Application of Innovative Pharmacy Benefit Management Strategies to the Military Health System

A White Paper Prepared for the Defense Health Agency
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Application of Innovative Pharmacy Benefit Management Strategies to the MHS

Executive Summary

Health employers and purchasers across the nation, as well as the Department of Defense (DoD) and the Military Health System (MHS), are facing rising health care costs, in part due to the increasing costs of prescription drugs. Many payers have succeeded in limiting health care spending growth through the judicious application of standard pharmacy benefit management (PBM) strategies, such as tiered formularies, generic substitution, cost sharing methodologies, and prior approval. Consistent with a recent shift in focus from a singular goal of cost savings for pharmaceuticals to the goal of accountable value in health care, new and innovative strategies are emerging that can complement the cost reductions associated with standard PBM strategies and increase value in care. Thus, advances in long-standing PBM cost-containment strategies and innovative approaches to reducing costs while improving health outcomes can provide the MHS with significant opportunities to achieve its Quadruple Aim. We describe in this paper newer strategies which hold the promise of reducing health care costs in the MHS through control of prescribing practices, promotion of better health, and reduction of health care spending on high-level complex care that occurs during crises. While some of the strategies we describe are already used by the MHS and its PBM contractors, a future detailed review of their impact within the MHS may reveal additional opportunities for improving health and reducing costs.

• We recommend conducting a needs assessment, a cost-benefit analysis of specific current and proposed strategies, and a comparison of current practices to successful models in other health care systems to identify opportunities for improvement within the MHS.

Background and Understanding

The Military Health System (MHS) serves over 9.6 million beneficiaries worldwide, supporting the Department of Defense (DoD) mission through Military Treatment Facilities (MTFs) and the TRICARE program’s network and out-of-network civilian health care professionals, institutions, pharmacies, and suppliers. The TRICARE program offers a number of health insurance coverage options, each with a pharmacy benefit package.

Health employers and purchasers across the nation, as well as the DoD and the MHS, are facing rising health care costs. Currently, the cost of pharmaceuticals in the MHS accounts for 13.6% of its budget (TRICARE Management Activity [TMA]/Office of the Chief Financial Officer [OCFO], 2013). According to the DoD’s fiscal year (FY) 2013 evaluation of the TRICARE program, the MHS budget increased only 3.5% from FY2012 to FY2013 (TMA/OCFO, 2013). However, from FY2010 to FY2012, prescription medication use by TRICARE PRIME beneficiaries rose by 5%, and in FY2012, was 35% higher than the MHS’s health maintenance organization benchmark (TMA/OCFO, 2013), thus placing pressure on the MHS to reduce costs across the system.

Importantly, prescription drug spending should be considered in the context of other factors, such as the value of prescription drug use on chronic disease management costs. For example, there is general consensus that in some populations, such as those with cardiovascular disease, appropriate use of evidence-supported drug regimens prevents recurrent events leading to offsets in other health care

• A comprehensive set of analyses and evaluations of the MHS beneficiary population and current PBM strategies, such as the ones we outline in this paper, will enable the MHS to better assess its strategic options to improve pharmacy management and care delivery. The recommendations focus on strategies to improve adherence, optimize medication regimens, enhance safety, and reduce costs.
utilization and spending (Choudhry et al., 2011a). For many chronic conditions, there is a full complement of highly effective generic medications available at very low cost. So although the number of patients being treated by a particular medication may increase, and therefore drug spending similarly increases, adherence to medication regimens can substantially reduce total health care costs by producing a healthier population that requires fewer hospitalizations and other health services (Braithwaite, Shirkhorshidian, Jones, & Johnsud, 2013; Roebuck, Liberman, Gemmill-Toyama, & Brennan, 2011). In this manner, some of the greatest health care cost savings opportunities may rest in a payer’s ability to improve adherence to essential medications. For example, Soumerai, Ross-Degnan, Avorn, McLaughlin, and Choodnovskiy (1991) found that when the New Hampshire Medicaid program imposed new caps on prescription drugs, utilization of essential medications by patients with serious mental illness dropped, resulting in sharp increases in emergency room visits, hospitalizations, and nursing stays.

Non-adherence to prescription medication continues to be major problem, contributing to poor health outcomes and increased costs of care. Medication non-adherence leads to $290 billion in annual unnecessary costs, representing 13% of the total health care expenditures in the United States (NEHI, 2009). Thus, the opportunity to reduce health care spending by improving adherence may be significant. Studies demonstrate that improvements in adherence reduce health care spending by 10–18%, even after accounting for increased medication costs (Bitton, Choudhry, Matlin, Swanton, & Shrank, 2013; Roebuck et al., 2011). In addition, according to the Congressional Budget Office, a 1% increase in prescription drug use among non-adherent patients would decrease overall spending on medical services by 0.2% (Congressional Budget Office, 2012).

