



Verification Program Accreditation Standards and Guide

Protecting the Public Health:
Helping Consumers Find Information About
Accredited Online Pharmacies that Sell
Affordable Medications

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Note: This accreditation guide provides applicants and accredited pharmacies with required standards, policies and “best practice” guidance for the PharmacyChecker Verification Program. It is not meant to be the final determination on what is deemed compliant with PharmacyChecker standards and policies. PharmacyChecker reserves the right to determine compliance with PharmacyChecker agreements, standards and policies as well as what constitutes “best practice” given the regulatory oversight, regulatory climate, geographical region, and online presence (if any) of an applicant or accredited pharmacy.

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A. Introduction

PharmacyChecker protects public health by publishing information that helps improve access by consumers to safe and affordable medications purchased online. Maximizing access to affordable medication is a global public health priority.¹

In 2016, about 45 million Americans did not fill a prescription for cost-related reasons.² According to the Harvard School of Public Health, over half of Americans who do not take prescription medication due to cost report becoming sicker. That means potentially 22.5 million Americans become sicker last year due to the cost of prescribed medication.³

To save money or avoid going without prescribed medications, according to a survey by the Kaiser Family Foundation, about 19 million Americans say that they have imported a prescription medication for personal use.⁴ The most recent survey data from the U.S. Centers for Disease Control and Prevention showed that about four million Americans buy medication outside the U.S. each year.⁵

It's likely that the majority of Americans who buy medications internationally are doing so from online pharmacies. In a Zogby poll commissioned by the organization Prescription Justice in February 2017, 4.2% of respondents said that they currently get prescription medication from a Canadian or other international online pharmacy. That percentage of the adult population – 10.6 million – appears higher than the other estimates, but demonstrates that the Internet is the main channel to affordable imported medication.⁶ An earlier PharmacyChecker analysis of

¹ World Health Organization, "The World Medicines Situation," 3rd ed., 2011, Geneva, see http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf [Last accessed 10/10/2014].

² R. Osborn, D. Squires, M. M. Doty, D. O. Sarnak, and E. C. Schneider, "In New Survey of 11 Countries, U.S. Adults Still Struggle with Access to and Affordability of Health Care," Health Affairs Web First, Nov. 16, 2016. See <http://www.commonwealthfund.org/publications/in-the-literature/2016/nov/2016-international-health-policy-survey-of-adults> [Last accessed 4/6/2017]; and U.S. Census Bureau data: <https://www.census.gov/quickfacts/table/PST045216/00> 18% of the adult population in 2016 is approximately 45 million.

³ USA Today/Kaiser Family Foundation/ Harvard School of Public Health, Health Care Costs Survey (conducted April 25 –June 9, 2005). The survey finds that 20% of respondents, adult Americans, report not filling a prescription due to cost; 54% of those respondents said their condition got worse as a result. Extrapolated to the 2014 population of adults 18 and older, the number is approximately 17.5 million people. See <http://kff.org/health-costs/poll-finding/health-care-costssurvey-summary-and-chartpack/> [Last accessed 7/5/2014].

⁴ Bluth, Rachel, "Faced With Unaffordable Drug Prices, Tens of Millions Buy Medicine Outside the U.S.," December 20th, 2016, Kaiser Health News, see <http://khn.org/news/faced-with-unaffordable-drug-prices-tens-of-millions-buy-medicine-outside-u-s/> [Last accessed 1/29/2017].

⁵ Cohen RA, Villarroel MA. Strategies used by adults to reduce their prescription drug costs: United States, 2013. NCHS data brief, no 184. Hyattsville, MD: National Center for Health Statistics. 2015. See <http://www.cdc.gov/nchs/data/databriefs/db184.htm> [Last accessed 12/11/2016].

