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**ACCESS TO LEGAL  
PHARMACEUTICALS ACT  
(ALPHA)  
H.R. 1652**

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Prepared by the Office of Congresswoman Carolyn B. Maloney.  
For more information, please contact Anna Cielinski at x5-7944.  
July 26, 2005.

# Congress of the United States

Washington, DC 20515

## ACCESS TO LEGAL PHARMACEUTICALS ACT

SIGN UP AS A **COSPONSOR** TO H.R. 1652 AND JOIN  
THIS BIPARTISAN MOVEMENT TO PREVENT THE EROSION OF THE  
FUNDAMENTAL RIGHT OF ACCESS TO CONTRACEPTION

April 19, 2005

Dear Colleague,

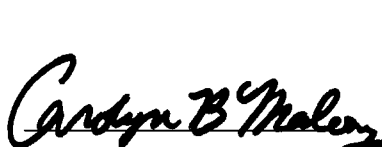
A disturbing trend has recently erupted in drug stores across the nation: pharmacists are refusing to fill women's prescriptions for legal contraception. In some cases, the pharmacists are refusing to tell women where they can fill the prescription; in others, they are refusing to return the prescription paper back to the women. These pharmacists indicate that based on their personal beliefs, any use of birth control is a form of abortion. These practices, which have been reported in more than a dozen states, were reported in *Washington Post* journalist Rob Stein's article, *Pharmacists' Rights at Front Of New Debate*, on March 28, 2005. Because of these refusals to fill legal prescriptions, women are being denied their legal right of access to contraception.

A November 2004 poll conducted by CBS and the NY Times indicated that 8 out of 10 Americans believe that pharmacists should not be permitted to refuse to dispense birth control pills. This opinion was strong despite party affiliation – 85% of Democrats and 70% of Republicans polled squarely opposed pharmacist refusals. And in Congress, we are gaining bipartisan support for the Access to Legal Pharmaceuticals Act. We are inviting you to sign on as a cosponsor, and help us prevent the erosion of a woman's fundamental right of access to legal contraception.

Irrespective of the pharmacist's right or choice to refuse filling the prescription, the pharmacies should be required to provide a woman with access to legal forms of birth control. Our bill would require the pharmacies to provide such access if indeed one of their pharmacists denies filling the prescription. Additionally, our bill ensures that women get their prescriptions filled or ordered without delay, and also without harassment or humiliation.

If you are interested in joining us as a cosponsor, or if you would like a copy of our bill, please have your staff contact Karen Persis, Carolyn Maloney's Legislative Fellow, at x5-7944 or via email at [karen.persis@mail.house.gov](mailto:karen.persis@mail.house.gov). or Liz Osborn, in Christopher Shays' office at [liz.osborn@mail.house.gov](mailto:liz.osborn@mail.house.gov).

Sincerely,



CAROLYN B. MALONEY

Member of Congress



CHRISTOPHER SHAYS

Member of Congress



DEBBIE WASSERMAN SCHULTZ

Member of Congress

Additional Original Cosponsors in the 109<sup>th</sup> Congress: Rep. Sherrod Brown, Rep. Peter DeFazio, Rep. Stephanie Tubbs Jones, Rep. George Miller, Rep. Luis Gutierrez, Rep. Tammy Baldwin, Rep. Jim Moran, Rep. Joseph Crowley, Rep. Patrick Kennedy, Rep. Lois Capps, Rep. Jim McGovern, Rep. Julia Carson, Rep. Susan Davis, Rep. Robert Brady, Rep. Zoe Lofgren, Rep. Peter Stark, Rep. Jim McDermott, Rep. Maurice Hinchey, Rep. Dennis Kucinich, Rep. Gwen Moore.

# **Access to Legal Pharmaceuticals Act**

## **Bill Summary**

Prepared by the Office of Carolyn B. Maloney

### **Section 1. Title.**

### **Section 2. Findings.**

### **Section 3. Duties of Pharmacies with Respect to Refusal of Pharmacists to fill Valid Prescriptions**

a. indicates that the Public Health Service Act is amended to add the following section:

