

EVALUATION OF EXPERIMENTAL AND OFF-LABEL MEDICATIONS IN THE SCHOOL SETTING

Off –label medications are those FDA approved legal medications that are prescribed for non-approved indications in children (medications prescribed in doses or routes outside the FDA guidelines, medications known to be safe in adults and prescribed without long-term studies demonstrating safety in the pediatric population, or medications approved to treat one type of medical condition but being prescribed for a different medical condition).

Experimental drugs are those medications involved in clinical trials that do not have FDA approval.

Ascension Seton Student Health Services and AISD policy generally prohibits the administration of any medication (including herbal supplements) that has not been authorized for pediatric use. The district recognizes that current studies suggest that FDA approved off-label medication can provide valuable therapeutic effects. The district also recognizes that pediatric experimental drugs that are undergoing formal study/clinical trials to determine the efficacy and safety for pediatric dosing are designed to protect participant safety and rights. The district understands that the prescription of off-label and experimental medications is based on the physician's reasonable medical evidence with the same judgment as exercised in medical practice in general.

To provide a student with a prescribed off-label or experimental medication a parent request will be considered after an evaluation is made of the following documentation/resources that will be made available to DCMC/AISD Student Health Services staff and AISD by the prescribing physician:

This request for additional information is in regard to:

Student Name: _____ **D.O.B.** _____

Medication: _____ **Dosage Prescribed:** _____

For the treatment of: _____

FDA Approved Off-label Medications (please provide at least one of following references supporting the use of the medication for the above student):

- ☐ Published anecdotal reports of use in children for the indication the prescriber names
- ☐ Current information from recognized medical journals or pediatric medical or mental health facility including recommended dosages for use in children
- ☐ Reports from the manufacturer
- ☐ Reports from a reliable pharmacy

Experimental Medications:

- ☐ Copy of the written protocol
- ☐ Study summary from the research organization
- ☐ Copy of the detailed consent form signed by the parent/guardian which:
 - ☐ describes the study (including the potential benefits and risks),
 - ☐ the signs and symptoms of adverse reactions to be reported, and
 - ☐ the name and telephone numbers of the investigator or research team.

Physician Signature: _____ Date: _____

Physician Stamp: _____