

Online Pharmacy Modified Registration Application

Under the Ryan Haight Act, if you are a pharmacist, and your DEA-registered pharmacy falls within the definition of an "online pharmacy" (set forth in 21 U.S.C. 802(52)), your pharmacy must, beginning on April 13, 2009, obtain from DEA a modification of its registration authorizing it to act as an online pharmacy. DEA will issue a certificate of registration indicating that such modification has been granted. Please read the Federal Register notice to determine if you fall within the definition of an online pharmacy before submitting an application for such modification of registration. [FR HYPERLINK]

Check one

I have read 74 FRXXXX, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and have determined that I fall within the definition of an online pharmacy. I want to **continue** this application to modify my registration to that of an Online Pharmacy.

I have read 74 FRXXXX, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and have determined that I **do not** fall within the definition of an online pharmacy. I **do not** want to continue to modify my registration to that of an Online Pharmacy.

DEA Registration/Application Update Request Login:

DEA Number (Required for registrants – Not Case Sensitive)

Business Name (Required – Not Case Sensitive)

As it appears on your registration. Example:

If “Smith’s, Pharmacy” is on your registration, then enter: **Smith’s**

If “Smith’s Pharmacy” (no comma) is on your registration, then enter: **Smith’s
Pharmacy**

Tax ID (Required if given on application)

Current Expiration Date (Required for registrants. Listed on registration certificate.)

Month (Drop Down Menu) **Day of Month** (Drop Down) **Year** (Drop Down)

State (from registered address) (Required)

State: _____ (Drop Down Menu)

Zip (Required)

Page 3

Modification of Registration

Name of Pharmacy (DEA will fill in this information)

1. Provide pharmacy’s telephone number: **(Auto Fill from CSA)**
2. Provide pharmacy’s active business email address: **(Auto Fill from CSA)**
3. Provide pharmacist-in charge information

(a) Name of Pharmacist-in charge

Last Name: _____ First Name: _____

(b) Professional degree: _____ (**RPH or PharmD**)

(c) States of licensure:

License Number: _____

State: _____

Expiration Date: _____

(d) Telephone number: ____ ____ ____ (**Pharmacist-in-Charge**)

4. List the States in which the pharmacy is licensed to dispense **controlled substances**.

License Number: _____

State: _____

Expiration Date: _____

5. Provide a listing of all Internet site addresses owned by the online pharmacy to conduct online business activities (also known as the uniform resource locator or URL).

6. Provide Practitioner's information that has a contractual relationship to provide medical evaluations or issue prescriptions for **controlled substances**, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.

(a) Practitioner's **DEA registration number**: _____

(Validate – CSA display)

(b) Practitioner's telephone number: ____ ____ ____

7. Provide the Drug Enforcement Administration registration number of any pharmacy that delivers, distributes, or dispenses **controlled substances** pursuant to orders made on, through, or on behalf of the online pharmacy. (*Pharmacy to pharmacy DEA #*)

Pharmacy DEA Number/s:

Page 4

Pursuant to section 311(d) of the Controlled Substances Act (21 U.S.C. 831(d)), you, as an online pharmacy, acknowledge and agree that thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, you must notify the Administrator and the State boards of pharmacy in any States in which you offer to sell, deliver, distribute, or dispense controlled substances. By fully completing and submitting this application, you will satisfy this requirement with respect to the Administrator. However, you must separately notify the State boards of pharmacy as required by the Act. You understand that subsequent online pharmacy registration renewals will be accomplished by the online process and the appropriate renewal fee will apply.

You, as an online pharmacy, acknowledge and understand that you may not engage in any activity of an online pharmacy as defined in 21 CFR 1300.04(h) until your application for modified registration to act as an online pharmacy is granted and a Certificate of Registration indicating the modification is issued by the Administrator (DEA Form 223).