**A Shift Towards Value**

In light of rising health care and pharmacy costs, prescription drug expenses represent opportunities for cost reduction and savings in the MHS. By applying pharmacy benefit management (PBM) techniques, employers and plans garner savings when purchasing, dispensing, and receiving reimbursement for prescription medications. For example, in the civilian sector, increasing implementation of strategies focused on pharmacy cost reduction resulted in an average annual cost decrease of 1.8% from 2011 to 2012 (Pharmacy Benefit Management Institute, 2013). Furthermore, largely driven by the increasing availability of generic medications, the prescription spending growth rate decreased from 5.5% in 2011 to 3.7% in 2012 (Pharmacy Benefit Management Institute, 2013). TRICARE has benefited from cost savings offered by several common PBM practices. For example, DoD’s ability to negotiate substantial drug rebates has shielded the MHS from increases in drug costs. In addition, under the National Defense Authorization Act of 2008, Congress mandated that the TRICARE retail pharmacy program be treated as an element of DoD and thus, subject to the same pricing standards as other federal agencies. Therefore, drug manufacturers started providing rebates to TRICARE on most brand-name prescription drugs in 2008. In 2012, the refunds saved DoD approximately $1.4 billion (TMA/OCFO, 2013). TRICARE has also benefited from promoting greater use of generic drugs, but the rate of their use among TRICARE beneficiaries (67% in 2011) trails behind the 78% generic fill rate for new and refilled prescriptions in the civilian sector (TMA/OCFO, 2013). Despite the use of common PBM practices, there exists a significant potential opportunity for greater cost savings in the MHS following examination and possible implementation of innovative PBM strategies successfully utilized within the civilian sector.

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1 Polypharmacy refers to the use of multiple medications and/or the administration of more medications than are clinically indicated, representing unnecessary drug use.
<table>
<thead>
<tr>
<th>Pharmacy Benefit Management Strategy</th>
<th>Description</th>
<th>Impact&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Direct Cost Containment</td>
</tr>
<tr>
<td>Standard Strategies</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Formulary Structure</td>
<td>The health plan’s list of covered drug entities, including therapeutic</td>
<td>-</td>
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<tr>
<td></td>
<td>classifications, tiering and co-pays</td>
<td></td>
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<tr>
<td>Generic Substitution</td>
<td>Allowing substitution for brand name medications with identical active</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>ingredient generic entities taking into account provider preferences</td>
<td></td>
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<tr>
<td>Step Therapy</td>
<td>The practice of beginning drug therapy with the most cost-effective and</td>
<td>-</td>
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<tr>
<td></td>
<td>safest drug therapy. Subsequent progression to other more costly or risky</td>
<td></td>
</tr>
<tr>
<td></td>
<td>drug therapies are instituted only if necessary, based on therapeutic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>outcomes and the risk/benefit of using the drug</td>
<td></td>
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<tr>
<td>Prior Authorization</td>
<td>Requires criteria to be met that ensures drug safety and efficacy for the</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>condition being treated before dispensing occurs</td>
<td></td>
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<tr>
<td>Pharmacy Networks</td>
<td>In this case, Military Treatment Facility (MTF), mail order, or retail</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>pharmacies</td>
<td></td>
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<tr>
<td>Mail Order</td>
<td>Prescriptions filled or refilled by a mail order pharmacy rather than an MTF</td>
<td>-</td>
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<tr>
<td></td>
<td>or retail pharmacy</td>
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<tr>
<td>Innovative Strategies</td>
<td></td>
<td></td>
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<tr>
<td>Clarity of Labels and Instructions</td>
<td>Use of standard concise labeling language according to industry best practice</td>
<td></td>
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<tr>
<td>Packaging</td>
<td>Packaging to assist patients in medication adherence (e.g., blister packs,</td>
<td>-</td>
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<tr>
<td></td>
<td>easy-open containers</td>
<td></td>
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<tr>
<td>Automated Calls and Text Messages</td>
<td>Use of technology to remind patients to refill or request new authorizations</td>
<td>-</td>
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<tr>
<td></td>
<td>for currently prescribed medications</td>
<td></td>
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<tr>
<td>Beneficiary Education</td>
<td>Providing patients with education regarding medication administration,</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>adherence, side effects, and reasons for continuing therapy</td>
<td></td>
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<tr>
<td>Medication Therapy Management</td>
<td>Regular patient outreach to specifically address drug regimens. Includes</td>
<td>-</td>
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<tr>
<td></td>
<td>discussions of effects of patient’s lifestyle and nutrition on drug therapies</td>
<td></td>
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<tr>
<td></td>
<td>with the goal of optimizing drug therapies for better therapeutic outcomes.</td>
<td></td>
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<tr>
<td>Reduction of Polypharmacy&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Optimizing the numbers of medications used by individual patients to reduce</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>drug interactions and improve safety and adherence</td>
<td></td>
</tr>
<tr>
<td>Health Information Technology</td>
<td>Use of electronic health records to reduce error, improve quality of care,</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>improve accuracy of diagnosis and facilitate data collection</td>
<td></td>
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<tr>
<td>Prescriber Education</td>
<td>Providing formulary and medication-specific information that improves safety,</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>adherence, and reduces costs</td>
<td></td>
</tr>
<tr>
<td>Reference Pricing</td>
<td>Determining a drug’s relative effectiveness for treatment, and then</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>reimbursing based on the least expensive option</td>
<td></td>
</tr>
<tr>
<td>Value-based Insurance Design</td>
<td>Providing best value (therapeutic efficacy to cost) through formulary</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>design and reductions in co-pays</td>
<td></td>
</tr>
<tr>
<td>Specialty Drug Strategy</td>
<td>Managing specialty drug use through ensuring that the correct drug is</td>
<td>-</td>
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<tr>
<td></td>
<td>prescribed to the correct patient at the correct time. Strategies include</td>
<td></td>
</tr>
<tr>
<td></td>
<td>using specific suppliers, requiring criteria to be met before usage and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>continuing patient outreach to promote effective and cost-efficient usage.</td>
<td></td>
</tr>
</tbody>
</table>
Strategies to Achieve Value and the Military Health System Quadruple Aim

Although some standard PBM strategies have been implemented in the MHS to reduce costs, there may be additional opportunities to advance TRICARE’s PBM program by applying lessons learned from programs and policies in the civilian sector. Refining these approaches and introducing some of the innovative programming developed elsewhere may support the MHS in achieving its Quadruple Aim of improving the experience, quality of care and health of the population, reducing costs, and promoting the readiness of the service men and women and other personnel covered by the MHS. Innovative PBM strategies may serve to promote better health, greater adherence to prescription drug, and safe use of prescribed drugs. Patient-centered approaches to facilitating drug therapies such as medication therapy management (MTM) and patient refill reminders directly support the patient with pharmaceutical use and may lead to a greater experience of overall care.