⁶ http://prescriptionjustice.org/Prescription_Justice_Zogby_Poll_Data_Feb_2017.pdf

a 2012 survey by the U.S. Food and Drug Administration showed just over six million people ordering online from foreign sources each year.⁷

The Internet presents both the opportunity to access much lower cost medication and serious dangers to the public health in the form of “rogue” online pharmacies, health scams, and counterfeit drugs. How can people who need affordable medication from abroad protect themselves?

PharmacyChecker was launched in 2003 to verify the credentials of online pharmacies and compare drug prices to help consumers searching for affordable prescription medication. Its information is available for free to patients worldwide. Peer-reviewed research⁸ and 15 years of experience, demonstrate that consumers ordering medications online are well served if they only purchase from websites that are verified for good online pharmacy practice standards by PharmacyChecker. Americans visiting PharmacyChecker also benefit from comparisons of drug prices among local U.S. pharmacies and patient assistance programs, ones sponsored by pharmaceutical companies.

Examples of online access to affordable medication from international pharmacies extend beyond U.S. consumers. In the United Kingdom, international online pharmacies have helped men who are most at-risk for contracting HIV obtain generic versions of the drug Truvada from India. A 40% decrease in HIV is attributed to this online access.⁹ Healthcare providers and patients in Australia have created a “Buyer’s Club” that makes use of the Internet to help patients with Hepatitis C obtain imported, affordable generic versions of Sovaldi.¹⁰

The mission of PharmacyChecker is to help consumers find safe and affordable medication when searching on the Internet.¹¹ Its programs protect public health by reducing the number of people who fail to take prescribed medication due to cost or availability, and greatly reducing the chance of them buying from a dangerous pharmacy website.

⁷ <https://www.pharmacycheckerblog.com/online-pharmacies-personal-drug-importation-and-public-health-how-many-americans-are-buying-medication-online-from-dangerous-websites>.

⁸ Bate, Roger, Ginger Zhe Jin and Aparna Mathur, “In Whom We Trust: The Role of Certification Agencies in Online Drug Markets,” *The B.E. Journal of Economic Analysis & Policy*. Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI: 10.1515/bejeap-2013-0085, December 2013.

⁹ Wilson, Clare, “Massive Drop in London HIV Rates May be Due to Internet Drugs,” January 19, 2017, *New Scientist*, see <https://www.newscientist.com/article/2117426-massive-drop-in-london-hiv-rates-may-be-due-to-internet-drugs> [Last accessed 3/24/2017].

¹⁰ Woolveridge, Richard, “Hepatitis C Drug Buyers Club Aims to Set Up a New Source of Support,” September 25th, 2015, *The Sydney Morning Herald*, see <http://www.smh.com.au/national/health/hepatitis-c-drug-buyers-club-aims-to-set-up-new-source-of-support-20150924-gjts1t.html> and <http://fixhepc.com/getting-treated/how-to-do-it/buyers-club.html> [Last accessed 3/24/2017].

¹¹ Archer, Diane, “Online Pharmacies Can Save You Money,” July 28, 2016, JustCare, see <http://justcareusa.org/online-pharmacies-can-save-you-money/> [Last accessed 3/24/2017].

B. Verification Program Overview

The PharmacyChecker Verification Program enables eligible pharmacies, (e.g. online and dispensing pharmacies), meeting program standards and policies to become accredited. The Program's practice and safety standards include but are not limited to the following standards:

Pharmacy / Pharmacist Licensure – the pharmacy must ensure that all prescriptions must be directly confirmed, dispensed and shipped by a licensed pharmacy that is also accredited in the Verification Program. Prescriptions must only be dispensed by a pharmacist licensed in the pharmacy's jurisdiction.

Valid prescription – the pharmacy must require a valid prescription and its website must clearly display this requirement.

Controlled Substances – the pharmacy may not market or sell controlled substances into the U.S., as defined by the U.S. Drug Enforcement Agency (DEA) unless based in the U.S., and in accordance with the Ryan Haight Act.

