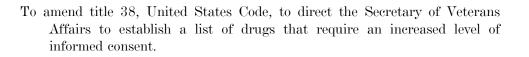


H.R.

114TH CONGRESS 1ST SESSION



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.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,

3 SECTION 1. REQUIREMENT OF INCREASED INFORMED 4 CONSENT FOR CERTAIN DRUGS.

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

2

"§7335. Requirement of increased informed consent

2

for certain drugs

3 "(a) LIST OF DRUGS.—The Secretary shall establish
4 within the Office of Specialty Care Service of the Veterans
5 Health Administration a panel to establish and maintain
6 a list of drugs, including psychotropic drugs, that may
7 only be furnished under this title to a patient with in8 creased informed consent of the patient or, in appropriate
9 cases, a representative thereof.

10 "(b) PANEL.—The Secretary shall determine the
11 composition, membership, and functions of the panel de12 scribed in subsection (a).

13 "(c) REQUIREMENTS.—If a medical professional pre14 scribes to a patient a drug covered by subsection (a), the
15 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

19 "(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;

1	"(B) refers the patient to an appropriate
2	pharmacy of the Department if the patient has
3	additional questions about the drug covered by
4	subsection (a); and
5	"(C) provides the patient with the oppor-
6	tunity to review the information provided re-
7	garding the recommended treatment and any
8	other possible treatments and—
9	"(i) provide consent by signing the
10	written form described in subsection (d) or
11	by calling or emailing the medical profes-
12	sional to provide consent; or
13	"(ii) schedule a follow-up appointment
14	with the medical professional to discuss the
15	recommended treatment during the three-
16	day period beginning on the date on which
17	the patient requests the appointment.
18	"(d) Written Form on Increased Informed
19	CONSENT.—The Secretary shall ensure that each patient
20	who is prescribed a drug covered by subsection (a) is pre-
21	sented a written form that provides for the increased in-
22	formed consent required by such subsection. Such form
23	shall meet the following criteria:
24	"(1) Includes—

1	"(A) the names of any drugs being offered
2	to the patient, including any other trade or the
3	generic name for such drug;
4	"(B) each side effect, if any, of the drug,
5	including dependency;
6	"(C) any alternative methods of treatment
7	or therapy not involving a drug that is covered
8	by subsection (a);
9	"(D) whether the drug is being offered for
10	a non-Food and Drug Administration approved
11	use;
12	"(E) whether the drug is being given in a
13	dosage that exceeds the dosages approved or
14	tested by the Food and Drug Administration;
15	"(F) the potential unknown dangers of
16	mixing drugs and dosages in sizes and combina-
17	tions that have not been approved or tested by
18	the Food and Drug Administration;
19	"(G) the known interactions between the
20	drug and other drugs or substances, including
21	alcohol; and
22	"(H) with respect to any treatment involv-
23	ing a drug covered under subsection (a) that
24	carries black box warnings—

1	"(i) a warning that such drugs will
2	only treat symptoms and will not cure or
3	treat any disease;
4	"(ii) a warning that the Food and
5	Drug Administration has not approved any
6	psychiatric drugs to be used in combina-
7	tion with other psychiatric drugs; and
8	"(iii) an opportunity to ask questions
9	and receive information regarding such
10	psychiatric drugs.
11	"(2) Is signed by the patient or, in appropriate
12	cases, a representative thereof to acknowledge that
13	the patient or representative, as the case may be,
14	has received the information under paragraph (1)
15	and has had adequate time to understand the infor-
16	mation and consider alternative treatments, includ-
17	ing, as appropriate, the opportunity to leave the
18	medical facility.
19	"(e) INFORMED CONSENT DEFINED.—In this sec-
20	tion, the term 'increased informed consent' means full and
21	informed consent that—
22	"(1) provides the patient who is being asked to
23	consent with—

"(A) a meaningful understanding of the 1 2 treatment to be provided based on such con-3 sent; and "(B) an opportunity to ask questions and 4 receive information regarding such treatment; 5 6 and "(2) is acknowledged in the written form de-7 scribed in subsection (d).". 8 (b) CLERICAL AMENDMENT.—The table of sections 9 at the beginning of such chapter is amended by inserting 10 after the item relating to section 7334 the following new 11 12 item: "7335. Requirement of increased informed consent for certain drugs.".