In Appendix A, we explore some of the PBM strategies, both standard and innovative, that have proven effective in reducing pharmacy costs in the civilian sector. The strategies vary by impact and costs of implementation and maintenance, and some have well established benefits while others have demonstrated only modest impact or have been understudied. Exhibit 1 below summarizes these strategies, as well as the impacts (i.e., cost, safety, health outcomes, adherence) associated with each.

A substantial portfolio of relatively new, innovative strategies exists for pharmacy systems across three general approaches to PBM design that may lead to greater value in health care for the MHS: increasing medication adherence, promoting safe use of medications, and expenditure containment strategies (see Exhibit 2). Among the most promising PBM approaches for improving quality and reducing costs are reference pricing and value-based insurance design (VBID). MTM and drug utilization review (DUR) appear to hold substantial promise as well. Most interventions to improve medication adherence have yet to demonstrate substantial improvements without significant involvement of trained staff like pharmacists and thus, a requirement for considerable investment. It should be noted, however, that medication non-adherence is a complex issue and requires a diverse portfolio of strategies, if meaningful and sustainable levels of adherence are to be achieved. Many of the adherence strategies described in Appendix A, and others, would be worthwhile additions to MHS’ portfolio of PBM strategies.

Some of the most effective new strategies are those that target specific populations of patients, either by disease, severity, or risk, including risk of poor health outcomes, low medication adherence, and/or vulnerability to adverse reactions to medication therapy. MTM is an example of an intensive, high cost strategy that when targeted to appropriate patients may result in net savings for an insurer or health system.

Finally, some strategies are only available or significantly enhanced when pharmacy services are linked to health care delivery systems and health care providers.

Exhibit 2 | Innovative Pharmacy Benefit Management Strategies

<table>
<thead>
<tr>
<th>Improve Adherence</th>
<th>Improve Quality and Reduce Costs</th>
<th>Reduce Medication Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td>Education</td>
<td>Motivational interviewing</td>
</tr>
<tr>
<td>Labeling and health literacy</td>
<td></td>
<td>Rewards</td>
</tr>
<tr>
<td>Packaging</td>
<td></td>
<td>Affect-based interventions</td>
</tr>
<tr>
<td>Automated calls</td>
<td></td>
<td>Patient communication</td>
</tr>
<tr>
<td>Simplification</td>
<td></td>
<td>Provider/health system</td>
</tr>
<tr>
<td>Pharmacist intervention</td>
<td></td>
<td>connection</td>
</tr>
<tr>
<td>Reminder phone calls</td>
<td></td>
<td>Social networks/support</td>
</tr>
</tbody>
</table>

Promote Safe Rx Use

- Reduce polypharmacy/
- Duplicative prescribing/
- Drug-disease interactions
- HIT/e-prescribing
- Interventions
- Brown bag/DUR

Source: Booz Allen Hamilton

Footnotes:

Strategies presented in this table are described in greater detail in Appendix A.
Citations for each strategy and associated impact are listed in Appendix B.
Polypharmacy refers to the use of multiple medications and/or the administration of more medications than are clinically indicated, representing unnecessary drug use.
With this linkage, advances in health information technology can be leveraged to enable monitoring of physician prescribing and promotion of safe and cost effective drug regimens, while enhancing efforts to support medication adherence. Such approaches to managing pharmacy benefits bring the added advantage of potential savings through a reduction in downstream health care utilization.

**Recommendations for Pharmacy Benefit Management in the Military Health System**

This paper has identified a number of standard and innovative strategies (see Appendix A for a detailed summary of these strategies) for reducing costs and improving quality through PBM. The MHS already uses a number of these strategies to control pharmacy costs, yet their pharmacy costs continue to rise. Based on current programs in the MHS and evidence for the most effective or promising strategies employed by pharmacy benefit managers and managed care organizations in the civilian sector, we provide several recommendations for increasing value through PBM in the MHS. These recommendations are described in the sections below and summarized in Exhibit 3.

**Improving Medication Adherence**

Strategies which improve adherence to medication therapy will improve health outcomes and lower overall costs of care for the MHS.

- We recommend a comprehensive evaluation of medication adherence as well as a linkage of pharmaceutical and clinical services data to gauge the extent to which poor adherence affects beneficiary health outcomes and costly health services use. This evaluation should consider the highest cost conditions in the MHS (i.e., musculoskeletal, psychiatric, and cardiovascular disorders) as a first step in gauging possible improvements in outcomes and cost savings through adherence promoting strategies.

- We recommend an evaluation of the cost-benefit of current adherence support strategies used in the MHS PBM program. This would enable the MHS to make strategic decisions about resource allocation and program implementation to address high cost medication non-adherence.

- Following these evaluations, we recommend that the MHS develop predictive models to identify individuals at risk for low medication adherence and poor health outcomes. Proactive identification of at-risk beneficiaries would enable the MHS to allocate resources, like MTM and other pharmacist-led interventions, for maximum impact. Moreover, it would provide the MHS with the opportunity to tailor interventions to the specific needs of individuals, further enhancing program effectiveness.