#### **Section 249. Duties of Pharmacies with Respect to Refusal of Pharmacists to fill Valid Prescriptions**

**a. In General.** Pharmacies receiving prescription drugs must comply with the following:

1. If a drug is in stock and a pharmacist refuses to fill it because of a personal belief, the pharmacy must ensure another pharmacist employed by the pharmacy fills it without delay.
2. If a drug is not in stock and a pharmacist refuses to order or offer to order it because of a personal belief or pharmacy policy, the pharmacy must ensure that
  - A. The individual requesting the drug will be informed immediately that the product is not in stock but can be ordered and
  - B. The drug will be ordered without delay.
3. Pharmacists employed by the pharmacy can't prevent or deter an individual from ordering or filling a valid prescription, and this includes
  - A. Refusing to return the prescription if the individual requests it be returned
  - B. Refusing to transfer the prescription if the individual requests it be transferred
  - C. Harassing or humiliating the individual.
  - D. Breaching the confidentiality of the individual

**b. Products not ordinarily stocked.** Subsection (a)(2) only applies with respect to ordering a specific product not in stock, and does not require the pharmacy to keep the product in stock; it just has to order it for the individual with a valid prescription if the pharmacy keeps in stock that type of product for such a health condition.

**c. Enforcement.**

1. A pharmacy is subject to civil penalties not to exceed \$5,000 per day of violation, not exceeding \$500,000 for all violations adjudicated in a single proceeding for violating this act.
2. A pharmacy is also subject to a private cause of action for any violation of this act.
3. There is a five-year statute of limitations for civil penalties and private causes of action, and it begins on the date the alleged violation first occurred.

**d. Definitions**

# **Q&As: ACCESS TO LEGAL PHARMACEUTICALS ACT<sup>1</sup> (ALPHA)**

**(H.R. 1652 in the House, S. 809 in the Senate)**

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## **Why do we need this Act?**

An individual's fundamental right of access to birth control is being attacked. Reports of some pharmacists refusing to fill prescriptions has been documented in twelve states.<sup>2</sup> The women that were denied were young and old; married and single; with children and without. Even women who were using birth control for other medical reasons aside from preventing conception have been denied access to the birth control pill. The Access to Legal Pharmaceuticals Act ensures timely access to contraception and is crucial to protecting a woman's health and autonomy, and to keeping pharmacists and politicians out of personal, private matters.

## **Who does this bill protect?**

The act protects an individual's access to legal contraception by requiring that if a pharmacist has a personal objection to filling a legal prescription for a drug or device, the pharmacy will be required to ensure that the prescription is filled by another pharmacist employed by the pharmacy who does not have a personal objection.

## **What types of actions are prohibited?**

Pharmacists cannot prevent or deter an individual from filling a legal prescription for drugs or devices. Refusing to return or transfer a prescription is prohibited under the Access to Legal Pharmaceuticals Act. The pharmacist cannot harass, humiliate, or intentionally breach the confidentiality of the individual attempting to fill the prescription for birth control.

## **If a pharmacist objects to filling a prescription, when does it have to be filled?**

The prescription must be filled without delay, and in a time frame consistent with the amount of time it would take the pharmacy to fill a prescription that is not personally objectionable to the pharmacist. Example: If it takes a pharmacy 1 hour to fill prescriptions for diabetes medication, it should take 1 hour to fill a prescription for birth control – no more, or no less.

## **What if the pharmacy has decided not to stock prescription contraception. Does ALPhA require the pharmacy to stock prescription contraception?**

If the pharmacy ordinarily stocks prescription contraception, this legislation provides that if an individual attempts to fill a prescription for a certain type of contraception, and that contraception is not in stock, the pharmacy must order (if the individual so requests) that prescription for that individual. The Access to Legal Pharmaceuticals Act does not require that a pharmacy that stocks some types of prescription contraception stock all types all the time. But if it does stock some types of prescription birth control, then it must order a type it doesn't ordinarily stock for an individual who requests that type of prescription birth control.

## **Will the pharmacy have to order Emergency Contraception if there is none in stock?**

If the pharmacy routinely stocks contraception, then a pharmacist who does not have a personal objection to the prescription must order, without delay, emergency contraception if the individual requests it be ordered after being informed the prescription is not in stock.

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<sup>1</sup>Prepared by the Office of Carolyn B. Maloney, April 2005.

<sup>2</sup>The twelve states are: California, Georgia, Louisiana, Illinois, Massachusetts, Minnesota, New Hampshire, North Carolina, Ohio, Texas, Washington, and Wisconsin.

## **What are the penalties for violating the Access to Legal Pharmaceuticals Act ?**

The pharmacy is subject to a private cause of action by the individual whose rights were violated, as well as civil penalties not to exceed \$5,000 per day of violation, not exceeding \$500,000 for all violations adjudicated in a single proceeding.

