Figure: 25 TAC §415.108(d)

DEPARTMENT OF STATE HEALTH SERVICES
NEW DRUG APPLICATION
(for inclusion in the DSHS/DADS Drug Formulary)

THE NEW DRUG APPLICATION PROCESS IS DESCRIBED ON THE SECOND PAGE 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., DSHS facility or local authority): _____

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 DSHS facility pharmacy and therapeutics committee

OR

☐ application is appropriate and complete

_____
signature of non-facility service system component clinical/medical director or designee

Section 415.108(a) - (c) of DSHS rules governing the use and maintenance of the DSHS/DADS Drug Formulary describes the procedures for applying to have a drug added to the formulary.

§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 DSHS/DADS Drug Formulary by completing the New Drug Application form 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 DSHS facility practitioner or a DSHS 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 the 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) approving the proposed drug on a trial basis for a specified period of time;

(3) approving the proposed drug as a reserve drug, with guidelines;

(4) postponing the decision until a later meeting; or

(5) denying the proposed drug's inclusion.

* The term "service system component" means DSHS, a DSHS facility, or local authority.