- Linking data from the pharmacy and clinical service lines of the MHS is critical for achieving these ends. The MHS is in a rare position of having complete clinical and pharmaceutical data on most of its beneficiaries. It should leverage this advantage to establish powerful tools, such as MTM, disease management, and population health programs, to improve medication adherence and health outcomes for beneficiaries throughout the system.

**Enhancing Medication Safety and Optimizing Regimens**

Enhancing medication safety and optimizing regimens may provide the MHS with additional opportunities for cost savings as well as for achieving greater quality and population readiness.

- We recommend a comprehensive assessment of polypharmacy in the MHS and a study to identify opportunities for regimen simplification. Regimen simplification would reduce pharmacy costs as well as the risk of adverse drug events, while potentially improving beneficiary comfort and satisfaction.

- We recommend linking pharmacy and service claims data to conduct studies of the epidemiology and costs of adverse drug events in the MHS. Such studies could be used as the foundation for adverse drug event surveillance systems. They would also support efforts to allocate resources for DUR.

- We recommend an evaluation of the costs and impact of current medication safety and evaluation programs (including MTM and DUR programs) in

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1. Polypharmacy refers to the use of multiple medications and/or the administration of more medications than are clinically indicated, representing unnecessary drug use.
the MHS, as well as cost-benefit assessments of expansion of these and similar programs.

Reducing Medication Costs
Medication spending would be reduced indirectly or as a byproduct of improved adherence promotion and medication safety programs, but new opportunities for direct reductions in drug costs still exist.

- We recommend that the MHS compare their cost-containment strategies to that of high performing health systems and pharmacy benefit managers to identify opportunities for improving formulary design and pricing strategies.
- We also recommend a cost and clinical outcomes analysis of implementing VBID and reference pricing.

In Summary
The MHS can identify opportunities for achieving pharmacy savings through the evaluation of current cost-containment and quality-improvement strategies. Such evaluation holds great promise for achieving savings through redesign of current programs and introduction of new strategies like VBID. Given its access to comprehensive pharmacy and clinical data, the MHS is also poised to establish novel programs for population health that can reduce drug and overall health care spending. The recommendations we outline above would provide the MHS with powerful data and tools for its effort to achieve the Quadruple Aim. Importantly, the proposed evaluations represent short term, low cost strategies for identifying potential savings within the MHS pharmacy benefit program and optimizing allocation of scarce resources. Other strategies, including the potential expansion of MTM, DUR and implementation of VBID or reference pricing, are longer term strategies with great promise for reducing costs and improving outcomes for MHS beneficiaries.
Appendices

Appendix A: Pharmacy Benefit Management Strategies in the Civilian Sector

In recent years, studies have shown the relative benefits of pharmacy benefit management (PBM) strategies in reducing payer costs and improving patient health outcomes in the civilian sector. While some of these studies were conducted on limited or narrow populations, some findings can be extrapolated to the TRICARE beneficiary population. In the following sections, a summary of standard and innovative PBM strategies is presented. These strategies have the potential to improve quality of care and reduce pharmacy costs across the Military Health System (MHS).

Standard Pharmacy Benefit Management Strategies

Several standard PBM strategies have proven effective in reducing costs for employers and other purchasers in the civilian sector. These approaches are described in the sections below.

Open and Closed Formularies and Tiered Formularies

With closed formularies, health plans cover the costs of a defined list of medications. This is in contrast to open formularies, which extend coverage to medications beyond the plan’s formulary. Open formularies are more costly but may increase consumer satisfaction because of enhanced access to preferred drugs.

Tiered formulary structures employed by most health plans are effective in lowering costs. A 2003 study examined the use of prescription drugs by employees and their dependents who had health care coverage from two large employers that contract with a large health insurer (Huskamp et al., 2003). The first employer moved from a one-tier formulary requiring the same copayment for any drug to a three-tier formulary and increased the levels of co-payments for all tiers. The second employer changed from a two-tier formulary (involving one level of co-payment for generic drugs and a second level for brand-name drugs) to a three-tier formulary that involved increases in the co-payments only for the non-preferred brand-name drugs that were assigned to the third tier. For the first employer, the changes had a large effect on the distribution of spending between the plan and its enrollees. Specifically, spending decreased as follows: 58% on ACE inhibitors, 15% on proton-pump inhibitors, and 14% on statins (Huskamp et al., 2003). The policy changes implemented by the second employer had smaller effects on the use of and spending on prescription drugs, but both demonstrated cost savings as a result of the tiered formulary.

The impact of co-payments in tiered formularies and other cost-sharing strategies depends in part on the extent to which patients value a particular drug. Studies have found price elasticity2 of 0.2 to 0.6 for drug expenditures by patients (Baicker & Goldman, 2011). Similarly, increased cost-sharing may decrease the use of drugs considered by the patient to be “nonessential” more than the use of “essential” drugs. Thus, a major challenge for pharmaceutical benefits managers employing cost-sharing strategies is the risk of medication non-adherence among beneficiaries. Adoption of tiered formularies and other strategies that shift costs to patients may result in underuse of prescribed medications and subsequent overuse of medical services (Huskamp et al., 2003). One study found that 35% of savings in drug costs are offset by the increase in other medical spending as a result of poor illness control (Baicker & Goldman, 2011).

Drug Utilization Review

Drug utilization review (DUR) involves systematic review of physician prescribing to identify use of unsafe medications or combinations of medications. Little data exists on the impact of this strategy, but it is likely that DUR reduces use of targeted medications (Academy of Managed Care Pharmacy, Shoemaker, Pozniak, Subramanian, & Mauch, 2010).