Information Security – the pharmacy's website must employ Secure-Socket Layer or equivalent technology to ensure protection of health and financial information of consumers.

Country Transparency – the pharmacy's website must disclose to consumers the specific country or, if applicable, the list of potential countries, from which a drug will be dispensed.

Location/Customer Service – the pharmacy's website must clearly publish a telephone number and mailing address that allows consumers to reach the pharmacy staff for customer service.

Pharmacist Consultations – the pharmacy's website must conspicuously publish that a pharmacist consultation with a licensed pharmacist is available for patients who have placed an order with the pharmacy and have questions about their medication orders.

Marketing Claims – the pharmacy's website must only make claims that are truthful and/or not misleading to the consumer, e.g. claims about generic medications may not refer to generic medications as "exactly the same as" or "identical to" their brand name counterparts; foreign versions of drugs sold in the U.S. can't be referred to as "FDA-approved".

Accredited pharmacies are authorized to publish the PharmacyChecker Seal which links to its online pharmacy profile, hosted on www.PharmacyChecker.com.¹² By clicking on the seal, consumers can obtain the information verified, and ensure the accreditation is valid.

¹² See a sample seal at: <https://www.pharmacychecker.com/sealprogram/choose.asp>

PharmacyChecker staff monitor compliance utilizing various audit techniques, such as mystery shopping, remote monitoring of websites, as well as inspections performed by PharmacyChecker personnel.¹³

Accredited pharmacies found to be out-of-compliance are subject to penalties and required to submit and enact plans of corrections. Failure to do so results in termination from the program.

C. Verification Program Accreditation Standards

Standards must be met by applicants seeking accreditation as well as accredited pharmacies wishing to maintain accreditation in the PharmacyChecker Verification Program:

PharmacyChecker uses the term “pharmacy” to collectively refer to online pharmacies, wholesale pharmacies and dispensing pharmacies (including veterinary pharmacies).

Section headers will identify where specific standards do not apply to a particular type of pharmacy. Additionally, the standards explicitly state “online pharmacy”, “dispensing pharmacy” or “wholesale pharmacy” where a standard only applies to that type of pharmacy.

Section I: Compliance with the Verification Program

1.0 All information provided to PharmacyChecker by the pharmacy, its owners, directors, employees, and/or any person associated with it must be truthful and accurate, and may not be defamatory or infringe any copyright, trademark, patent, trade secret, or moral right or other intellectual property or proprietary right of any kind (collectively "IP Rights").

1.1 A Pharmacy, its owners, directors, employees, and/or any person associated with it must provide PharmacyChecker with all information relevant to their operations. Omitting information, especially unfavorable information, is considered untruthful, deceitful and fraudulent and may result in immediate termination of review of a pharmacy’s application and/or termination of a pharmacy’s accreditation.

1.2 PharmacyChecker reserves the right to refuse and/or disqualify Verification Program accreditation applications if pharmacies, owners, directors, employees and/or any person associated with it, was, directly or indirectly, found by PharmacyChecker to be in violation of the Verification Program or has previously been rejected, denied, terminated and/or banned from the Verification Program.

¹³ Pharmacies located in Australia, Canada, Israel, New Zealand, South Africa, United Kingdom, or the United States are inspected by the governing regulatory authority, where required. An additional inspection by PharmacyChecker is required for pharmacies in India and Turkey, and international pharmacy operations on free trade zones in Barbados, Mauritius, and Singapore to ensure high standards in line with pharmacies in the United States. Inspections conducted by PharmacyChecker focus on personnel, prescription processing systems, drug safety, sanitary conditions, storage, and mail order safety practices.

1.3 PharmacyChecker Verification Program application, inspection (where applicable) and monthly accreditation fees are non-refundable.

