Summary

Background

Over the past few decades, pharmaceuticals have become increasingly important in the delivery of medical care. They have also represented one of the fastest growing components of both U.S. civilian and Department of Defense (DoD) health care expenditures. Several factors have contributed to the acceleration of pharmacy costs, including the pace at which new drugs enter the market, the prices of these new drugs, and the increasing availability of prescription drug benefits through private insurance.

In recent years, service delivery organizations that purchase drugs on behalf of beneficiaries have begun to manage the purchase and dispensing of medications more aggressively through what is typically referred to as “pharmacy benefits management” or “formulary management.” This process typically entails managing pharmaceutical care through the development of a formulary (i.e., a list of covered drugs) and the implementation of processes to monitor and control access to those drugs. More than 90 percent of health maintenance organizations (HMOs) use some type of formulary process to manage pharmacy benefits (Hoescht, 1999).

Formulary processes can be in the form of either “closed” or “open” systems. A closed formulary is a system that offers a limited set of selected pharmaceutical products, with other non-formulary drugs made available only by waiver or exemption. An open formulary is a system in which the availability of drugs is based on their status as generic, preferred, or non-preferred pharmaceuticals. Pharmacy benefits are also managed through the amount of co-payments, with different, or tiered, price structures for various drugs.

Determination of the actual drugs to be included on a formulary or preferred drug list is typically delegated to a Pharmacy and Therapeutics (P&T) committee—a representative group of clinicians, primarily physicians and pharmacists, for the health plan. Health plans and insurers have frequently delegated the task of pharmacy benefits or formulary development to pharmacy benefit managers (PBMs).
The MHS can move toward a more integrated formulary (i.e., a list of covered drugs) through the use of prior authorization requirements and uniform limitations on certain pharmaceuticals, such as limitations that would be monitored by the DoD's on-line national pharmacy data transaction system. These requirements and limitations would be overseen by a central pharmacy benefit management group. However, the DoD's ability to adopt a Uniform Formulary (UF) for all its MTFs has several practical constraints. Moreover, whether and how the DoD will be able to apply a Uniform Formulary to health care providers outside the traditional boundaries of the highly structured MTFs (such as TRICARE contract providers) is unclear.

There are many advantages and disadvantages to formulary systems. On the one hand, they represent an opportunity to incorporate systematic reviews of scientific evidence on clinical effectiveness and cost effectiveness into coverage decisions and management activities, thereby potentially improving health outcomes while reducing costs. On the other hand, overly restrictive formularies may potentially reduce the quality of care by limiting a patient's access to clinically indicated medicines.

The long-term effects of formularies on patient care and health outcomes are largely unknown. A number of studies\(^1\) suggest that formulary policies can reduce health plans' pharmacy costs without impinging on patient care. However, other studies\(^2\) have highlighted potential adverse consequences of arbitrarily restricting access to medications.

### DoD Pharmacy Program Redesign

Section 701 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2000 (Public Law 106-65, codified at Title 10, United States Code, Section 1074g), directs the DoD to establish a single Uniform Formulary to govern Military Health System (MHS) beneficiaries' access to pharmaceuticals. The military health benefit is organized and delivered through two systems in two distinct settings—the *direct-care system* (with care delivered by TRICARE in military owned and operated treatment facilities, i.e., MTFs) and the *purchased-care system* (with care delivered by civilian providers outside MTFs under contract to TRICARE, also known as network providers). Both systems provide

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\(^1\)Foulke and Siepler, 1990; Ganz and Saksa, 1997; Dearing et al., 1998; McCombs and Nichol, 1993; Gold et al., 1989; Weiner, Lyles, and Steinwachs, 1991; Futterman, Fillit, and Roglieri, 1997; and Monane et al., 1998.


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military beneficiaries with access to pharmaceuticals and currently have very different pharmacy management activities. The Uniform Formulary Program segment of the Pharmacy Benefits Redesign Program, as legislated by Congress, will require an integration of these two systems and the development of additional administrative systems.

Prior to 1999, no single entity within the DoD had responsibility for administering and coordinating pharmacy programs (U.S. General Accounting Office, 1999a). Since then, the DoD has chartered the PharmacoEconomic Center under TRICARE and created and implemented the Pharmacy Data Transaction Service, which is an electronic database designed to track prescriptions dispensed across the MTFs, network retail pharmacies, and the National Mail Order Pharmacy (NMOP).

Work is still under way to implement all requirements of the NDAA legislation and to introduce the UF across the MHS. The details of the UF are still in the rule-making and comment stage as of this writing. The proposed legislation is subject to change during the comment period and will not be considered final until it is published in the Federal Register.