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2 Price elasticity refers to sensitivity to an increase in price resulting in a decrease in demand.
One study reviewed the use of DUR and the effects of a DUR program on the use of prescription controlled substances (Daubresse et al., 2013). The intervention group consisted of state health plans sending controlled substance letters to prescribers of members meeting or exceeding a plan-specific controlled substance score. The comparison control group did not receive such letters. The reductions in the mean controlled substance score for the intervention group (34%) were greater than the reductions in the comparison group (25.5%; Daubresse et al., 2013).

**Generic Substitution**
Generic substitution provides cost savings for payers and enrollees by reducing overall drug costs and co-pays, respectively. A study conducted from 1997 through 2000 found that broader generic substitution of antihistaminic, cardiac, gastrointestinal, and hypoglycemic agents would generate annual savings of approximately $8.76 billion across all payers nationally (Haas, Phillips, Gerstenberger, & Seger, 2005). In addition, a study of Medicaid prescription medication spending in 2000 found that $229 million, or approximately 1% of the total amount reimbursed for prescription medications by Medicaid, could have been saved by wider use of generic medications (Phillippe, Andrus, Sims, & McDaniel, 2010).

**Step Therapy**
Step therapy requires patients to be treated with low cost, often generic “first line” agents for a given condition. Those agents must demonstrate therapeutic failure before the health plan will pay for more costly second or third line agents. This strategy has demonstrated cost savings in the civilian sector. In one health maintenance organization setting which utilized step therapy, the cost per day for depression treatment with anti-depressants decreased by 11.7% and adherence to medication therapy improved (Dunn, Cannon, Mitchell, & Curtiss, 2006). This combination of change in cost and increased utilization led to a 13% decrease in the antidepressant drug cost, compared to a 7.6% decrease within the control group. Overall, there was a drug cost savings of 9% based on the change in policy requiring step therapy covering this specific class of drugs.

**Prior Authorization**
Under prior authorization, prescribers must obtain approval from the health plan or pharmacy benefit manager before the medication will be covered. This typically requires a written or verbal justification for use of the medication and may also require demonstration that lower cost first line medications were used without benefit (similar to step therapy). The strategy can also be implemented to reduce the use of potentially unsafe medications (Ross et al., 2012). Use of prior authorization reduces spending by payers on high cost drugs (Green et al., 2010; Lu et al., 2011), but its effect on adherence and health outcomes is less clear, and may in fact, be detrimental (Bergeson, Worley, Louder, Ward, & Graham, 2013).

**Pharmacy Networks**
Approximately 50% of health insurance plans use closed pharmacy networks and require single specialty distribution drug channels for prescriptions covered under their pharmacy benefit (Sullivan, McDonald, Stern, & Tegenu, 2008). This approach allows plans to steer enrollees towards designated pharmacies through lower co-pays. In return for the dedicated market share, pharmacies typically offer plans deep discounts on drug costs. One study estimated that use of preferred and limited pharmacy networks could generate $115 billion in savings across Medicaid, Medicare, and the civilian sector (Pharmaceutical Care Management Association, 2013).

**Mail Order**
Mail order pharmacies can achieve economies of scale through bulk processing, use of 90-day supplies to reduce volume of units processed, lower labor costs, and lower drug costs negotiated with manufacturers as compared to that which retail pharmacies are able to achieve. The Lewin Group (2006) estimates that if both the Medicare and civilian sectors utilized mail order dispensing to its maximum potential, a 10-year overall savings would reach $167 billion. Moreover,
data indicate that use of mail order pharmacies is associated with greater medication adherence and health outcomes, which may offset some of the costs of mail order program implementation and maintenance (Devine, Vlahiotis, & Sundar, 2010; Duru et al., 2010; Iyengar, Henderson, Visaria, & Glave, 2013; Office of the Secretary, Department of Defense [DoD], 2013).

Innovative Pharmacy Benefit Management Strategies
Greater value in health care may be achieved through three general approaches to PBM redesign: improving medication adherence, promoting safe use of medications, and containing expenditures. Many innovative strategies have demonstrated benefit within the civilian sector and hold promise for the MHS. These strategies are discussed in the sections below.

Improving Medication Adherence
Non-adherence to prescription medication is a major public health problem, contributing to poor health outcomes and increased costs of care. It is estimated that approximately one-third of adults have poor adherence to some or all of their prescribed medications (Osterberg & Blaschke, 2005) and adherence rates for essential therapies are often worse. For example, one national study of commercially-insured patients who experienced a heart attack demonstrated that adherence to essential cardio-protective therapy was less than 50% (Choudhry et al., 2011b). Non-adherence consists of skipping doses of medications, failing to fill initial prescriptions (24% of prescriptions; Fischer et al., 2011), abandoning prescriptions at the pharmacy (3%; Shrank et al., 2010a), and failing to refill medications (e.g., 44% of statin prescriptions after three months of use; Benner et al., 2002).

Reasons for medication non-adherence fall into two broad categories, unintentional and intentional. Unintentional reasons include forgetting to take a medication, or being unable to pay for a medication, get to the pharmacy, or contact a doctor. The intentional category is broader and includes misinformed beliefs about medications and illness, problems with side effects, and poor understanding of how medications should be used (Choudhry et al., 2011b).

The multi-factorial nature of medication non-adherence calls for multi-dimensional interventions to promote adherence. Various strategies have been developed to address intentional and unintentional causes of non-adherence, many with promise for health plans and pharmacy benefit managers.