You, as an online pharmacy, understand that the Administrator may deny an application for a modification of registration if the Administrator determines that the issuance of such modification would be inconsistent with the public interest. In determining the public interest, the Administrator considers the factors listed in 21 U.S.C. 823(f).

Check one

I have read/acknowledged the above requirements and I want to continue to modify my registration to that of an Online Pharmacy.

I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 5

Pursuant to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), you, as an online pharmacy, certify that you are authorized by the appropriate state authority(ies) to modify your existing DEA registration to authorize you to dispense schedule II-V controlled substances by means of the Internet.

Pursuant to section 311(b) of the Controlled Substances Act (21 U.S.C. 831(b)), you, as an online pharmacy, acknowledge and agree to comply with the requirements of State law concerning the licensure of pharmacies in each State from which and to which you, deliver, distribute, or dispense, or offer to deliver, distribute, or dispense controlled substances by means of the Internet **as required by Section 303 (f), unless exempt from such registration.**

Check one

I have read/acknowledged the above requirements and I want to continue to modify my registration to that of an Online Pharmacy.

I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 6

You understand that in accordance with section 401(h) of the Act (21 U.S.C. 841(h)), as of April 13, 2009, it is unlawful for any online pharmacy to deliver, distribute, or dispense a controlled substance by means of the Internet unless such online pharmacy is validly registered with a modification of DEA registration authorizing the dispensing of controlled substances by means of the internet.

Pursuant to section 309(e) of the Controlled Substances Act (21 U.S.C. 829(e)), you, as an online pharmacy, acknowledge and agree that no controlled substance that is a prescription drug may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

Pursuant to 21 CFR 1306.09, you, as an online pharmacy, acknowledge

and agree that a prescription for a controlled substance may only be dispensed by means of the Internet by a pharmacist, acting in the usual course of his professional practice, and employed in a retail pharmacy whose registration has been modified to authorize it to act as an online pharmacy.

Check one

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I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 7

Pursuant to section 307(d) of the Controlled Substance Act (21 U.S.C. 827 (d)), you, as an online pharmacy, understand you are required to report the dispensing of controlled substances by means of the Internet to the Administrator in the manner set forth in 21 CFR 1304.55. This report will include the total quantity of each controlled substance (**product type by NDC number**) that the pharmacy dispenses each calendar month. Monthly reports must be submitted electronically using online reporting, electronic file upload, or other means approved by DEA. Reporting shall include all controlled substances dispensed via Internet transactions, mail-order, face-to-face transactions, or any other means. The report shall be submitted to DEA by the 15th day of the following month.

Check one

I have read/acknowledged the above requirements and I want to continue to modify my registration to that of an Online Pharmacy.

I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 8

Pursuant to section 311(a) of the Controlled Substances Act (21 U.S.C. 831(a)), you, as an online pharmacy, agree to display at all times on your homepage, in a visible and clear manner, a statement that your online pharmacy complies with the requirements of section 311 of the Act (21 U.S.C. 831) with respect to the delivery or sale or offer for sale of controlled substances.

Pursuant to section 311(c) of the Controlled Substances Act (21 U.S.C. 831(c)), you, as an online pharmacy, acknowledge and agree to post the following Internet Pharmacy Site Disclosure information in a visible and clear manner on the homepage of each Internet site you operate, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage:

- 1) The name and address of the pharmacy as it appears on the pharmacy's DEA certificate of registration.
- 2) The pharmacy's telephone number and email address.
- 3) Name of pharmacist-in charge, professional degree, States of licensure, and telephone number.
- 4) List of States in which the pharmacy is licensed to dispense controlled substances.
- 5) Certification that the pharmacy is registered to deliver, distribute, or dispense by means of the Internet, controlled substances.
- 6) The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
- 7) The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to act as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner."

Pursuant to section 311(d)(2)(A) of the Controlled Substances Act (21 U.S.C. 831(d)(2)(A)), you, as an online pharmacy, certify that the Internet Pharmacy Site Disclosure information disclosed on your website, under penalty of perjury, is true and accurate.

