Testimony Before the U.S. Senate Committee on Veterans' Affairs

Hearing on Prescription Drug Issues in the Department of Veterans Affairs

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Mr. Chairman, Members of the Committee. I am honored and pleased to be here today to share some of my thoughts on the Veterans Health Administration's (VHA) management of pharmaceuticals and on the findings of the Institute of Medicines,[1] and the General Accounting Office's[2] studies of this issue. For the last year and a half I have been a health policy and communications Analyst, Consultant and Educator focusing on issues and projects related to the quality of healthcare and the development and use of new medical treatments. In this capacity I have given talks and participated in over 40 meetings across the country discussing these topics. I am currently a Consultant to the Pharmaceutical Research and Manufactures of America, the Association representing America's Research-based Pharmaceutical companies, but I want to make it clear that the views I am expressing are my own.

Introduction:

It is important to remember that the current focus on the VA's National Formulary is due to the clinical and economic value of modern pharmaceuticals. Over the past 10-20 years pharmaceuticals have become a more important part of healthcare, and patients and providers are increasingly looking to pharmaceuticals as their preferred treatment option. Due to their clinical importance and value, providers and consumers of healthcare are also seeing a growing percentage of their healthcare spending going to pharmaceuticals. In sum, the pharmaceutical industry has succeeded in bringing many better treatment options to the bedside and the pharmacy shelf, but with this success has come increased scrutiny from those paying for healthcare services. The VHA is no exception, and as it has been reorganizing the Veterans Healthcare System, it has had to confront pharmaceutical management issues. Although much of the reorganization has been positive, such as expanding outpatient clinics, I believe that some of the clinical aspects of its management of pharmaceutical care have been problematic for veterans and the quality of their healthcare.[3]

There are three key points I would like to make: First, the quality of care received by America's veterans should be the focus for assessing the VHA's pharmacy programs. Second, veterans receiving care from the Veterans Healthcare System are significantly different from patients receiving care through private managed care plans or state Medicaid programs. Third, although the VHA's formulary and pharmacy practices are often compared to those employed by private managed care plans and state Medicaid agencies, the VHA, as a government program must operate differently, and it is limited in some of the ways it can deliver and manage veterans'

[1] "Description and Analysis of the VA National Formulary," IOM 2000

[2] "VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs," GAO-01-183

[3] Part of the challenge of modern healthcare is integrating the management of all components of the healthcare delivery system. It is easier to manage each component – and its budget – separately, but such an approach creates barriers for capitalizing on the benefits of new innovations, both in technology such as pharmaceuticals and in processes for delivering care, such as new medicines or disease management programs.

healthcare. I will expand upon each of these areas, and conclude with some thoughts about future directions.

Quality of Healthcare for Veterans:

Quality in healthcare is often defined by different individuals and experts in a variety of ways. For example, the IOM asserted that healthcare quality "can be assessed by examining the structure, process, and outcomes of delivery of care." Another frequently used measure of quality is patients' satisfaction, which is often measured as waiting times for both an appointment and within the healthcare system."[4]

The definitions I prefer, focus on the individual patient. One definition is, "The right treatment for the right patient at the right time." Assessing quality at the individual patient level is achieved through outcome measurements. As the VA's Primer on Outcomes states, "Outcomes measurements help bring the focus of the entire health care delivery system back to the patient. Rigorous and continuous evaluation of the processes of care through outcomes measurement and analysis will ultimately improve the quality of care."[5] The "Principles of a Sound Drug Formulary System," which was endorsed by the VA, "recognizes that patient care may be compromised if its formulary system is not optimally developed, organized and administered.[6]

As quality can be defined in many different ways, can it can also be analyzed in many different ways. The IOM and the GAO have each reviewed and analyzed the VHA's pharmacy system, and I would like to highlight some of their findings while commenting upon some of the limitations of their studies. I will make these comments not to criticize in any way the good work of the IOM or the GAO, but rather as a starting point to suggest approaches and promote thinking about future analyses of the Veterans Health System and VHA management because I strongly believe it is important to understand what we know -- and what we don't know -- in order to plan for future improvements.

One of the worrisome findings in both the IOM and GAO studies is that the VA's activities in collecting and analyzing data to assess outcomes concerning its National Formulary system have been insufficient or lacking, and thus overall VHA's oversight in this area has not been comprehensive nor integrated with other aspects of quality monitoring and improvement. This contrasts both with the VA's Outcomes Primer statement that, "Reliable data collection is necessary to develop strong evidence for health care decision making," and the VA's data showing utilization changes and cost savings. Although the IOM did try and assess the effects of these utilization changes on veterans' healthcare, they were restricted in their ability to do so by the VA's data limitations and because they were conducting a retrospective analysis rather than being able to evaluate the effects prospectively during implementation of the formulary policies.