Strategies to Address Unintentional Medication Non-adherence

Free Generic Medication
Encouraging greater use of generic medications not only reduces medication costs for the payer but can save patients money and improve their adherence, while effectively treating many common chronic diseases (Shrank, Choudhry, Liberman, & Brennan, 2011). Within tiered pharmacy benefit plans, patients initiated on generic medications tend to adhere better to those medications over the long term compared to those initiated on branded medications because of lower out-of-pocket costs (Shrank et al., 2006).

To increase use of generics and reap the downstream health benefits, several payers have experimented with providing generic medications at no cost to their beneficiaries, as TRICARE does at military treatment facilities and for some mail order prescriptions. To date, these efforts have resulted in small yet statistically significant increases in generic drug use and decreases in spending. For example, Blue Cross Blue Shield of Minnesota provided free generic drugs to beneficiaries with ischemic heart disease or diabetes and found a 14% increase in generic uptake relative to generic uptake prior to program implementation (Rodin, Heaton, Wilson, Garrett, & Plocher, 2009). Another managed care company contracted with MedVantx to provide bottles of free 30-day samples of generic drugs through automated dispensing kiosks in doctors’ offices. The program, which was used by 301 physicians, resulted in a 1.3% increase in generic drug use compared to control
practices and generated approximately $400,000 in savings after discounting administrative and medication costs for the free generic program (Scott, Culley, & O'Donnell, 2007). In addition, a program of vouchers provided by physicians for free generic medications resulted in a 1.8% absolute increase in generic drug uptake compared to controls (Bhargava, Greg, & Shields, 2010).

**Clarity of Medication Labels and Instructions**

Low health literacy, or the inability to understand and use health information to make appropriate health decisions for oneself, has repeatedly been associated with poor medication adherence (Noureldin et al., 2012). For example, the difficulty patients have reading and understanding prescription drug labels and their subsequent misinterpretation of instructions for prescription drug use (Davis et al., 2009) is well-documented in the literature. Recent studies have demonstrated that typical prescription drug labels are highly variable and do not follow evidence-based recommendations for readability or comprehension (Shrank et al., 2007).

The Universal Medication Schedule, a new, evidence-based approach to formatting prescription drug labeling for better comprehension by patients with low health literacy, is being tested in a randomized controlled trial and has shown promise for improving patients’ understanding of prescription instructions (Shrank et al., 2010b; Wolf et al., 2011a). However, improving labeling and prescription instructions may have limitations. For example, one large pharmacy chain (Target) redesigned prescription drug labels to improve readability and understanding, but an evaluation of the program found no improvement in adherence or health outcomes with use of the new label (Shrank et al., 2009).

**Improved Medication Packaging**

Improved prescription drug packaging can include the use of pillboxes and blister packs. For example, a small study of blister packaging increased the rate of on-time prescription refilling by 21% and the medication possession ratio by 14% (Schneider, Murphy, & Pedersen, 2008). A randomized controlled trial of Veterans Health Administration beneficiaries at Walter Reed Hospital combined use of blister packs with medication education and follow-up by a pharmacist. This intervention resulted in an increase in hypertension medication adherence from 61% to 95% and a concomitant decrease in systolic blood pressure of 6 mmHg (Lee, Grace, & Taylor, 2006). In addition, including calendar reminder functions in packaging also shows promise for improving adherence (Zedler, Kakad, Colilla, Murrelle, & Shah, 2011).

**Automated Calls and Text Messages**

Research has demonstrated that automated phone calls to patients marginally improves adherence to long-term therapy, but can be administered at very low cost (Bender et al., 2010; Vollmer et al., 2011). With the improvement of interactive voice recognition (IVR) technology, such interventions are expected to improve in efficacy. For example, Bender et al. (2010) observed 32% greater adherence among patients in an IVR group compared with patients who did not receive IVR telephone calls. Similarly, text messaging has recently emerged as a tool for promoting medication adherence. Early success has been demonstrated with adolescents and young adults, but the strategy appears to work with middle aged and older adults as well (Free et al., 2013; Park, Howie-Esquível, Chung, & Dracup, 2014. For example, Park et al. (2014) found that patients who received a text message for antiplatelet medication had a higher percentage of correct doses taken, number of doses taken, and prescribed doses taken on schedule. A recent systematic review of the literature demonstrated that a variety of health information technology-based patient reminder systems, often involving one- or two-way communication with clinicians, consistently improved adherence to cardiovascular and diabetes medications (Misono et al., 2010). Such approaches may be best used in conjunction with, and not in replacement of, patient counseling and in-person interaction with providers (Granger & Bosworth, 2011).
Beneficiary Education

Education by health care providers and administrators for their beneficiaries would seem a key part of any intervention to promote improved medication adherence. However, few studies focusing exclusively on better education have resulted in substantial improvements in adherence. Syntheses of existing research indicate that education must be part of a multi-factorial approach to improving medication use in order to provide meaningful changes in behavior (Kripalani, Yao, & Haynes, 2007).

Strategies to Address Intentional Medication Non-adherence

Rewards

The effectiveness of value-based insurance design (VBID, see below) has encouraged the use of financial incentives to promote adherence. VBID lowers patient out of pocket costs for drugs and other therapies that prevent and reduce disease complications, emergency department visits, and/or hospitalizations. Simply removing financial barriers to effective therapy has modest effects on behavior, as noted above, but larger financial incentives may be a more powerful motivator. Many believe that by allocating the same resources as needed for VBID, greater behavior change could be achieved by making it financially easier to adhere to therapy. Recent studies rooted in behavioral economics have successfully demonstrated that financial rewards, when appropriately structured, can be used to successfully promote smoking cessation and weight loss (Volpp, Asch, Galvin, & Loewenstein, 2011). Large-scale trials are currently underway to test the impact of financial rewards on medication adherence.

