Department of Defense

Pharmacoeconomic Center

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Fort Sam Houston, TX 78234-6190

MCCS-GPE 14 July 1998

MEMORANDUM FOR Assistant Secretary of Defense (Health Affairs)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee Meeting

1. In accordance with the Office of the Assistant Secretary of Defense (Health Affairs) [OASD(HA)] Policy 98-025, signed 23 March 1998, a meeting of the DoD P&T committee convened on 13-14 July 1998, at Fort Sam Houston, TX.

2. MEMBERS PRESENT:

COL William D. Strampel, MC	Co-chairman
COL Errol L. Moran, MS	Co-chairman
COL Rosa Stith, MC	US Army Representative
LTC Judith O'Connor, MC	US Army Representative
Ms. Danielle Doyle, DAC	US Army Representative
CDR Terrance Egland, MC	US Navy Representative
CDR Matt Nutaitis, MC	US Navy Representative
LCDR Denise Graham, MSC	US Navy Representative
LTC William Sykora, MC	US Air Force Representative
LtCol John R. Downs, MC	US Air Force Representative
MAJ Greg Russie, BSC	US Air Force Representative
CDR Robert Rist	US Coast Guard Representative
Mr. John Lowe	VA Representative
LtCol Wayne Cheatum, BSC	DMSB Representative
Capt Debra Parrish, BSC	DSCP Representative
Ms. Ray Nan Berry	Foundation Health Representative
Mr. William Hudson	Humana, Inc. Representative
Mr. Gene Lakey	TriWest Representative

3. OTHERS PRESENT:

CAPT Chuck Bruner	USCG
COL Patricia Hobbs, BSC	USAF

COL James Normark, BSC	USAF
COL Ernest Sutton, MC	USA
COL Roger F. Williams, MS	USA
Mr. Shelby Tanner, SJA	USA

4. ISSUES DISCUSSED:

a. P&T Committee members introduced themselves and gave a background review of their experience. COL Moran introduced the members of the DoD Pharmacy Board of Directors, managed care support contractors, and other attendees.

b. MAJ Russie gave a presentation on the global perspective of formulary management and an overview of the drug distribution systems within DoD.

c. COL Moran provided the committee with a background review of how and why this committee was formed and the role of the PEC.

d. Mr. Shelby Tanner explained the need for each member to fill out an OGE 450 form (Financial Disclosure Statement). Each member is required to fax a copy of this form to the PEC by next meeting date.

e. Selection of physician co-chair: COL Strampel, as a representative of TRICARE Management Activity, will serve as co-chair.

f. Meeting schedules, locations and meeting process: The next P&T committee meeting will be held 13 November 1998, in conjunction with the AMSUS meeting, in San Antonio, TX. Exact location to be determined. Subsequent meetings will be scheduled at each future meeting. The committee will request through the appropriate commands that an alternate representative be nominated for each member in the event the primary member is unable to make a meeting. The uniform for meetings will be casual civilian attire. Discussions will be limited to agenda items, unless there is a pressing issue. Submissions of topics for inclusion on the agenda should be submitted as soon as possible. The deadline for items to be included on the agenda is 30 days prior to meeting.

g. Policies/procedures regarding communication and interaction between pharmaceutical representatives and DoD P&T committee members: All communication, dealing with P&T issues, are to be routed through the PEC. COL Moran will assign a PEC staff member (non-P&T member) as a liaison. Individual members will determine to what extent they will interact with pharmaceutical representatives at their facility.

h. CDR Egland questioned who was the approval authority for P&T issues and meeting minutes. COL Moran responded that, as per the policy that established this committee, the P&T committee is the final approving authority for any and all changes to the BCF/NMOP and the meeting minutes, which will be posted to the PEC web page.

i. Policies/procedures for including/excluding/deleting products on the BCF/NMOP and Special Purchase Request Data Sheet: All Medical Treatment Facilities (MTFs) may submit requests for changes to the DoD P&T committee. Such requests must be recommended by the MTF P&T committee and approved by the MTF commander and must provide all information as required by Appendix A of the policy that established the DoD P&T committee. All MTFs will be notified of this requirement. The special purchase data sheet (Appendix B of the DoD P&T policy) will not come into effect until therapeutic classes are closed. Patient care will be the main focus as opposed to saving money.

j. Mechanism for interim changes: When an issue arises that requires timely action, COL Moran will call together a subgroup of the membership to develop a decision, which will then be communicated to all members for a consensus. This process will be accomplished within 48 hours. Such actions will be formally approved at the next scheduled meeting. In order to facilitate this process, COL Moran requested that each member inform him of all leaves or absences.

k. Treatment guidelines development: COL Moran informed the membership that DoD and VA are working together to develop treatment guidelines for specific diseases. The current joint effort includes: Tier 1: smoking cessation, hypertension, and lower back pain; Tier 2: reactive airway diseases, hyperlipidemia, AMI, and diabetes; Tier 3: depression/suicide prevention. A PEC member is involved in each of the workgroups. Decisions by these workgroups may affect decisions this P&T committee makes and vice versa.

l. Contracting Issues:

(1) Joint ventures with the VA:

(a) A Federal Pharmacy Executive Steering Committee (FPESC) was formed which will meet in August 1998 to identify classes of drugs suitable for joint contracting efforts. Both co-chairs of the DoD P&T committee are members of the FPESC.

