Part 199.21

Pharmacy Benefits Program

Revision:  
Rule:  

(a) General--  
   (1) Statutory authority.  
   (2) Pharmacy benefits program.  
      (i) Applicability.  
      (ii) Applicability exception.  
   (3) Uniform formulary.  

(b) Definitions.  
   (1) Clinically necessary.  
   (2) Therapeutic class.  
   (3) Over-the-counter drug.  

(c) Department of Defense Pharmacy and Therapeutics Committee--  
   (1) Purpose.  
   (2) Composition.  
   (3) Executive Council.  

(d) Uniform Formulary Beneficiary Advisory Panel.  

(e) Determinations regarding relative clinical and cost effectiveness for the selection of pharmaceutical agents for the uniform formulary--  
   (1) Clinical effectiveness.  
   (2) Cost effectiveness.  

(f) Evaluation of pharmaceutical agents for determinations regarding inclusion on the uniform formulary.  

(g) Administrative procedures for establishing and maintaining the uniform formulary--  
   (1) Pharmacy and Therapeutics Committee determinations.  
   (2) Beneficiary Advisory Panel.  
   (3) Uniform formulary final decisions.  
   (4) Transition to the Uniform Formulary.  
   (5) Administrative procedure for newly approved drugs.  

(h) Obtaining pharmacy services under the retail network pharmacy benefits program.  
   (1) Points of service.  
   (2) Availability of formulary pharmaceutical agents.  
      (i) General.  
      (ii) Availability of formulary pharmaceutical agents at military treatment facilities (MTF).
(3) Availability of non-formulary pharmaceutical agents.--
    (i) General.
    (ii) Availability of non-formulary pharmaceutical agents at military treatment facilities.
    (iii) Availability of clinically appropriate non-formulary pharmaceutical agents to members of the Uniformed Services.
    (iv) Availability of clinically appropriate pharmaceutical agents to other eligible beneficiaries at retail pharmacies or the TMOP.

(4) Availability of vaccines/immunizations.

(5) Availability of selected over-the-counter (OTC) drugs under the pharmacy benefits program.

(i) **Cost-sharing requirements under the pharmacy benefits program**--
    (1) General.
    (2) Cost-sharing amounts.
        (xii) Special copayment rule for OTC drugs in the retail pharmacy network.
    (3) Special cost-sharing rule when there is a clinical necessity for use of a non-formulary pharmaceutical agent.

(j) **Use of generic drugs under the pharmacy benefits program.**

(k) **Preauthorization of certain pharmaceutical agents.**

(l) **TRICARE Senior Pharmacy Program.**

(m) **Effect of other health insurance.**

(n) **Procedures.**

(o) **Preemption of State laws.**

(p) **General fraud, abuse, and conflict of interest requirements under TRICARE pharmacy benefits program.**

(q) **Pricing standards for retail pharmacy program**--
    (1) Statutory requirement.
    (2) Manufacturer written agreement.
    (3) Refund procedures.
    (4) Remedies.
    (5) Beneficiary transition provisions.

(r) **Refills of maintenance medications for eligible covered beneficiaries through the mail order pharmacy program**--
    (1) In general
    (2) Medications covered.
    (3) Refills covered.
    (4) Waiver of requirement.
    (5) Procedures.