Promoting Safe and Appropriate Prescription Drug Use

Medication Therapy Management Programs and Pharmacist Interventions

Medication therapy management (MTM) programs, typically involving pharmacists, are designed to optimize regimen effectiveness and patient safety while supporting medication adherence through medication review, medication reconciliation, and patient counseling. While the data on large scale MTM programs are limited, they suggest overall improvements in adherence and outcomes for patients and cost-savings for payers when targeted to appropriate patients (Academy of Managed Care Pharmacy et al., 2010; Moore, Shartle, Faudskar, Matlin, & Brennan, 2013). One recent systematic review comparing different modes of adherence interventions found that face-to-face pharmacist interventions have shown greater success in improving cardiovascular and diabetes adherence than other provider-based interventions (Cutrona et al., 2010). Furthermore, adherence improvements were between 7% and 27% among the five randomized controlled trials included in Cutrona et al. (2010).

Pharmacists and others may enhance safety and the likelihood of adherence by simplifying drug regimens whenever possible. Simply reducing the number of doses a patient requires each day is associated with improved adherence (Schroeder, Fahey, & Ebrahim, 2004). Observational studies have shown an important relationship between adherence and the number of prescribers, the number of pharmacies used, and the amount of refill synchronization (Choudhry et al., 2011b). These studies show that patients with multiple physicians prescribing multiple medications
that are filled at multiple pharmacies negatively affect patient adherence. Interventions such as creating medical 'homes' and pharmacy 'homes' may improve the patient’s ability to access information about all medications in one place as well as simplifying access to medications, resulting in improved adherence.

Pharmacists may use a variety of effective strategies for promoting medication adherence. Substantial enthusiasm is currently seen in provider groups and health plans for the use of motivational interviewing. The rationale is that greater patient engagement in their medication use should meaningfully alter behavior. Study findings have been mixed, but promising (Solomon et al., 2012). For example, a recent systematic review showed a 34% improvement in adherence in patients who received behavioral-cognitive adherence interventions, most commonly motivational interviewing (Easthall, Song, & Bhattacharya, 2013). The cost of providing the adherence support interventions was not assessed, but could be substantial.

Reducing Polypharmacy
A number of studies have examined the risks associated with polypharmacy and strategies to overcome those risks. In one study, clinical pharmacists performed an intervention with patients at high risk of harm from polypharmacy, including drug therapy reviews, educating both physicians and patients about polypharmacy and drug safety, and working directly with patients (i.e., in-person counseling) to correct issues arising from polypharmacy (Zarowitz, Stebelsky, Muma, Romain, & Peterson, 2005). The intervention was associated with a 67.5% reduction in polypharmacy events, as well as a 52.2% reduction in the number of prescriptions per patient per month, and a 49.1% reduction in prescription costs. Persistent use of the pharmacist intervention continued to foster benefits. Specifically, in the second intervention period there was a 39% reduction in polypharmacy events and a 9.5% reduction in prescription costs per member per month.

Health Information Technology Interventions
Health information technology has been used to promote medication safety by alerting clinicians to abnormal lab results that may be related to medication use. However, the few published trials on this strategy have not demonstrated actual improvements in medication monitoring and avoidance of errors (Fischer, Tjia, & Field, 2010; Hayward, Parnes, & Simon, 2009). Computer order entry by clinicians, also addressed in few rigorously conducted studies, appears to have a modest but significant impact on reducing potentially harmful medication errors in ambulatory settings (Ojeleye, Avery, Gupta, & Boyd, (2013; Radley et al., 2013).

Many errors due to paper-based prescriptions can be avoided through electronic prescribing (e-prescribing). e-Prescribing may reduce medication errors, increase both physician and pharmacy efficiency, and avoid interpretation errors of hand-written prescriptions. Evidence concerning the impact of e-prescribing on error rates is generally mixed (Grossman, Cross, Boukus, & Cohen, 2012). However, one study demonstrated a significant reduction in the number of inappropriate medications dispensed (2.2% to 1.8%) for a system in which the dispensing pharmacist was alerted to problematic prescriptions (Raebel et al., 2007). A similar program resulted in changes to more appropriate drug regimens for 24% of the 43,007 triggered alerts (Monane, Matthias, Nagle, & Kelly, 1998). Aside from the latter studies and outside of DUR and MTM, there is scant literature on the role of information technology to enhance medication safety in the pharmacy setting.

Prescriber Education
A variety of prescriber interventions have been described to address medication safety, promote use of higher value medications, and improve adherence. These include mailed education coupled with free drug samples, as well as online and in-person group education. However, few have a meaningful impact on drug safety and appropriate prescribing behaviors (Pearson, Ross-Degnan, Payson, & Soumerai, 2003).

3 DoD may still be unable to accept e-prescriptions from civilian providers. This challenge and the impact on cost may be particularly salient for smaller military installations that utilize a majority of civilian provider services. These installations would bear the cost of expensive software installation and integrations that could be better absorbed by larger institutions. Additional resources, such as hardware and software, require additional funding as opposed to reallocation of current resources.
Academic detailing is a form of prescriber education that deserves particular focus because it is one of the few educational strategies that has shown consistent benefit. Academic detailing typically involves one-on-one or group counseling of prescribers by a pharmacist who discusses the cost and health benefits of specific medications for a target disease (Soumerai, 1998). One study found that academic detailing improved rates of first line anti-hypertensive medication prescribing while also generating cost-savings (Simon et al., 2005; Simon et al., 2007).