(b) There currently are several contracting initiatives ongoing. These include: long-acting diltiazem, generic albuterol inhaler, generic cimetidine and ranitidine, and the SSRI class of drugs.

(2) Strategies and technical evaluation factors for product selection: DoD very much wanted to join with the VA in contracting for one or more HMG-CoA reductase inhibitors (statins), however, the VA unilaterally decided to continue with their current contract for lovastatin and simvastatin. Therefore, DoD (PEC and the Board of Pharmacy) decided to pursue a separate contract. COL Moran explained the proposed contracting strategy. He also explained the technical evaluation factors that the PEC is proposing for selecting the agent(s). The committee approved, unanimously, both the strategy and the technical evaluation factors.

(3) Categories for future contracting: COL Moran explained that efforts to pursue contracts are generally based on high-dollar, high-volume agents or drug classes. As such, the following list of drugs/classes were considered for contracting initiatives: Proton pump inhibitors, ACE inhibitors, long-acting nifedipine, and glucose test strips. The committee approved pursuing contracting initiatives for these, whether jointly with the VA, or unilaterally through the Defense Supply Center Philadelphia (DSCP). The decision to pursue joint contracts will be made by the

FPESC. Once efforts are underway, the interim decision process will be utilized for decisions on contracting strategies and use of technical evaluation factors.

m. BCF issues to be addressed:

(1) Deletion of Idoxuridine Ophthalmic Soln - no longer available: Committee concurred. In the future, all discontinued drugs will be automatically removed from the BCF and the committee will be notified at the next scheduled meeting. (CLOSED)

(2) Request from Madigan Army Medical Center (MAMC) to remove blood glucose test strips from BCF: The committee unanimously agreed that test strips should remain on the BCF because of the need to provide a uniform benefit across the Military Health System. COL Moran will prepare and send a response letter to MAMC, explaining the committee's decision. (CLOSED)

(3) Other issues: Mr. Bill Hudson, Humana, asked "When a class is closed, how long is it locked out for?" COL Moran responded that drug classes would only be closed through the issuance of a contract and that most contracts are for five years with annual renewal options. (CLOSED)

n. NMOP Issues to be addressed:

(1) Capt Parrish provided the committee with a brief history and summary of the NMOP program. She explained to the committee that DSCP is utilizing the formulary, prepared by the PEC, as a preferred agent list. If a prescription comes in for something that is not on the list, the mail order contractor, Merck-Medco (M-M), will call the physician and ask if the item can be switched to something that is on the list. If the prescriber does not want to change, then M-M will fill the prescription as written. (CLOSED)

(2) Combination products where both ingredients are currently on the preferred drug list: Since the patient would be required to pay two co-pays and the government two dispensing fees, the committee decided that the majority of such combination products should be added to the NMOP formulary. However, if the cost/benefit ratio comes into question (i.e., the price of the combination product is more than the cost of the two individual ingredients and the two dispensing fees), then the issue will be brought before the committee. (CLOSED)

(3) Dispense as written: The contractor fills between 2,000 and 3,000 such prescriptions per month. The Statement of Work (SOW) states that mandatory generic substitution will be utilized, unless the doctor justifies that a brand name product is necessary. Capt Parrish reviews all of these claims and there are many justifications that are questionable. She suggested that one way to handle such prescriptions is for M-M to FAX the prescriber a standardized form to justify the use of a brand name. Prescriber would be required to return the completed form prior to filling the prescription. If the doctor refuses to fill out the form, the medication will not be dispensed as written. The committee approved this recommendation with a few changes to include the date the physician reported the adverse reaction to the FDA. The following products will be dispensed as written: Birth control pills, carbamazepam (Tegretol®), digoxin (Lanoxin®), phenytoin sodium (Dilantin®), and warfarin sodium (Coumadin®). Currently, thyroids are also dispensed as written. That is to say, Synthroid filled with Synthroid, Levothroid with Levothroid, etc. (CLOSED)

(4) Coverage of antibiotics: Current policy is a maximum of a 21-day supply, if not on the exempt list (approximately 38 anti-infectives – includes antivirals, antifungals, & antibiotics).

The committee agreed that antibiotics should be filled through the NMOP, but only up to a 30-day supply, unless included on the exempt list. If a prescription is received for a greater than 30-day supply and drug is not on the exempt list, but has a definitive FDA approved diagnosis, the prescription will be filled for the greater amount. If the same occurs, but no diagnosis is given, the prescription will be filled for a 30 day supply. The explanation of benefits will direct them to member services to determine how to facilitate the 90 day supply. When a diagnosis is provided, M-M will fill the balance of the prescription and the additional co-pay for the patient will be waived. However, the government will incur the additional dispensing fee expense. CDR Egland will lead a subgroup (CDR Graham, Capt Parrish, and Ms. Doyle) to review the exempt list for potential changes. Capt Parrish will provide him with a printout of questionable greater than 30-day prescriptions. (OPEN)

(5) Coverage of vitamins: The committee decided that no changes need to be made.