1.4 If the **dispensing pharmacy** is dispensing prescription orders referred by an online pharmacy, which is not an accredited pharmacy of the PharmacyChecker Verification Program, the dispensing pharmacy must adhere to all Verification Program requirements, including but not limited to valid prescription requirement (standard 3.0), product selection (standard 6.0), not dispensing controlled substances to U.S. (standard 2.12), no exports for resale (standard 5.0) when dispensing to consumers in the U.S.

Section II: Compliance with the Law

2.0 The pharmacy must only offer and sell products and services in full compliance with all state and federal (whether U.S., Canadian, or other country/region) laws, rules, regulations and generally accepted industry standards of ethical business conduct, applicable in the jurisdiction where its pharmacy, and/or other pharmacies to which it refers prescriptions, is located (collectively "Law").

a. Licensure

(Standards 2.1 to 2.19 do not apply to ***Online Pharmacy***)

2.1 The pharmacy must possess all pertinent pharmacy and business licenses required for operation in the geographic region in which it is located (includes license from applicable regulatory body, import license, export license, and all licenses/registrations required based on the pharmacy's business model, practice and scope).

2.2 **Dispensing pharmacy** must at all times employ a licensed pharmacist, and other qualified personnel, as required by law and to meet PharmacyChecker standards, for the management of its pharmacy, and the dispensing of prescription drugs.

2.3 **Dispensing pharmacy** must only permit licensed pharmacists to dispense prescription drugs.

b. Wholesale Distribution

2.4 **Wholesale pharmacy** must employ or contract with qualified personnel, as required by law for the management of the wholesale business.

2.5 **Wholesale pharmacy** may not sell and/or distribute prescription drugs to any pharmacy, hospital, licensed prescriber, or other entity without receiving and verifying the customer's relevant credentials, such as a valid pharmacy or doctor's license.

2.6 If located **outside** the U.S., pharmacy may not market, sell and/or wholesale distribute controlled substances, as defined by U.S. law- [federal](#) and/or state, to pharmacies, hospitals,

licensed prescribers or other entities in the U.S., unless the pharmacy possesses a valid U.S. DEA registration and is expressly permitted by U.S. law to wholesale distribute controlled substances to customers in the U.S.

2.7 If located **within** the U.S., wholesale distribution of controlled substances (including marketing, selling and/or distributing) must comply with federal and state laws.

[See 5.0, No Exports for Re-Sale]

c. Sterile and Non-Sterile Compounding

2.8 If located **outside** the U.S., pharmacy may not market, sell, process and/or dispense compounded preparations (sterile and/or non-sterile) internationally.

2.9 If located **within** the U.S. and providing services that include sterile and/or non-sterile compounding, pharmacy must provide such preparations and services in full compliance with all federal and state laws, rules, and regulations.

d. Outsourcing Facilities (503B registration)

2.10 If providing services that include the manufacturing of sterile drug preparations for bulk sale to hospitals and other healthcare providers in the U.S., the pharmacy must register with the U.S. FDA as an Outsourcing Facility for human drug compounding prior to distributing any sterile drug preparations.

2.11 If providing services that include the manufacturing of sterile drug preparations for bulk sale to hospitals and other healthcare providers in the U.S., the pharmacy must provide proof of registration with U.S. FDA as an Outsourcing Facility to PharmacyChecker.

e. DEA License

2.12 If located **outside** the U.S., pharmacy may not market, sell, process and/or dispense prescription orders for controlled substances, as defined U.S. law, [federal](#) and/or state, to patients in the U.S.

2.13 Pharmacies located **within** the U.S. marketing, selling, processing and/or dispensing prescription orders for controlled substances must possess a valid U.S. DEA Registration.

f. License Status / Disciplinary History

2.14 All pertinent pharmacy and business licenses held by the pharmacy must be valid.

2.15 The **dispensing pharmacy** and/or the Pharmacist-in-Charge may not have been subject to significant recent and/or repeated disciplinary violations that affect the safety of the pharmacy operation.