[4] In July 1999 Testimony, the GAO found that "Currently, the VA does not track information on primary and specialty clinic appointment waiting times." GAO/T-HEHS-99-158

[5] "Using Outcomes to Improve Health Care Decision Making," Zimmerman, Daley, Kizer and Feussner, VA and AHSR, 1997

[6] October 2000, "Principles of a Sound Drug Formulary System," was endorsed by the VA's PBM, the AMA, the Academy of Managed Care Pharmacy, the Alliance of Community Health Plans, the American Society of Health-System Pharmacists, the National Business Coalition on Health, and the U.S. Pharmacopeia.

The IOM did find that hospitalizations for certain heart and ulcer conditions did not change with the implementation of restrictions for medicines for these illnesses. Such a finding is in some ways reassuring that the outcomes for patients with these conditions did not change. However,

this conclusion could be questioned because, in part, it assumes that the percentage of veterans using the Veterans Healthcare System who have outside insurance coverage, such has Medicare, has not changed and similarly that veterans use of non-VA facilities has not changed. These assumptions, and hence the IOM's conclusion, may be questioned in light of the GAO's 1999 finding that "several [VISN] directors commented that they are experiencing increased demand by veterans whose primary care is provided elsewhere but who obtain from the VA specialty care and services not covered by private insurance or Medicare." [7] [8]

In addition, measuring inpatient admissions as a surrogate for outcomes would also miss adverse events treated in VA outpatient clinics, as well as in private outpatient settings. Given that the IOM also found that the VA's Patient Safety Event Registry "does not appear to be a reliable source for identifying ADEs (Adverse Drug Events)," this could be another factor complicating the evaluation of the effects of the VA's National Formulary and pharmacy policies on the quality of healthcare for veterans.[9]

Therefore, without measuring the utilization of healthcare services for individual patients both within and outside of the Veterans Healthcare System, it is uncertain how total utilization and outcomes have been affected by the VA's formulary policies.

The IOM also found some problems with the VA's non-formulary exceptions process and therapeutic interchange practices. Both of these policies affect the individualized nature of clinical medicine. Although we would all like to believe that the practice of medicine is much more a science than an art, individual patient variation still plays a significant part in clinical care, and as the VA's Technical Advisory Panel concluded, population-based approaches to healthcare decision making and delivery, such as practiced by managed care plans and being adopted by the VA, have ethical implications. [10] The changing nature of medicine – with new knowledge replacing old dictums – also makes such system-wide clinical decision-making both

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[7] GAO/T-HEHS-99-109

[8] It could be argued that if VA patients' use of private sector health facilities has not changed then the conclusion would be valid. However, the availability of emergency care differs between the VA and private health facilities, and thus if there were an increase in outside insurance coverage and acute adverse events, then the utilization of these non-VA health services might be expected to increase disproportionately.

[9] The VA endorsed, "Principles of a Sound Drug Formulary System," calls for a formulary system that "Provides for the monitoring, reporting, and analysis of adverse results of drug therapy (e.g., adverse drug reactions, medication errors) to continuously improve quality of care.

[10] The VA's Technology Assessment Program 1996 report on issues related to transferring managed care principles to the VA stated that the following managed care principles were used by private health plans that would be appropriate "models to the VA:

- care should be integrated throughout disease processes;
- resource use should be managed through the management of quality, i.e., by the management of variation;
- incentives should be aligned to the well-being of the enrolled population, not to the punishment of physicians for individual clinical decisions;
- the ethical impact of a population-based approach to health care decision making and delivery should be addressed through technology assessment."

difficult and dangerous, particularly when the system is structurally encumbered from changing rapidly.

Another challenge the VHA faces in making decisions about therapeutic interchange is the limitations of the data available to them about individual patient variability between medicines. The FDA only achieves such conclusion about the interchangeability of medicines for generic versions of already approved medicines based upon bioequivalency data – not for different chemical compounds. In fact, the FDA was so concerned about adverse drug events (ADEs) from therapeutic interchange in private health systems, that it specifically launched an effort through its MedWatch program looking for such ADEs.[11]

Several other factors complicate the reliability of conclusions made when analyzing data about any group of medicines in a class. These include:

- The different natures of the populations used in the individual studies;
- The reporting of group averages can often be misleading when trying to make efficacy comparisons;[12] and
- Study populations may be less ill than the population to which the conclusions will be applied. Because of the greater disease burden in the real-life population, such as that seen at VA health centers, there is a greater possibility of adverse events due to the higher rates of concurrent diseases and additional medicines used.