The proposed rule introduces a three-tier co-payment structure based upon a pharmaceutical agent’s classification in the UF (i.e., generic, formulary, or non-formulary) and the point of service from which the agent is acquired (i.e., an MTF, retail network pharmacy, retail non-network pharmacy, or the NMOP). For the direct-care system (i.e., drugs dispensed at the MTF), the proposed UF will resemble an expanded basic core formulary (BCF) and will continue to allow local MTF P&T committees to make additions to the formulary based on the scope of care. For the NMOP (for prescriptions written by either a direct-care provider or purchased-care provider), the proposed UF will make non-formulary medications available at the third-tier co-payment amount. In the retail network pharmacies (again, for prescriptions written by either direct-care or purchased-care providers), the UF will make 30-day supplies of non-formulary medications available at the third-tier co-payment amount.

The proposed UF program will represent a major management shift in the purchased-care system, in which formularies, currently, are open and offer few opportunities for the DoD to manage the cost of pharmacy benefits. Thus, through the proposed UF, the DoD will gain the ability to determine how prescriptions are dispensed, from a cost standpoint, in the purchased-care sector. The DoD will gain this ability through higher co-payments, which will create incentives for beneficiaries to opt for preferred formulary medications and to
consider filling their prescriptions for such medications through the MTF pharmacies or through the NMOP.

Survey of Military Health System Prescribers

To assess the impact of the uniform formulary on the care delivered in the Military Health System, particularly in regard to perceived access to pharmaceuticals, Congress required two surveys of MHS prescribers, one prior to UF implementation (the baseline survey) and another following the UF implementation (the follow-up survey). At the request of the TRICARE Management Activity (TMA) and in compliance with Section 701 of the NDAA for FY 2000, RAND conducted the first of these surveys in mid-2001. The purpose of the first survey effort was to measure and evaluate the perceptions of prescribers who practice at MTFs and prescribers who practice under TRICARE contract in the civilian sector. The survey sought feedback regarding obstacles prescribers face in providing beneficiaries with formulary medications, non-formulary medications (or “non-preferred” medications as they may currently be called), and quality pharmacotherapeutic care. The baseline survey described in this report assesses how prescribers’ perceptions of and attitudes toward formularies may be currently influencing their decisions on prescribing pharmaceutical products.

Because military benefits (including pharmacy benefits) are delivered in two distinct systems—direct-care and purchased-care—and because these two systems currently have two different formulary management systems, two separate survey instruments were designed for MHS prescribers.3 One survey instrument was aimed at TRICARE prescribers working within the direct-care system in MTFs, and a second survey instrument was aimed at prescribers who provide services to military beneficiaries at network facilities under contract to TRICARE.

Seven hundred MTF (i.e., direct-care) prescribers and 600 network (i.e., purchased-care) prescribers were sampled using data obtained from claims records for fall 2000. We drew a stratified sample within each of the two target populations to ensure representation of specific analytic groups of interest (e.g., non-M.D. providers, specialists, and others). Prescribers were asked a series of questions about their knowledge of and degree of familiarity with formularies, formulary development, and management practices. They were also asked

3“Prescribers” as defined by the FY 2000 NDAA are physicians, physician assistants, and nurse practitioners with prescribing privileges.
specific questions about their perceptions of the impact of formulary management on their own prescribing behavior and the quality of care provided to their patients. Participants were also questioned about their background and medical practice. Sixty-nine percent of eligible MTF (direct-care) prescribers and 39 percent of eligible network (purchased care) prescribers responded.

Conclusions

MTF prescribers who responded to the survey reported a high degree of familiarity with the formulary and formulary management practices in place at their own MTFs. In general, MTF respondents perceived formulary management as contributing toward quality of care and agreed that controlling costs through such formulary management is important.

Network prescribers who responded to the survey reported interacting with multiple formularies and formulary management practices. Network respondents reported less familiarity and comfort with formulary lists and the rules governing their use. They did not believe that formulary management was contributing to the quality of care they provided.

Some differences were observed within each sample. For example, within the direct-care system, primary-care providers reported having a higher level of familiarity and greater comfort with formulary management techniques than did secondary-care providers. Direct-care providers within smaller MTFs also reported greater familiarity with the activities of P&T committees and with the rules governing non-formulary prescriptions at their MTF than did direct-care providers at larger MTFs. Within the purchased-care system, primary-care providers interacted with a greater number of preferred or formulary drug lists than did their secondary-care provider counterparts.

A follow-up RAND survey, which will be administered approximately six months subsequent to implementation of the UF, will assess changes in prescribing behaviors and in prescribers’ perceptions and attitudes about formulary management in general, as well as assess prescribers’ actual experiences with the DoD Uniform Formulary specifically.