2.16 The **wholesale pharmacy** and/or the manager of the wholesale business may not have been subjected to recent and/or repeated disciplinary sanctions that affect the safety of the wholesale operation.

2.17 The pharmacy must notify PharmacyChecker immediately if the pharmacy or one of its pharmacists, owners, directors, employees, and/or any person associated with it becomes the subject of any adverse and/or potentially adverse government or other regulatory action relating to its license or the dispensing/distribution of medications.

2.18 The Pharmacist-in-Charge of the **dispensing pharmacy** is responsible for providing accurate and truthful information to PharmacyChecker, including disclosure of all discipline history, including, but not limited to, complaints, probation, and/or suspensions by any regulatory body.

2.19 The manager of the **wholesale pharmacy** is responsible for providing accurate and truthful information to PharmacyChecker, including disclosure of all discipline history, including, but not limited to, investigations, complaints, probation, and/or suspensions by any regulatory body.

Section III: Prescription Required

(Standards 3.0 to 3.5 do not apply to ***Wholesale Distribution***)

3.0 Pharmacy must only process and/or dispense prescription medication orders upon receipt of a valid prescription, issued by a healthcare provider licensed and authorized to prescribe in the jurisdiction where the prescriber practices.

3.1 If located **outside** the U.S., pharmacy may not accept and/or process prescription medication orders that have been obtained through remote medical consultation (“prescribing”) services for patients ordering from the U.S. unless expressly permitted under U.S. federal and/or state laws or regulations.

3.2 If located **within** the U.S., pharmacy may only accept and/or process prescription medication orders obtained through remote medical consultation (“prescribing”) service where expressly permitted under federal and/or state laws or regulations.

3.3 Pharmacy may neither offer nor provide remote medical consultation (“prescribing”) services to patients in another country/region, except where expressly permitted by law in that country/region.

3.4 Pharmacy must adhere to the strictest requirement for a prescription when marketing, selling, processing and/or dispensing medications internationally (i.e. if the medication does not require a prescription in the pharmacy’s jurisdiction but does require a prescription in the

country the medication will be dispensed to, the pharmacy must not process and/or dispense the medication prior to receipt of a valid prescription).

3.5 Pharmacy must clearly publish on its website that a valid prescription is required for the purchase of a prescription medication.

3.6 Pharmacy must ensure that prescriptions meet the definition of valid prescription and contain all required elements, in accordance with PharmacyChecker policy 17-02 *Valid Prescription Requirement*, which at a minimum requires:

3.7 Pharmacy must only process and/or dispense medications that have been issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established:

- a. The patient has a legitimate medical complaint, illness or disease;
- b. A face-to-face physical examination adequate to establish the legitimacy of the medical complaint, or treatment of the illness or disease has been performed by the prescribing practitioner, or through a telemedicine practice where explicitly permitted under federal or state laws or regulations through a telemedicine practice; and
- c. A logical connection exists between the medical complaint, illness or disease, the medical history, and the physical examination and the drug prescribed.

3.8 Pharmacy must only process and/or dispense prescriptions that have been written in ink or typewritten, dated and signed on the date when issued and include:

- the patient's full name and address;
- the practitioner's full name, and address;
- DEA number (where applicable for U.S. pharmacies dispensing controlled substances);
- Drug name;
- Strength;
- Dosage form;
- Quantity prescribed;
- Directions for use; and
- Number of refills authorized (if any)

3.9 Pharmacy, its owners, directors, employees, and/or any person associated with it, must neither affiliate with nor refer customers to companies that market, sell, process and/or dispense prescription medications, as defined by U.S. law to the U.S. unless pursuant to a valid prescription received by the pharmacy.

3.10 Pharmacy, its owners, directors, employees, and/or any person associated with it, including through ownership or affiliation with another company must not market, sell, process and/or dispense prescription medication, as defined by US law, to the U.S. unless pursuant to a valid prescription received by the pharmacy.