These factors all contribute to the different results produced in a clinical trial, where conditions and patients are closely monitored, versus those in real world clinical practice.[13] The VA uses this argument, along with the veterans being more ill than average patients, for not making medicines readily available once they are approved by the FDA. Thus, the VA argues that the data on newly approved drugs is not sufficient to safely provide them to veterans, but it uses similar data to decide which medicines are therapeutically interchangeable. Further, while acknowledging that veterans are more ill than average, and some have specialized health needs, the VA's dictum against newly approved medicines ignores the clinical value of innovative medicines. This knotted logic illustrates my concern about making system-wide clinical policies and decisions without the treating physician being able to truly individualized care for a particular patient.[14] The incentives for VHA physicians to comply with the VHA's formulary policies and directives are another factor concerning the effects the VHA's formulary system has on the quality of care for veterans. Although there appears to be little analysis in this area, the centralized nature of the VHA's management, and because VHA local and regional managers are

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[11] System-wide therapeutic interchange policies are an example of a population-based approach to healthcare decision-making and delivery.

[12] For example, if two medicines have both been shown to be effective in treating a disease in 70% of patients in clinical trials, this may – or may not – mean they are comparable because each medicine may have a 70% likelihood of being effective in any given individual, but its success or failure in an individual may not predict likelihood of the success of failure of the other medicine in the same patient. This is the situation for the SSRI class of medicines used to treat depression.

[13] The VA's Outcomes Primer (1997) states, "clinical epidemiologists have sought to establish 'real world' effectiveness of diagnostic tests and treatments. These researchers have been concerned not only with the 'intervening' variables that characterize disease status, but with the 'patient outcome' variables that characterize patients' health status."

[14] The VA asserts that individual physicians can obtain off-formulary medicines for their patients when need, but the GAO in its January 2001 study found that 60% of the providers they surveyed said the average waiting time for non-formulary approvals was 9 days. GAO/HEHS-00-34

attempting to monitor formulary compliance, raises questions about what incentives and disincentives VHA physicians are facing in providing care to veterans.

How concerned should we be about the effects of these pharmaceutical and practices on the individual veteran? The GAO found that 10 percent of prescriptions were for drugs in the VA's closed classes.[15] [16] How, many veterans this affects are unknown. The best way to determine the effects would be through a comprehensive, patient-based analysis of the utilization of the restricted drugs and classes in the VA's National Formulary.

Several surveys have also been conducted to assess the quality of the VHA's pharmaceutical management systems. Each of these surveys has its methodological problems and limitations. The IOM identified some of these in its review of both VHA's written survey and the telephone survey conducted by Yankelovich Partners. The GAO also conducted a mail survey for its January 2001 Report.[17] The Yankelovich survey captured some "experiential data" – to borrow a term from the GAO's lexicon – on actual patient outcomes: It found that 23% of the 418 VA physicians surveyed had personally had a patient experience a negative outcome because of problems accessing medicines within the VA's National Formulary system. I find this to be of concern, particularly when it is combined with the IOM"s finding that as of the time of their survey, the VA's Patient Safety Event Registry did "not appear to be a reliable source for identifying ADEs."

These conclusions are consistent with the GAO's and the IOM's findings that the VA's National Formulary system has been implemented without sufficient data collection and quality focused oversight tools in place. While the GAO in part focused on the VA's problems in ensuring compliance with the National Formulary policies and "standardizations," I am much more concerned about the lack of data and oversight related to quality of care and outcomes measurements. The VA's National Formulary could be viewed as a large experiment where only a few of the possible effects were chosen for monitoring and analysis. Specifically, the VA has closely monitored and reported effects on utilization and costs, but the effects on quality of patient care – albeit much more difficult parameters to measure – have not received the nearly the same attention by the VA. (These same data inadequacies may also exist within many private health plans, and in the following sections I will discuss the implications of the differences between the VHA and other health systems.)

The bottom line is that unless outcomes and adverse events are examined, changes can't be made to improve outcomes and avoid adverse events, and the effects on quality brought about by changes to the systems and processes will not be known until secondary and more significant adverse events become apparent. This is analogous to shaving your face in a fogged-up mirror. You may know that the blade needs to changed because you face feels rough or you find blood

[15] GAO December 1999 Study, " VA Health Care: VA's Management of Drugs on Its National Formulary."

[16] A 1998 analysis comparing IMS data and the medicines excluded from the VA's closed classes found that the VA's National Formulary excluded 12 of the 100 medicines most frequently prescribed in the private market. Since the list of 100 medicines included generic medicines, the percentage of excluded innovative medicines was greater than 12%, i.e. closer to 25%.