Check one

I have read/acknowledged the above requirements and I want to continue to modify my registration to that of an Online Pharmacy.

I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 9

Pursuant to section 311(e) of the Controlled Substances Act (21 U.S.C. 831(e)), you, as an online pharmacy, understand and agree that on and after the date you apply for a modified registration, you will display on your homepage, in the manner described in 21 CFR 1304.40(d), a declaration that you have made the required notifications to the DEA Administrator.

"In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. 831 and 21 CFR 1304.40."

Pursuant to 21 CFR 1301.19, if you, as an online pharmacy, chose to discontinue the modification of registration authorizing you to dispense controlled substances by means of the Internet, you acknowledge and agree that you shall so notify the Administrator by requesting to modify your registration to reflect the appropriate business activity. Once the registration has been so changed, the pharmacy may no longer dispense **controlled substances** by means of the Internet.

Check one

I have read/acknowledged the above requirements and I want to continue to modify my registration to that of an Online Pharmacy.

I **do not** want to continue to modify my registration to that of an Online Pharmacy.

Page 10

RECAP OF INFORMATION

Please review your responses. Click the change buttons on the left to make any required changes. Then submit the application using the **Submit button** below.

<u>Step – 1 Business Activity</u>	
<u>CHANGE</u>	Business Activity: _____
<u>Step – 2 Personal Information</u>	
<u>CHANGE</u>	Pharmacist-in-Charge:
	Last Name: _____
	First Name: _____
	Degree: _____
	State Licensure: Number: _____
	State: _____
	Expires: _____
	Email Address: _____
	Telephone number: _____

Step – 3 State Licenses To Dispense Controlled Substances

CHANGE State License: Number: _____
State: _____
Expires: _____

Step - 4 Internet Sites

CHANGE Uniform Resource Locator (URL): _____

Step – 5 Contractual Practitioner’s Information

Practitioner’s DEA Number/s: _____

CHANGE

Telephone Number: _____

Step – 6 Pharmacy Operating on behalf of the Online Pharmacy

DEA Registration Number/s _____

CHANGE

Warning: Section 843(a)(4)(A) of Title 21, United States Code, states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to imprisonment for not more than four years, a fine of not more than \$30,000.00 or both.

By typing my full name in the space below, I hereby certify that the foregoing information furnished on these application/DEA forms pages is true and correct and understand that this constitutes an electronic signature for purposes of these applications/DEA forms only.

***Name of Certifying Applicant/Official**

This electronic application/DEA form must be certified by the applicant/registrant,

if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, information on who can certify this application.

**SUBMIT
REQUEST**

CANCEL

ADDITIONAL INFORMATION

1. No modification of registration will be issued unless a completed application form has been received (21 CFR 1301.19).
 2. In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is 1117-0014. Public reporting burden for this collection of information is estimated to average 15 minutes per response.
 3. **PRIVACY ACT INFORMATION:** To the extent that the information provided in the Online Pharmacy Modified Registration Application is protected by the Privacy Act, providing this information is voluntary. The authorities for the collection of this information are sections 102, 302, 303, 309, and 311 of the Controlled Substances Act, as amended (21 U.S.C. §§ 802, 822, 823, 829, and 831), and 21 CFR Parts 1300, 1301, 1304, and 1306. The principal purpose for which the information will be used is to obtain information required to evaluate applications for modification of registration in accordance with the requirements of the Controlled Substances Act. The information may be disclosed to Federal, State, and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. For additional guidance regarding how your information may be used or disclosed, along with a complete list of the Privacy Act routine uses related to this collection, please consult the Drug Enforcement Administration's System of Records Notice entitled "Controlled Substances Act Registration Records," JUSTICE/DEA-005, 52 Fed. Reg. 47208 (Dec. 11, 1987). Failure to furnish the requested information will preclude the processing of the application and the issuance of a modified registration.
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