## **Who is supporting this legislation?**

### **Members of Congress:**

**Senate:** Sen. Frank Lautenberg, Sen. Barbara Boxer, Sen. Hillary Clinton, Sen. Jon Corzine, Sen. Daniel Inouye

**House:** Rep. Neil Abercrombie, Rep. Gary Ackerman, Rep. Tom Allen, Rep. Joe Baca, Rep. Brian Baird, Rep. Tammy Baldwin, Rep. Melissa Bean, Rep. Xavier Becerra, Rep. Shelley Berkley, Rep. Howard Berman, Rep. Tim Bishop, Rep. Rick Boucher, Rep. Robert Brady, Rep. Corrine Brown, Rep. Sherrod Brown, Rep. Lois Capps, Rep. Dennis Cardoza, Rep. Russ Carnahan, Rep. Julia Carson, Rep. William Clay, Rep. Emanuel Cleaver, Rep. Joseph Crowley, Rep. Elijah Cummings, Rep. Susan Davis, Rep. Peter DeFazio, Rep. William Delahunt, Rep. Rosa DeLauro, Rep. Norm Dicks, Rep. Eliot Engel, Rep. Anna Eshoo, Rep. Lane Evans, Rep. Sam Farr, Rep. Bob Filner, Rep. Barney Frank, Rep. Charles Gonzalez, Rep. Al Green, Rep. Gene Green, Rep. Raul Grijalva, Rep. Luis Gutierrez, Rep. Jane Harman, Rep. Alcee Hastings, Rep. Maurice Hinchey, Rep. Rush Holt, Rep. Steve Israel, Rep. Jesse Jackson, Jr., Rep. William Jefferson, Rep. Eddie Bernice Johnson, Rep. Nancy Johnson, Rep. Stephanie Tubbs Jones, Rep. Patrick Kennedy, Rep. Ron Kind, Rep. Mark Kirk, Rep. Jim Kolbe, Rep. Dennis Kucinich, Rep. Tom Lantos, Rep. Rick Larsen, Rep. Barbara Lee, Rep. Sheila Jackson Lee, Rep. John Lewis, Rep. Zoe Lofgren, Rep. Nita Lowey, Rep. Edward Markey, Rep. Doris Matsui, Rep. Carolyn McCarthy, Rep. Betty McCollum, Rep. Jim McDermott, Rep. Jim McGovern, Rep. Marty Meehan, Rep. Gregory Meeks, Rep. Robert Menendez, Rep. Michael Michaud, Rep. Juanita Millender-McDonald, Rep. George Miller, Rep. Gwen Moore, Rep. Jim Moran, Rep. Jerrold Nadler, Rep. Grace Napolitano, Rep. John Olver, Rep. Major Owens, Rep. Frank Pallone, Rep. Nancy Pelosi, Rep. Charles Rangel, Rep. Steve Rothman, Rep. Lucille Roybal-Allard, Rep. Martin Sabo, Rep. Linda Sanchez, Rep. Loretta Sanchez, Rep. Jan Schakowsky, Rep. Adam Schiff, Rep. Allyson Schwartz, Rep. Jose Serrano, Rep. Christopher Shays, Rep. Rob Simmons, Rep. Louise Slaughter, Rep. Adam Smith, Rep. Hilda Solis, Rep. Pete Stark, Rep. Ted Strickland, Rep. Ellen Tauscher, Rep. Mike Thompson, Rep. John Tierney, Rep. Chris Van Hollen, Rep. Nydia Velazquez, Rep. Debbie Wasserman-Schultz, Rep. Maxine Waters, Rep. Diane Watson, Rep. Henry Waxman, Rep. Anthony Weiner, Rep. Robert Wexler, Rep. Lynn Woolsey

**Organizations:** NARAL, Planned Parenthood, National Women's Law Center, American Medical Students Association, American College of Gynecologists and Obstetricians, American Association of University Women.

### **Statistics**

A November 2004 poll conducted by CBS and the NY Times indicated that 8 out of 10 Americans believe that pharmacists should not be permitted to refuse to dispense birth control pills. This opinion was strong despite party affiliation – 85% of Democrats and 70% of Republicans polled squarely opposed pharmacist refusals.

