

APPENDIX 1: NEW DRUG APPLICATION FORM

415 — C
EXHIBIT A

TEXAS DEPARTMENT OF MENTAL HEALTH AND MENTAL RETARDATION

NEW DRUG APPLICATION
(for inclusion in the *TDMHMR Drug Formulary*)

** (THE NEW DRUG APPLICATION PROCESS IS DESCRIBED ON THE BACK OF THIS FORM.) **

Date: _____

Name of practitioner submitting the application: _____

Name of entity with which the practitioner is associated by employment or contract (i.e., state hospital, state school, state center, or local authority (state-operated community services (SOCS) or community MHMR center)):

Information regarding new drug:

Therapeutic Classification	
Generic Name	
Trade Name(s)	
Manufacturer(s)	
Dosage Form(s)	

Explain the pharmacological action or use of this drug:

Explain the advantages of this drug over those listed in the formulary:

State which drugs this new drug would replace or supplement:

application is approved

signature of chairman of facility pharmacy and therapeutics committee

OR

application is appropriate and complete

signature of clinical/medical director or designee

Section 415.108 of TDMHMR rules governing the use and maintenance of the *TDMHMR Drug Formulary* (25 TAC, Chapter 415, Subchapter C) describes the procedures for applying to have a drug added to the formulary, which are:

§415.108. Applying to Have a Drug Added to the Formulary.

- (a) Any member of the Executive Formulary Committee, any service system component* practitioner, or any contract practitioner may apply to have a drug added to the *TDMHMR Drug Formulary* by completing the New Drug Application Form DF-1, referenced as Exhibit A in §415.112 of this title (relating to Exhibit) and including:
 - (1) published articles in biomedical literature that substantiate the efficacy and safety of the proposed drug;
 - (2) information on the advantages of the proposed drug compared with similar formulary drugs;
 - (3) a list of formulary drugs that the proposed drug would replace or supplement; and
 - (4) cost effectiveness data.
- (b) Submitting the application.
 - (1) If the person submitting the application is a facility** practitioner or a facility contract practitioner, then that practitioner submits the application to the facility's pharmacy and therapeutics committee for approval. If the committee approves the application, then it forwards the application to the Executive Formulary Committee.
 - (2) If the person submitting the application is a non-facility service system component practitioner or a non-facility service system component contract practitioner, then that practitioner submits the application to the component's clinical/medical director or designee who determines if the application is appropriate and complete, and if so, forwards the application to the Executive Formulary Committee.
 - (3) If the person completing the application is a member of the Executive Formulary Committee, then that person submits the application directly to Executive Formulary Committee.
- (c) The Executive Formulary Committee considers the drug application and recommends:
 - (1) approving the proposed drug's inclusion and, if appropriate, approving audit criteria and recommending dosage guidelines;
 - (2) denying the proposed drug's inclusion;
 - (3) approving the proposed drug on a trial basis for a specified period of time;
 - (4) approving the proposed drug as a reserve drug, with guidelines; or
 - (5) postponing the decision until a later meeting.

* The term "service system component" means a state hospital, state school, state center, or local authority (state-operated community services (SOCS) or community MHMR center).

** The term "facility" means a state hospital, state school, or state center.