[DISCUSSION DRAFT]

114TH CONGRESS
1ST SESSION

H. R. _____

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to establish a list of drugs that require an increased level of informed consent.

IN THE HOUSE OF REPRESENTATIVES

Ms. BROWNLEY of California introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to establish a list of drugs that require an increased level of informed consent.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REQUIREMENT OF INCREASED INFORMED CONSENT FOR CERTAIN DRUGS.

(a) IN GENERAL.—Chapter 73 of title 38, United States Code, is amended by inserting after section 7334 the following new section:

"§ 7335. Requirement of increased informed consent for certain drugs

''(a) LIST OF DRUGS.—The Secretary shall establish within the Office of Specialty Care Service of the Veterans Health Administration a panel to establish and maintain a list of drugs, including psychotropic drugs, that may only be furnished under this title to a patient with increased informed consent of the patient or, in appropriate cases, a representative thereof.

''(b) PANEL.—The Secretary shall determine the composition, membership, and functions of the panel described in subsection (a).

''(c) REQUIREMENTS.—If a medical professional prescribes to a patient a drug covered by subsection (a), the Secretary shall ensure that the medical professional—

''(1) prepares and presents to the patient or, in appropriate cases, a representative thereof the written form described in subsection (d); and

''(2) except in emergency situations—

''(A) ensures that the patient signs an initial form acknowledging that the patient has received information for regarding the recommended treatment and any other possible treatments but is not a commitment to pursue any treatment plan;

"(B) refers the patient to an appropriate pharmacy of the Department if the patient has additional questions about the drug covered by subsection (a); and

"(C) provides the patient with the opportunity to review the information provided regarding the recommended treatment and any other possible treatments and—

"(i) provide consent by signing the written form described in subsection (d) or by calling or emailing the medical professional to provide consent; or

"(ii) schedule a follow-up appointment with the medical professional to discuss the recommended treatment during the three-day period beginning on the date on which the patient requests the appointment.

"(d) WRITTEN FORM ON INCREASED INFORMED CONSENT.—The Secretary shall ensure that each patient who is prescribed a drug covered by subsection (a) is presented a written form that provides for the increased informed consent required by such subsection. Such form shall meet the following criteria:

"(1) Includes—

"(A) the names of any drugs being offered to the patient, including any other trade or the generic name for such drug;

"(B) each side effect, if any, of the drug, including dependency;

"(C) any alternative methods of treatment or therapy not involving a drug that is covered by subsection (a);

"(D) whether the drug is being offered for a non-Food and Drug Administration approved use;

"(E) whether the drug is being given in a dosage that exceeds the dosages approved or tested by the Food and Drug Administration;

"(F) the potential unknown dangers of mixing drugs and dosages in sizes and combinations that have not been approved or tested by the Food and Drug Administration;

"(G) the known interactions between the drug and other drugs or substances, including alcohol; and

"(H) with respect to any treatment involving a drug covered under subsection (a) that carries black box warnings—

''(i) a warning that such drugs will only treat symptoms and will not cure or treat any disease;

''(ii) a warning that the Food and Drug Administration has not approved any psychiatric drugs to be used in combination with other psychiatric drugs; and

''(iii) an opportunity to ask questions and receive information regarding such psychiatric drugs.

''(2) Is signed by the patient or, in appropriate cases, a representative thereof to acknowledge that the patient or representative, as the case may be, has received the information under paragraph (1) and has had adequate time to understand the information and consider alternative treatments, including, as appropriate, the opportunity to leave the medical facility.

''(e) INFORMED CONSENT DEFINED.—In this section, the term 'increased informed consent' means full and informed consent that—

''(1) provides the patient who is being asked to consent with—

"(A) a meaningful understanding of the treatment to be provided based on such consent; and

"(B) an opportunity to ask questions and receive information regarding such treatment; and

"(2) is acknowledged in the written form described in subsection (d).".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 7334 the following new item:

"7335. Requirement of increased informed consent for certain drugs.".