## EXAMPLES OF PHARMACY REFUSALS<sup>1</sup>

**Fall 2004, Massachusetts:** A University of Massachusetts sophomore attempted to refill her prescription for oral contraceptives online. However, when she arrived at the local CVS pharmacy to pick up the prescription, the pharmacist told her that he had deleted her request from the computer because he did not want to fill it. Fortunately, another pharmacist in the store filled the prescription while the student waited. CVS policy requires pharmacists who object to filling certain prescriptions to find another pharmacist in the store or another store location where the customer can get the prescription filled. University Drive Pharmacist Denies a Student Birth Control, *The Massachusetts Daily Collegian* (Dec. 13th 2004).

**September 2004, New Hampshire:** Suzanne Richards, a 21-year-old single mother, went to a drive-through pharmacy to fill a prescription for emergency contraception. The pharmacist, Todd Sklencar, told Richards he was morally opposed to prescribing the pill and refused to transfer her prescription to another pharmacy. By the time a pharmacist willing to fill the prescription contacted Richards, the optimal time frame for taking the pills had passed. Laconia Woman Denied Morning After Pill By Pharmacist, *Assoc. Press* (Sept. 26, 2004).

**Summer 2004, Alabama:** Eleven state health department nurses quit their jobs rather than dispense emergency contraception to women at family planning clinics in Alabama. At the request of Congressman Robert Aderholt, Health and Human Services Secretary Tommy Thompson clarified that the Title X statute does not require state family planning clinics to offer emergency contraception. However, Dr. Tom Miller, family planning director of the Alabama Department of Health, stated that he believes offering EC is good public health policy and that state clinics will continue to offer this contraceptive option. U.S. Advises Alabama on Contraception, *Assoc. Press* at <http://www.newsday.com/news/politics/wire/sns-ap-morning-after-pill,0,7055462,print.story?coll=sns-ap-politics-headlines> (last visited Oct. 20, 2004)).

**Spring 2004, Texas:** In March 2004, at an Eckerd pharmacy in Denton, Texas, a rape victim attempted to fill a prescription for emergency contraceptive pills (ECPs) in an effort to guard against an unwanted pregnancy. Gene Herr, along with two other pharmacists, denied the woman access to the pills, citing religious convictions. A friend of the rape victim explained that the decision to deny the pills amounted to a second victimization, "I had been...watching my friend, her emotional state going down and down. . .And I knew I was going to have to go out to that car and say, 'Sorry, you know, morally they say you're wrong.'" Because the three co-workers violated Eckerd's drug dispensation policy which states that no pharmacist can decline to fill a prescription based solely on moral or religious grounds, they were fired. Herr explained that he believes the pills could have killed the embryo if the woman had already conceived. In fact, ECPs will not work if a woman is already pregnant. Pharmacist's Refusal to Fill Emergency Contraception Script Raises Questions, *Women's Health Wkly.* (Mar. 18, 2004).

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<sup>1</sup>This document was prepared by NARAL in April 2005.

**Spring 2004, North Richland Hills, Texas:** A CVS pharmacist refused to fill a woman's birth control pill prescription, citing personal beliefs. The pharmacist told the woman to get the prescription filled at a Walgreens down the street. The woman, Julee Lacey, a 32-year-old married mother of two and first grade teacher left the store without getting her prescription filled and did not go to Walgreens because she didn't have time to set up a new account. Lacey's husband then attempted to get the prescription filled at CVS - the same pharmacist refused to fill the prescription. The next day, CVS delivered the birth control pills to Lacey's home, free of charge. Pharmacist Refuses to Fill Birth Control Prescription, *Forth Worth Star-Telegram* (Apr. 1, 2004).

**Summer 2002, Wisconsin:** On July 6, 2002, a student in Menomonie, Wisconsin, walked into a K-mart pharmacy and asked the pharmacist on duty, Neil Noesen, to refill her prescription for birth control pills. When, after being questioned by Noesen, the young woman revealed that she was taking the pills for contraceptive purposes, Noesen refused to refill her prescription, as he believed that the pills would cause an abortion. Not only did the pharmacist deny the woman the prescription she needed to be refilled that same day, but he also refused to inform her of her right to transfer her prescription to another pharmacy. Because the patient was prevented from taking the first tablet until the second day of her cycle, the effectiveness of the pills was decreased, making the chances of her becoming pregnant greater. In February 2005, an administrative law judge found that Noesen, "'fell far short of satisfying the standard of care' outlined in the code of ethics for pharmacists, and he hadn't done enough to ensure that the patient had another way to have her prescription filled." As a result, the judge recommended that the state restrict Noesen's pharmacy license. Stacy Forster, Reprimand Advised for Pharmacist, *Milwaukee Journal Sentinel* (Feb. 28, 2005); Anita Weier, Patient, Pharmacist Collide: birth control pill conflict shows dilemma, *The Capitol Times*, (Mar. 16, 2004); Todd Richmond, Hearing Concludes in Madison in Pharmacist Case, *Assoc. Press* (Oct. 12, 2004).

