

MINUTES

## POLICY BOARD

September 21, 1999  
Dallas, TX

**Members Present:** Dr. Murphy, Chair. Mr. Clark, Dr. Holohan, Dr. Feussner, Dr. Mather, Mr. Grams, Mr. Albinson, Mr. Sinclair, Dr. Parrino representing Network 1, Mr. Malphurs, Mr. Farsetta, Mr. Biro, Dr. Nocks, Mr. Husson, Mr. Deal, Dr. Roswell, Mr. Dandridge, Ms. Miller, Ms. Belton, Dr. Petzel, Mr. Ng, Ms. Crosetti, Dr. Higgins, Ms. Oshinski for Dr. Cummings, Dr. Chong, Mr. Gardner, Dr. Batliner, Dr. Galey, Dr. Wiebe, Mr. Jenkins, Mr. Robinson for Ms. Bradley, Mr. Pernick for Mr. Duffy.

**Guests for Presentations:** Mr. Ogden, Dr. Lehmann, Ms. Koerber, Mr. Hamerschlag

Topic	Discussion/Recommendations/Action
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**VIAGRA****Reference documents:**

1. Minutes, Policy Board, dtd 1/21/99
2. Memo from USH, Subj: Use of the Drug Viagra within the Veterans Health Administration, dtd 4/9/99
3. OGC opinion, Subj: Writing Prescriptions for Nonformulary Drugs, dtd 3/24/99
4. Clinical Practice Guideline for Erectile Dysfunction, dtd 6/99
5. Draft VHA Directive titled Writing Prescriptions for Veterans to Purchase at their own Expense, undtd
6. Memo from Chair, Viagra Task Force, Subj: Viagra Update, dtd 7/2/99

Issues related to use of Viagra were discussed at the January 21, 1999, Policy Board at which time Viagra Task Force recommendations were advanced and the Under Secretary approved the following:

- Exclusion of Viagra from the VA National Formulary
- Continuation of Viagra use at VA expense for those VA patients currently receiving Viagra that are re-evaluated and fit the (then soon to be released) guidelines on erectile dysfunction
- Proceeding with a cooperative study to address the safety of the drug in the veteran population that uses VA healthcare
- Policy Board reassess VA policy about use of the drug in six months in light of any new pertinent data about its safety and efficacy

**Discussion:**

The Medical Advisory Panel (MAP) erectile dysfunction (ED) guidelines submitted to Policy Board are currently under review by VHA's guideline review committee. The Technology Review Panel has also conducted a review, with findings consistent with those in the MAP ED guidelines. The guidelines specific to use of Viagra are consistent with earlier recommendations. Exclusion of Viagra from the National Formulary, with provisions for non-formulary use, remains appropriate. It was noted that there is VISN formulary inconsistency in this regard.

A proposal for a cooperative study is under peer review. The approval process likely will not result in funding before 2001 with findings available three or more years hence. For that reason, the research office recommends a post-marketing surveillance study be undertaken.

As a broader but related matter, General Counsel has opined on the subject of writing prescriptions for non-formulary drugs. GC holds that VA providers may legally write prescriptions for pharmaceuticals not on VA's formulary, to be filled at the veteran's expense, when the veteran prefers to use an alternative to a drug included on the VA formulary and the veteran understands that VA will provide the equivalent formulary version. (OGC staff clarified that written acknowledgement of informed consent on the part of the veteran is not required.) Based on that opinion, a VHA directive is in draft, which will make clear that the intent is not to shift costs to veterans but to add flexibility that supports veteran preferences. Comments on the draft should be provided directly to the Pharmacy Benefits Management SHG.

**Recommendations:** Motion made, seconded and approved without dissent to accept, as a standard, the ED guideline (with national guideline committee approval) and continue use of Viagra based on the guideline, without

inclusion on the National Formulary. Allow VISN formularies to include or exclude the drug.

Action: Pending Under Secretary action.

