

[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.

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IN THE HOUSE OF REPRESENTATIVES

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

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**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:

1 **“§ 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 in-  
8 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 de-  
12 scribed in subsection (a).

13 “(c) REQUIREMENTS.—If a medical professional pre-  
14 scribes to a patient a drug covered by subsection (a), the  
15 Secretary shall ensure that the medical professional—

16 “(1) prepares and presents to the patient or, in  
17 appropriate cases, a representative thereof the writ-  
18 ten form described in subsection (d); and

19 “(2) except in emergency situations—

20 “(A) ensures that the patient signs an ini-  
21 tial form acknowledging that the patient has re-  
22 ceived information for regarding the rec-  
23 ommended treatment and any other possible  
24 treatments but is not a commitment to pursue  
25 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—

1           “(A) a meaningful understanding of the  
2           treatment to be provided based on such con-  
3           sent; and

4           “(B) an opportunity to ask questions and  
5           receive information regarding such treatment;  
6           and

7           “(2) is acknowledged in the written form de-  
8           scribed in subsection (d).”.

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

“7335. Requirement of increased informed consent for certain drugs.”.