**December 1996, Ohio:** In Ohio, this issue first received attention in 1996, when pharmacist Karen Brauer was fired from a Cincinnati Kmart after refusing to fill a woman's prescription for birth control pills. Brauer contended that she was following her conscience when she denied a 32-year-old woman her request for the pills. Brauer justified her actions by explaining, "This is the Fifth Commandment...I want to opt out of the willful decision to kill." Because of her belief that her right to refuse to dispense drugs on moral grounds was violated, Brauer filed suit against Kmart in 1999. Kmart, along with women's rights organizations and educated professionals, agreed that pharmacists have a responsibility to meet customer needs and that patients should not be subjected to pharmacists' personal moral decisions. Five years later, the case is still pending in federal court. Dennis M. Mahoney, Prescription for Dispute, *The Columbus Dispatch* (Dec. 14, 2001).

.....  
(Original Signature of Member)

109TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To establish certain duties for pharmacies when pharmacists employed by the pharmacies refuse to fill valid prescriptions for drugs or devices on the basis of personal beliefs, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mrs. MALONEY (for herself, [see attached list of cosponsors]) introduced the following bill; which was referred to the Committee on

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**A BILL**

To establish certain duties for pharmacies when pharmacists employed by the pharmacies refuse to fill valid prescriptions for drugs or devices on the basis of personal beliefs, and for other purposes.

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. SHORT TITLE.**

4 This Act may be cited as the "Access to Legal Phar-  
5 maceuticals Act".





1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) An individual’s right to religious belief and  
4 worship is a protected, fundamental right in the  
5 United States.

6 (2) An individual’s right to access legal contra-  
7 ception is a protected, fundamental right in the  
8 United States.

9 (3) An individual’s right to religious belief and  
10 worship cannot impede an individual’s access to legal  
11 prescriptions, including contraception.

12 **SEC. 3. DUTIES OF PHARMACIES WITH RESPECT TO RE-**  
13 **FUSAL OF PHARMACISTS TO FILL VALID PRE-**  
14 **SCRIPTIONS.**

15 (a) IN GENERAL.—Part B of title II of the Public  
16 Health Service Act (42 U.S.C. 238 et seq.) is amended  
17 by adding at the end the following section:

18 **“SEC. 249. DUTIES OF PHARMACIES WITH RESPECT TO RE-**  
19 **FUSAL OF PHARMACISTS TO FILL VALID PRE-**  
20 **SCRIPTIONS.**

21 **“(a) IN GENERAL.—**A pharmacy that receives pre-  
22 scription drugs or prescription devices in interstate com-  
23 merce shall maintain compliance with the following condi-  
24 tions:

25 **“(1) If a product is in stock and a pharmacist**  
26 **employed by the pharmacy refuses on the basis of a**



1 personal belief to fill a valid prescription for the  
2 product, the pharmacy ensures, subject to the con-  
3 sent of the individual presenting the prescription in  
4 any case in which the individual has reason to know  
5 of the refusal, that the prescription is, without delay,  
6 filled by another pharmacist employed by the phar-  
7 macy.

8 “(2) Subject to subsection (b), if a product is  
9 not in stock and a pharmacist employed by the phar-  
10 macy refuses on the basis of a personal belief or on  
11 the basis of pharmacy policy to order or to offer to  
12 order the product when presented a valid prescrip-  
13 tion for the product—

14 “(A) the pharmacy ensures that the indi-  
15 vidual presenting the prescription is imme-  
16 diately informed that the product is not in  
17 stock but can be ordered by the pharmacy; and

18 “(B) the pharmacy ensures, subject to the  
19 consent of the individual, that the product is,  
20 without delay, ordered by another pharmacist  
21 employed by the pharmacy.