Reducing Medication Costs

Reference Pricing
With reference pricing, the most cost effective medication for a given condition is defined as the reference for each condition or class. Patients may receive more expensive medications, but are required to pay the difference in cost from the reference medication. A province-wide study in Canada demonstrated that reference pricing led to reductions in medication costs without adversely affecting medication adherence (Schneeweiss et al., 2002). A recent systematic review of the literature demonstrated that reference pricing policies reduce payer spending for targeted drug classes by 12–58%, as well as reduce patient out-of-pocket spending, without adverse health consequences (Lee, Fischer, Shrank, Polinski, & Choudhry, 2012).

Value-based Insurance Design
Payers and self-insured employers are increasingly implementing PBM designs that link co-payments to the value of the medication rather than the acquisition cost of the medication. Such VBIDs reduce co-payments for highly effective and low-cost medications, while increasing co-payments for medications that offer little value to patient health. A recent systematic review of the literature regarding VBIDs for a host of conditions showed that such strategies consistently improve adherence to therapy without increasing the total cost of care (Lee, Maciejewski, Raju, Shrank, & Choudhry, 2013).

For the highest-risk patients, VBID may represent an important opportunity to both improve quality of care and reduce total costs. In one national randomized controlled policy trial conducted by Aetna, almost 6,000 patients who experienced a myocardial infarction were randomized to either usual care or to first dollar coverage for cardiovascular medications (i.e., elimination of all co-payments; Choudhry et al., 2011a). The patients who received their medications for free experienced 14% fewer subsequent vascular events. Total costs of care were approximately $5,000 less for patients receiving first dollar coverage, though the study was powered on clinical events and this level of savings did not achieve statistical significance (Choudhry et al., 2011a). Nonetheless, Aetna chose to scale this program nationally, and a number of other commercial insurers have followed suit.

Specialty Drugs
As new technology expands exponentially and our aging population burgeons, specialty drug use continues to grow, accounting for greater total prescription drug spending for all payers, including the MHS. Experts concur that this area is a priority for active PBM, involving multiple approaches aimed at monitoring utilization and health outcomes (Sammer, 2010).

A specialty drug is defined as a unique biological substance that, when administered, mimics a bodily function or response. These drugs, which are often not available in generic forms, are frequently very
Appendix B: Citations for Exhibit 2

**Generic Substitutions**: Direct Cost Containment (Haas, Phillips, Gerstenberger, & Seger, 2005), Increase Adherence (Shrank et al, 2006)

**Step Therapy**: Direct Cost Containment (Dunn, Cannon, Mitchell, & Curtiss, 2006), Improve Safety (American Society of Health-System Pharmacists, 2008; Grabowski & Mullins, 1997)

**Prior Authorizations**: Direct Cost Containment (Green et al., 2010; White et al., 1997), Improve Safety (Ross et al., 2012)

**Pharmacy Networks**: Direct Cost Containment (Pharmaceutical Care Management Association, 2013)

**Mail Order**: Direct Cost Containment (Devine, Vlahiotis, & Sundar, 2010; Lewin Group, 2006), Improve Adherence (Devine et al., 2010)

**Clarity of Labels and Instructions**: Improve Safety (Wolf et al., 2011b), Improve Health Outcomes (Wolf et al., 2011b), Improve Adherence (Wolf et al., 2011b)

**Packaging**: Improve Safety (Berman, 2004; Lee, Grace, & Taylor, 2006), Improve Health Outcomes (Lee et al., 2006), Improve Adherence (Schneider, Murphy, & Pedersen, 2008)

**Automated Calls and Text Messages**: Increase Adherence (Park, Howe-Esquivel, Chung, & Dracup, 2014)

**Beneficiary Education**: Improve Safety (Gates, Setter, Corbett, & Baker, 2005; Meredith et al., 2002), Improve Health Outcomes (Lee et al., 2006), Improve Adherence (Kripalani, Yao, & Haynes, 2007)

**Medication Therapy Management**: Improve Safety (Doucette, McDonough, Klepsier, & McCarthy, 2005), Improve Health Outcomes (Academy of Managed Care Pharmacy, Shoemaker, Pozniak, Subramanian, & Mauch, 2010), Improve Adherence (Cutrona et al, 2010; Moore, Shartle, Faudskar, Matlin, & Brennan, 2013)

**Reduction of Polypharmacy**: Direct Cost Containment (Zarowitz, Stebelsky, Muma, Romain, & Peterson, 2005), Improve Safety (Zarowitz et al., 2005), Improve Health Outcomes (Farrell, Merkley, & Ingar, 2011), Improve Adherence (Farrell et al., 2011)

**Health Information Technology**: Improve Safety (Raebel et al., 2007), Improve Health Outcomes (Monane, Matthias, Nagle, & Kelly, 1998), Improve Adherence (Misono et al., 2010)

**Prescriber Education**: Direct Cost Containment (Simon et al., 2007), Improve Safety (Siegel et al., 2003; Soumerai, 1998), Improve Health Outcomes (Simon et al., 2007)


**Value-based Insurance Design**: Improve Health Outcomes (Choudhry et al., 2011a), Improve Adherence (Choudhry et al., 2014; Lee, Maciejewski, Raju, Shrank, & Choudhry, 2013)

**Specialty Drug Strategy**: Direct Cost Containment (Mullins, Lavallee, Pradel, DeVries, & Caputo, 2006; Sammer, 2010), Improve Safety (Mullins et al., 2006), Improve Health Outcomes (Mullins et al., 2006; Sullivan, 2008), Improve Adherence (Mullins et al., 2006; Sullivan, 2008)
Appendix C: References


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