(6) Review of product limitations in NMOP: The committee decided the following:

(a) Fertility Drugs – remain as a maximum of 30-day supply. PEC to review and provide recommendation to the committee. (OPEN)

(b) Diabetic Test Strips – change to a maximum of 400 strips per 90 days for insulin dependent diabetics and 100 strips per 90 days for non-insulin dependent diabetics. Same limitations for BCF. (CLOSED)

(c) Insulin syringes – remain at a maximum of 300 per 90 days. Same limitation for BCF. (CLOSED)

(d) Anti-emetics – remain at 15 tablets/30 days to max of 45 tablets/90 days. (CLOSED)

(e) Impotence – Viagra® to remain at maximum of 6 tablets per 30 days. Caverject® and Muse® changed to maximum of 6 per 30 days. (CLOSED)

(f) Migraine therapy – Imitrex® to remain as a maximum of 48 tablets of 25mg, 24 tablets of 50mg, and 8 injections per 30 days. New agents, such as the nasal product will default to the M-M clinical max. The committee recommends that the DoD/VA Practice Guideline Group consider addressing the need for guidelines for treating this condition. A letter will be sent to the group. (OPEN)

(g) High Dollar Pharmaceuticals – to remain unchanged; list includes a 30-day supply for myeloid stimulants, Interferon Alpha, Interferon Gamma, Erythroid stimulants, Sandostatin®, anti-hemophilic factors, and factor IX preps; and includes a 90-day supply for interferon beta, growth hormones, and Copaxone®. (CLOSED)

(h) Retin-A® – to remain unchanged; only to patients up to age 35. (CLOSED)

(i) Prenatal Vitamins – to remain unchanged; only to women up to age 45. Same limitations for BCF. (CLOSED)

COL Hobbs suggested that any future quantity limitations and preferred agent status that applies to the NMOP should also be the same for the retail network. The committee agreed, however, such changes will probably have to be approved by TMA-West.

(7) New FDA approved products – "mapping" to preferred agent list: "Mapping" refers to the process where newly marketed pharmaceuticals, that are not included on the NMOP, are matched against a drug or class of drugs that are on the NMOP. This will allow M-M to call prescribers of these newly marketed pharmaceuticals and request a change. Capt Parrish stated that until a newly marketed agent is "mapped", M-M would not be able to fill any prescriptions

for the agent. The committee's decision was that the PEC would perform all "mapping" of these new agents within 180 days of FDA approval. (CLOSED)

(8) Adderall®: This product is a Class II agent and cannot be "mapped" to another Class II agent because of Federal Regulations. The committee approved addition to the NMOP. (CLOSED)

(9) Coverage of agents specifically excluded by CHAMPUS: The following agents will not be provided by NMOP: lancets, OTC products (unless specifically included), drugs for cosmetic use (i.e., Renova®, Propecia®), devices, Clozaril®, smoking deterrents, injectable medications (unless specifically included), and vitamins (unless specifically included). (CLOSED)

(10) Same drugs, different manufacturers with different prices – NJ law prohibits substitution: These include Desogen®/OrthoCept®, TriPhasil®/Trilevlen®, Prinivil®/Zestril®, and Trandate®/Normodyne®. Capt Parrish requested, and received, the committee's approval to seek alternatives through MM to possibly move the filling of those prescriptions to another state where those items are interchangeable. (CLOSED)

(11) Birth control pills – 28-day packages are cheaper than 21-day packages: Capt Parrish will work with the DAPA section at DSCP to see if 21-day package price could be changed to matched the 28-day package price. (OPEN)

(12) Time limits for refills – SOW currently states that 75% must be used before refilling: Until recently, M-M had been filling all refill requests, regardless of time limit. M-M has been informed that they will follow 75% rule. Now, M-M returns refill requests to patients unfilled, if 75% rule is not met. The committee stated that the needs of the patients have to be considered and that undue hardship should not be placed on them. Mr. Lowe responded that the VA does not return early refill requests, that these are held until the established time limits are met, then the requests are filled and mailed to the patient. COL Strampel asked if this could also be done by M-M. Capt Parrish stated that this would require a modification in the SOW and could possibly cost the government more. Issue is tabled until next meeting by which time Capt Parrish will check to see if and how much a change in the SOW will cost. (OPEN)

o. Viagra® policy: Issues of concern are safety and cost. Since Health Affairs has already written a "draft" policy and it appears that it will be imminently approved, the committee will defer on this issue. (OPEN)

5. ADJOURNMENT: The meeting was held from 1400-1700 on 13 July 1998 and from 0800-1515 on 14 July 1998. The next meeting will be held on 13 November 1998. The office of record for official minutes is the Pharmacoeconomic Center, Fort Sam Houston, TX 78234.

ERROL L. MORAN
COL, MS
Co-chairman

WILLIAM D. STRAMPEL
COL, MC
Co-chairman