Under Secretary for Health Comments:

*Approved with two caveats:  
 ① Do not place on VISN formularies  
 at present to avoid appearance of inconsistent guideline application ②  
 Review non-formulary use six months after guideline approved.*

#### VERA Research Support

Reference document:  
 EDM, VERA Research Support  
 dtd 9/7/99

Based on concerns that VERA research support funds are not being provided to the medical centers conducting research appropriately, a Research and Development Office (RDO) task force was convened and made recommendation to the Under Secretary. The Under Secretary approved a recommendation to reassign responsibility for distribution of VERA those research support funds that support investigator salaries to the RDO and retain the remainder of the funds in VERA. Based on continuing concerns regarding allocation of these funds, the Acting Under Secretary asked that the VERA Research Support Work Group reexamine the issue. In brief, the work group recommended:

1. Develop and implement a system for accounting of medical care appropriation spent in support of research (with completion of system design by April 1, 2000),
2. Assure the system includes agreement on expense items to measure, system to be used to collect and report data, salaries to include; salary support and other expense items to be separately collected; and use of the DSS, RDIS and any additional systems necessary to collect and report appropriate information.
3. Networks pass through research support VERA allocation as it is computed for each medical center, "care line", or "product line" and each such entity explicitly obligate and account for VERA research support funds so allocated to support the salaries of researchers, research facilities and administrative costs.
4. Specific purpose funds for this purpose be effective for FY 2000 and the recommendations be revisited in April 2000 when the accountability/ accounting systems have been identified and preliminary data is available.
5. A communications effort be mounted that involves negotiation of protected time for research, involves local research office in accounting system implementation, involves medical center management in grant approval process, provides feedback about documentation to researchers and encourages network directors to meet with researchers when making facility visits.

**Discussion:** While the VERA research support allocation recognizes and seeks to support costs of patient care associated with research, the strength of recommendations overall is that they provided for accounting systems to assure accountability for such support. The funds distribution processes and practices should have uniformity across the system to assure equity and rationalize how funds are allocated. VISN involvement in the process is required in that funds are no longer allocated strictly to individual facilities but also to product or care lines, the latter crossing facility boundaries. Other issues discussed included:

- Essential nature of accountability systems and measures
- Past history of poor communication across a number of fronts recognized in Recommendation 5. Above
- Importance of research in delivery of high quality care within VHA
- Importance of striking an appropriate balance of protected time for

- research, education and clinical care activity
- Past effort and ongoing need to understand all costs associated with research, direct and indirect (in the context of how VERA research support was determined using CDR, "hidden costs", various funding sources) and need assure that incentives are not created which could result in inflated research costs or disincentives to support research

**Recommendations:** Motion made, seconded and approved by majority vote to approve work group recommendations.

**Action:** Pending Under Secretary action. *Approved. Chair of Under Secretary for Health Comments: The workgroup to be ACOS/Research from field.*

**RFP for New Clinical Program Initiatives**

**Reference documents:**  
VHA Notice 99-01 dtd 5/26/99 and proposed changes thereto

Based on comments and suggestions of Policy Board at an earlier meeting, proposed changes have been drafted and submitted for comment. Member comments should be provided to Dr. Meehan in the Research and Development Office by September 30 after which time the document will be advanced through usual channels to the Under Secretary for approval.

**Recommendations:** N/A  
**Under Secretary for Health Comments:** \_\_\_\_\_

**Compliance Program**

**Reference document:**  
EDM, Subj: VHA Compliance Program, undtd

VHA Chief Finance Officer requests concept approval to proceed with development and implementation of a mandatory, integrated compliance program at HQ, VISN, and facility levels based on the seven components of the HHS model hospital compliance plan.

**Recommendation:** Approve concept - consensus. *Concur*  
**Under Secretary for Health Comments:** \_\_\_\_\_

**Process for Review of Legislative Proposals**

**Reference documents:**  
Draft IL, same subject, undtd

Based on discussion at an earlier meeting, a proposed process for legislative proposal review was submitted for review and comment. Comments should be provided to Bill Ramsey in the Policy and Planning Office.

**Recommendations:** N/A  
**Under Secretary for Health Comments:** \_\_\_\_\_

*Frances M. Murphy, M.D.*  
Frances M. Murphy, M.D., M.P.H.  
Chairperson

**Minutes Accepted:**  
**Recommendations and Actions Approved/Disapproved:**

*Thomas L. Garthwaite*  
Thomas L. Garthwaite, M.D.  
Acting Under Secretary for Health

*10/19/99*  
Date