and will continue under, a new patient safety center of inquiry known as the VA Center for Medication Safety, a joint project funded for 3 years by the VA's National Center for Patient Safety and the VA PBM.

PATIENT SAFETY QUALITY-IMPROVEMENT INITIATIVES

As a corollary to its ability to monitor drug utilization, the VA PBM has formalized processes to improve patient safety by utilizing educational tools and continued monitoring to ensure appropriate use. In addition to the standard educational tools, the VA PBM's Web site (http://www.vapbm.org) improves access to national directives on drug use, pharmacotherapeutic guidance, medication safety topics, and other pharmacotherapeutic information specific to the system. These resources increase the quality of care by directly communicating information to providers. This information is updated on an as-needed basis as new information become available in published, peer-reviewed literature.

For cases where concomitant therapy has resulted in adverse interactions and clinical sequelae, the VA PBM has taken the initiative to intervene at the provider level by forwarding information letters to pre-

scribers through the VISN formulary committees. Several interactions have been addressed, including (1) concomitant use of selective serotonin reuptake inhibitors with codeine, where the former may decrease the metabolism of codeine to morphine by inhibiting cytochrome P-450 2D6, thereby decreasing its therapeutic benefit[21-23]; (2) the potential interactions between protease inhibitors and the hydroxymethylglutaryl coenzyme-A reductase inhibitors (statins) lovastatin and simvastatin, where protease inhibitors may inhibit statin metabolism, leading to higher drug concentrations and, possibly, an increased risk for myopathy and rhabdomyolysis[24-31]; and (3) the combination of statins and fibrates, which has the potential to induce rhabdomyolysis and death.[32-37] Next, in monitoring new drugs used increasingly throughout the VA system, the VA PBM conducted an analysis on ziprasidone, an atypical antipsychotic, which can cause potential cardiovascular risks through prolonged QTc intervals, especially in patients who have cardiovascular disease, use concomitant drugs that can prolong QTc, or take drugs that inhibit the metabolism of ziprasidone.[38-49] The evaluation tracked patients with a diagnosis of schizophrenia and looked at histories of cardiovascular disease, antipsychotic switching patterns, discontinuation rates of ziprasidone, and concomitant use with contraindicated medications. The VA PBM also initiated a database review of oxycodone, a drug with abuse potential. Results prompted the VA PBM to develop national criteria for use as well as an employee education program, and to institute an automated system to periodically review patients who obtained a prescription for any formulation of oxycodone nationwide.

Moreover, the VA PBM conducts drug use evaluations to analyze adverse drug events, assess compliance with predetermined criteria and standards of practice, and estimate related pharmaceutical costs.[7] An example of a drug use evaluation completed by the VA PBM evaluated the clinical impact of a systemwide switch from troglitazone to rosiglitazone or pioglitazone with respect to potential exacerbation of congestive heart failure or hepatotoxicity after the market withdrawal of troglitazone.[11] This project further evolved into the development and implementation of the nationwide VA Thiazolidinedione Registry, which monitor rates and relative risk of adverse outcomes such as congestive heart failure, hepatotoxicity, hyperlipidemia, and mortality in the VA diabetic patient population. (Other registries and safety outcomes projects include the Antipsychotic and Diabetes Outcomes Study, the Fluoroquinolone Glycemia Safety Study, and the Leflunomide Registry.)

The VA PBM performed a drug use evaluation to investigate rabeprazole therapy after a systemwide therapeutic interchange from lansoprazole. The results revealed that many patients switched to rabeprazole discontinued therapy because of symptom recurrence due to inadequate titration of rabeprazole doses, demonstrating the need for provider education. In another national drug use evaluation, the VA PBM assessed the appropriate use of tamsulosin for benign prostatic hypertrophy. Results showed provider noncompliance with national criteria, manifested by unnecessary and increased utilization of this agent, which prompted the VA PBM to implement a formal provider education process.[10]

PRESCRIPTION BENEFITS IN THE VA COMPARED WITH OTHER PLANS

The VA formulary system differs from other governmental and private formulary systems. First, VA is a national healthcare system with a standardized prescription benefit that VISNs can expand to meet local needs. In other managed care settings like Medicaid, formularies and drug access vary due to specific contracts negotiated between each state and the plans.[4] The VA national formulary may list fewer therapeutic alternatives within drug classes or may close classes to 1 preferred drug. However, VANF does not exclude some drugs/classes or restrict prescriptions amounts or medication quantities. By contrast, Medicaid limits the use of costly, potentially abusive, cosmetic, and/or "lifestyle" drugs.[4] In addition, veterans utilizing the prescription benefit within the VA do not pay out of pocket for prescription drugs prescribed by VA physicians if receiving treatment for a service-connected injury or ailment. Otherwise, copayments are small ($7.00 per 30-day supply) and limited to non-service-connected treatment. In comparison, pharmacy benefit plans in the private sector often have tiered copayments.

SUMMARY

The VA PBM has made significant progress in efficiently managing the clinical, economic, and pharmacy-related outcomes of patients; evaluating and endorsing the appropriate use of pharmacotherapies; ensuring the availability of drug products and supplies; and controlling the cost of pharmaceuticals. As a federal organization, the VA has faced unique challenges in the development of its PBM (eg, interaction with media, politicians, and other special interest groups). In our experience, success in this environment has depended

on multidisciplinary cooperation of medical and pharmacy experts, reliance on evidence to guide decisions and provide accurate responses to patients and other stakeholders, focused competitive bidding to encourage the most cost-effective use of pharmacy expenditures, and willingness to continually evaluate the success or failure of our program. We encourage other pharmacy benefit management groups to evaluate their programs, and share information with the academic community.

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