

Strengthening Informed Consent for Prescription Medications

Currently, only-oral informed consent is outlined on page ten of the 2020 VHA Handbook, viz.,

- (1) Documentation of Treatments and Procedures That Require Only Oral Informed Consent (a) Treatments and procedures that are low risk and within broadly-accepted standards of medical practice (e.g., administration of most drugs...)

This regulation is contradictory. Veterans are being prescribed large amounts of antidepressants, antipsychotics, benzodiazepines, opioids and stimulants, which all contain an FDA Black Box Warning. The Black Box Warning is the highest risk warning according to FDA regulations. Suicidal ideation is one of the chief side effects of these Black Box Warning medications, and yet Veterans receive only-oral informed consent by VHA regulation. This means that the Department of Veterans Affairs is prescribing Veterans at risk of death by suicide medications whose greatest side-effects are suicidal ideation and increased risk of death by suicide—and *not* providing these Veterans with comprehensive explanations of these risks, information of alternative therapeutic courses of action made available by VA, or requiring signatory consent by veteran patients.

The prevention of veteran deaths by suicide has rightfully become the top priority for Congress and the Administration; yet even with the continued spending and research, the most recent VA report on veteran deaths by suicide demonstrates more fatalities and at faster rates. This has been the trend for the past ten years.

The VHA Handbook was most recently revised in July of 2020. There was no modification of this regulation.

The Veterans Education Project, therefore, respectfully urges the Committee to codify Signatory Informed Consent for all medications prescribed by the Department of Veterans Affairs to veterans that contain FDA Black Box Warning, as VA partially practices with the prescription of long-term opioids, Clozapine, Thalidomide, and Buprenorphine.