[17] Of concern in the GAO survey was that they received responses from "many prescribers" who wrote only a few prescriptions, and thus the average findings may not reflect the experience of active clinicians.

on your fingers, but wiping off the mirror and looking at what you are doing is certainly a both a quicker and cheaper solution in the long run, because preventing adverse outcomes is better than treating them.

Differences Between VA Patients and Patients in Private Health Plan or Medicaid:
Although private health plans are often criticized for having the same data collection priorities as described above, it is important to appreciate the differences between veterans obtaining care at VHA facilities and patients obtaining care at private health plans, and the implications this can have for the quality of healthcare veterans receive.

Not only is the VA caring "for a population that is disproportionately elderly and ill,"[18] [19] [20] but many veterans also lack the economic resources to choose another option for their healthcare, i.e. they can't vote with their feet to see another doctor, and they can't afford to pay out-of-pocket for a medicine the VA won't provide for them. These differences between the Veterans Healthcare System's patient population and the population cared for through private health plans have significant implications for comparing their management practices.[21]

Of course, not all veterans who use the Veterans Healthcare System lack economic resources. Some are also Medicare beneficiaries, and use the VA for benefits Medicare does not currently provide, i.e. pharmaceuticals. Within this group of patients, there are certainly individuals who can afford to purchase medicines not provided by the VA. This leads to a troubling practice that I call "healthcare disintegration." By that I mean, the patient's team of healthcare providers is divided so not only may the patient be receiving prescriptions from more than one physician, but they are almost certainly having prescriptions filled by more than one pharmacist – who may not know what other medicines the patient is taking.[22]

The significance of these clinical and economic factors is that methods for delivering healthcare, and of financial incentives for patients and providers, cannot always be readily transferred from the one system to another. In the clinical arena, delivery systems developed for private sector health systems may not fit the needs of patient populations with greater needs for mental health and substance abuse treatments. In the economic area, private health plans use financial incentives, unavailable to the VA, to push patients and providers to use certain medicines, and the structure of these incentives have been evolving very rapidly over the last decade, from closed formularies to three tiered, to now four or even five tiered formularies. One interesting private sector health plan utilizes a program called 10-50-1000 to create financial incentives for

[18] IOM Study – characterization in Committee Chair's Preface.
[19] ~ 9 million Veterans are Medicare beneficiaries.
[20] Estimates of Hepatitis C prevalence among veterans were put at 8-10 percent in 1999, (GAO/T-HEHS-99-158), and over 670,000 Veterans treated by the VA have mental illnesses, and 366,000 have a substance abuse diagnosis. (VA Testimony, 6/20/2001)
[21] Similarly, VA patients are very different from those covered by Medicaid. Simply put, the Medicaid patients are younger women and children, or elderly in long-term care settings, whereas the VA patients are predominantly male and elderly.
[22] I recently encountered this situation with a family friend with diabetes and cardiovascular conditions. The VA provides him with some of his medicines, and he obtains those the VA will not provide from the local pharmacy. Neither pharmacist knows or has records about all the medicines he is taking. This not only complicates his healthcare, potentially putting him at increased risk for drug-drug interactions, but it also undermines any analysis based solely upon VA data. This type of "disintegration" of the patient's healthcare team is also one of the hidden hazards of purchasing medicine via the Internet or from foreign sources.

patients and their physicians: A $10 co-payment for preferred brand medicines, a 50% co-payment for a non-preferred brand medicine, and an annual $1000 out-of-pocket cap. Some private health plan formularies allow a patient to pay a lower tier's co-payment amount if, for medical reasons, they cannot take the preferred medicine in that therapeutic class. The decision about this lower co-payment is made within the health plans local administration. Innovations like this are not possible within the Veterans Healthcare System because of its centralized decision-making structure and standardization, and the economic limitations of many VA patients.

Limitations of the VA Health System as a Government Program:

Although significant restructuring of the VA's Health System has occurred in the past several years, it still differs from private health systems in many ways, including:

- Limited flexibility in managing its annual budget because such a great percentage of it is committed to relatively fixed cost areas such as personnel and facilities;[23]
- Limited flexibility in hiring or firing of personnel, and buying or selling buildings or land;
- Access to government monsopony benefits such as the Federal Supply Schedule prices for pharmaceuticals which already provides the VHA with procurement prices lower than those available in the private market;
- Regulatory procedures must frequently be followed to change policies and practices; and
- Limited ability to change the structure of benefits.