22 “(3) The pharmacy does not employ any phar-  
23 macist who engages in any conduct with the intent  
24 to prevent or deter an individual from filling a valid  
25 prescription for a product or from ordering the prod-



1       uct (other than the specific conduct described in  
2       paragraph (1) or (2)), including—

3               “(A) the refusal to return a prescription  
4               form to the individual after refusing to fill the  
5               prescription or order the product, if the indi-  
6               vidual requests the return of such form;

7               “(B) the refusal to transfer prescription  
8               information to another pharmacy for refill dis-  
9               pensing when such a transfer is lawful, if the  
10              individual requests such transfer;

11              “(C) subjecting the individual to humilia-  
12              tion or otherwise harassing the individual; or

13              “(D) breaching medical confidentiality with  
14              respect to the prescription or threatening to  
15              breach such confidentiality.

16       “(b) PRODUCTS NOT ORDINARILY STOCKED.—Sub-  
17       section (a)(2) applies only with respect to a pharmacy or-  
18       dering a particular product for an individual presenting  
19       a valid prescription for the product, and does not require  
20       the pharmacy to keep such product in stock, except that  
21       such subsection has no applicability with respect to a prod-  
22       uct for a health condition if the pharmacy does not keep  
23       in stock any product for such condition.

24       “(c) ENFORCEMENT.—



1           “(1) CIVIL PENALTY.—A pharmacy that vio-  
2           lates a requirement of subsection (a) is liable to the  
3           United States for a civil penalty in an amount not  
4           exceeding \$5,000 per day of violation, not to exceed  
5           \$500,000 for all violations adjudicated in a single  
6           proceeding.

7           “(2) PRIVATE CAUSE OF ACTION.—Any person  
8           aggrieved as a result of a violation of a requirement  
9           of subsection (a) may, in any court of competent ju-  
10          risdiction, commence a civil action against the phar-  
11          macy involved to obtain appropriate relief, including  
12          actual and punitive damages, injunctive relief, and a  
13          reasonable attorney’s fee and cost.

14          “(3) LIMITATIONS.—A civil action under para-  
15          graph (1) or (2) may not be commenced against a  
16          pharmacy after the expiration of the five-year period  
17          beginning on the date on which the pharmacy alleg-  
18          edly engaged in the violation involved.

19          “(d) DEFINITIONS.—For purposes of this section:

20                 “(1) The term ‘employ’, with respect to the  
21                 services of a pharmacist, includes entering into a  
22                 contract for the provision of such services.

23                 “(2) The term ‘pharmacist’ means a person au-  
24                 thorized by a State to practice pharmacy, including  
25                 the dispensing and selling of prescription drugs.



1           “(3) The term ‘pharmacy’ means a person  
2 who—

3                   “(A) is authorized by a State to engage in  
4 the business of selling prescription drugs at re-  
5 tail; and

6                   “(B) employs one or more pharmacists.

7           “(4) The term ‘prescription device’ means a de-  
8 vice whose sale at retail is restricted under section  
9 520(e)(1) of the Federal Food, Drug, and Cosmetic  
10 Act.

11           “(5) The term ‘prescription drug’ means a drug  
12 that is subject to section 503(b)(1) of the Federal  
13 Food, Drug, and Cosmetic Act.

14           “(6) The term ‘product’ means a prescription  
15 drug or a prescription device.

16           “(7) The term ‘valid’, with respect to a pre-  
17 scription, means—

18                   “(A) in the case of a drug, a prescription  
19 within the meaning of section 503(b)(1) of the  
20 Federal Food, Drug, and Cosmetic Act that is  
21 in compliance with applicable law, including, in  
22 the case of a prescription for a drug that is a  
23 controlled substance, compliance with part 1306  
24 of title 21, Code of Federal Regulations, or suc-  
25 cessor regulations; and



1           “(B) in the case of a device, an authoriza-  
2           tion of a practitioner within the meaning of sec-  
3           tion 520(e)(1) of such Act that is in compliance  
4           with applicable law.

5           “(8) The term ‘without delay’, with respect to  
6           a pharmacy filling a prescription for a product or or-  
7           dering the product, means within the usual and cus-  
8           tomary timeframe at the pharmacy for filling pre-  
9           scriptions for products for the health condition in-  
10          volved or for ordering such products, respectively.”.

11          (b) **EFFECTIVE DATE.**—The amendment made by  
12          subsection (a) takes effect upon the expiration of 30 days  
13          after the date of the enactment of this Act, without regard  
14          to whether the Secretary of Health and Human Services  
15          has issued any guidance or final rule regarding such  
16          amendment.

