

BILL # SB 1477

TITLE: psychotropic drugs; testing; informed consent

SPONSOR: Gray, L.

STATUS: Senate Engrossed

PREPARED BY: Matt Busby

FISCAL ANALYSIS

Description

SB 1477 requires state-funded institutions or agencies that test psychotropic drugs or test the effects of any other previously prescribed or administered psychotropic drug to receive written informed consent from participants. The bill also requires that the Department of Health Services (DHS) provide an annual report to the Governor and the Legislature describing reported side effects discovered during testing.

Estimated Impact

The bill is estimated to have minimal fiscal impact. Universities in the state that conduct research on psychotropic drugs already obtain informed consent from those who participate in the study. The University of Arizona (UA), Arizona State University (ASU) and Northern Arizona University (NAU) all anticipate that there will be no cost to them as a result of the legislation.

DHS estimates a cost to the department of \$1,000 to \$10,000 to provide the required report.

Analysis

The United States Department of Health and Human Services requires that all clinical trials involving human research subjects and receive any amount of federal funds obtain informed consent from participants. However, even clinical trials that are not federally funded must receive approval from the Institutional Review Board (IRB) that has jurisdiction over the study. IRBs are put in place by an institution to protect the rights and welfare of participants and have informed consent requirements for clinical trials.

The UA, ASU, and NAU all perform clinical trials at some level and have multiple IRBs that provide oversight and have informed consent requirements in place. The only requirement of the bill that the universities do not currently perform is reporting all adverse side effects of the psychotropic drugs being tested and providing complete financial disclosures of the tests to DHS. UA, ASU, and NAU all anticipate that the bill would not result in any additional cost to them.

The Department of Corrections, the Department of Juvenile Corrections, and DHS all report they do not conduct clinical trials with psychotropic drugs. DHS is unaware of any other state agency besides the state universities that would conduct tests with psychotropic drugs.

The bill also requires DHS to provide a report to the Governor and the Legislature of all adverse side effects of the drugs discovered during the testing as reported by the testing institution or agency. DHS estimates a fiscal impact of \$1,000 to \$10,000 for costs associated with staff time required to develop operating procedures, a substantive policy statement and rules, a reporting and tracking process, and the generation of the annual report.

Local Government Impact

None.