In contrast, private sector health plans are constrained only by the terms of the contracts they have with patients, employers, and providers, as well as by some state and Federal laws. Specifically, as a Federal program, state laws do not bind the VA and thus it can bestow privileges on health care providers beyond what state laws would allow. For example, the VA is able to allow VA pharmacists to enforce therapeutic substitution policies, and give the veteran a medicine different from what their treating physician prescribed without a new prescription order from a physician. The VA endorsed "Principles of a Sound Drug Formulary System" specifically states that "Therapeutic substitution, the dispending of therapeutic alternatives without the prescriber's approval, is illegal and should not be allowed."

Overall, private health plans have much greater flexibility than the VA, and each faces different directives and forces when working to respond to the challenges of a changing healthcare environment and evolutions in biomedical science. For example, because so much of the VA's budget it consumed by relatively fixed cost areas, in times of financial constraints, savings programs must be directed towards budget items that are not fixed, e.g. pharmaceuticals.[24]

These budgetary constraints drive the VA's decision making into silo or sector thinking and management. Private health plans, because of their greater structural and financial flexibility, can more easily integrate the management of all components of their health delivery system, and thus explicitly attempt to initiate practices which will produce cost savings in one area while knowingly increase costs in another area. For example, a large health plan instituted a disease management program for patients with congestive heart failure. After one year's experience

[23] "VA's massive, aged infrastructure could be the biggest obstacle confronting VA's ongoing transformation efforts." GAO/T-HEHS-99-109

[24] Pharmaceuticals represent the single largest component of these "unfixed" expenditures – even though within the VHA's overall spending, pharmaceuticals are very small compared to facilities and personnel costs. An analysis I conducted several years ago showed that ~65% of the VA's health budget was spent on inflexible expenditures such as personnel and facilities, while about 9% was spent on pharmaceuticals.

with over 1,900 patients, they found they for these patients, hospitalization costs had decreased 78%, outpatient pharmaceutical spending had increased 60% ($243,000), with the net savings in caring for these patients totaling $9.3 million. [25] Moreover, this intervention produced better clinical outcomes, with patients better able to perform activities of daily living, and the mortality rate was only 10 percent compared to an expected 25 percent. This type of integrated management is difficult for the VA because of it's data limitations, and so much of its spending is for fixed cost items and thus it cannot realize savings from such utilization substitutions.[26]

Private health plans also have much greater flexibility in their arrangements with both providers and patients. For example, health plans can relatively quickly, reorganize contracts with providers, reprioritize co-payments and deductibles payments due from patients, sell off assets and even change premium structures. This gives health plans much greater flexibility in managing financial constraints, and in responding to the changing nature of clinical medicine.

Conclusions:

- The Veterans Healthcare System is a unique component of the U.S. healthcare system, serving an important role in providing healthcare services to America's veterans. Because of its unique character, any comparison of the Veterans Healthcare System to other health systems must recognize the differences – clinical, economic and regulatory – between the VA and non-governmental healthcare systems – both here in the U.S. and in other countries.
- While the VHA provides healthcare to over 3 million U.S. veterans each year, these individuals are not a representative sample of Americans, but rather they are predominantly male, older, have more healthcare problems and needs than average, and have lower financial resources. These last two points, while well known to VA observers, are important because together they mean that many of these patients are more vulnerable both clinically and economically than patients in private health plans who are protected by their ability to choose other health plans, or treatments not preferred nor offered by their health plans.
- To truly evaluate the effectiveness of a health system, and any changes being made to "improve" it, clinical outcomes are the gold standard. Recognizing the difficulty in measuring and analyzing data for clinical outcomes does not change their importance. Rather, it highlights the importance of examining whatever analyses are available, the limitations of these analyses and what insight they can provide into the effects changes to any component of the health system may be having on actual clinical outcomes.
- Overall, because outcomes are the key goal, in evaluating any health system it is important to look at four key areas of structure and planning: 1. How access is provided to health care services and the effect access limits and practices have on clinical outcomes; 2. How innovations are adopted by the system to improve outcomes; 3. In planning for future improvements to a health system, what should this future looks like, i.e., what is the vision; and 4. What is the plan for getting to that envisioned future from where the system exists today. Recognizing its unique characteristics and limitations, all these principles can be applied to the Veterans Healthcare System, and its management of pharmaceutical access and delivery.

[25] 1996 Year-Long Study of 1,915 Humana Members reported in "Managed Care Pharmacy," April 1998, pp 42-44

[26] In 1999, the GAO stated "VA's data systems do not fully track treatment specific costs, making it difficult for VA to determine the exact cost savings it could realize by discontinuing care to some veterans or reducing benefits." GAO/T-HEHS-99-158