Section IV: Requirements for Shared Services

a. Affiliating Pharmacy

4.0 Pharmacy may neither affiliate with nor refer customers to, except as otherwise expressly permitted by law in the U.S., healthcare providers, clinics or other parties for consultation to generate or initiate prescriptions for patients who are not physically examined by the healthcare provider, if selling to patients in the U.S.

4.1 In the marketing and sale of prescription medications, a pharmacy's website, if applicable, must only link or otherwise refer customers to prescription drug selling websites and/or refer prescription orders for dispensing to licensed pharmacies that are approved in the PharmacyChecker Verification Program.

4.2 Pharmacy must ensure that all prescription medication orders that are processed through its website are directly dispensed and shipped by the licensed pharmacies listed in its application, or, with notification to PharmacyChecker, which is confirmed as received by PharmacyChecker, to another pharmacy that is approved in the PharmacyChecker Verification Program.

4.3 **Online pharmacy** must complete a PharmacyChecker Shared Pharmacy Services Agreement Form, in accordance with PharmacyChecker policy *17-01 Shared Pharmacy Services: Agreements Between Accredited Companies* for each pharmacy that dispenses prescription orders referred by the online pharmacy.

4.4 **Online pharmacy** must immediately notify PharmacyChecker in writing that it has ceased referring prescription orders to a dispensing pharmacy.

4.5 If the **dispensing pharmacy** is dispensing prescription orders referred by an online pharmacy, which is an accredited pharmacy in the PharmacyChecker Verification Program, the pharmacy must complete a PharmacyChecker Shared Pharmacy Services Agreement Form, which provides acknowledgement from the pharmacy's Pharmacist-in-Charge that the pharmacy dispenses prescription orders referred by the online pharmacy in accordance with PharmacyChecker policy *17-01 Shared Pharmacy Services: Agreements Between Accredited Companies*

4.6 Pharmacy shall conduct shared pharmacy services in accordance with PharmacyChecker policy *17-01 Shared Pharmacy Services Agreement Between Accredited Companies*, which at a minimum requires:

4.7 Pharmacy to have a written contract/agreement that outlines the services provided and the responsibilities of each accredited pharmacy in complying with PharmacyChecker

agreements, standards, and policies related to marketing, selling, processing and/or dispensing prescription medications;

4.8 Pharmacy to share a common electronic file or technology (“database”) that allows access to information necessary to perform the duties outlined in the shared service contract/agreement between accredited pharmacies. The database must be secure and cannot be duplicated, downloaded, or removed from the original platform; and

4.9 Each pharmacy must maintain confidentiality and integrity of patient information.

Market, Sale, and/or Processing of Prescription Medication Orders

Section V: No Exports for Resale

5.0 Neither a pharmacy nor its owners, including through ownership in other companies, may market, sell and/or intentionally ship medications for resale in the U.S. except where expressly permitted by U.S. law.

Section VI: Pharmaceutical Product Selection

b. Verification Program Requirements for Selection

6.0 Pharmacy must only market, sell, process and/or dispense medications that have been approved for sale in at least one of the following countries/regions: Australia, Canada, European Union, India (subject to additional requirements/restrictions, as per PharmacyChecker Policy 16-05 *Marketing / Dispensing Indian Pharmaceutical Products Internationally*), Israel, New Zealand, Singapore, South Africa, Turkey, United Kingdom, or the United States.

c. Pharmaceutical Products Approved for Sale in India

6.1 If marketing, selling, processing and/or dispensing medications approved for sale in India, the pharmacy must comply with the additional requirements/restrictions defined by PharmacyChecker policy 16-05 *Marketing/Dispensing Indian Pharmaceutical Products Internationally*.

d. Singaporean Pharmacies and Wholesale Suppliers Pharmaceutical Products

6.2 Pharmacies located in Singapore must only purchase prescription medications from licensed wholesale suppliers that are also accredited in the PharmacyChecker Verification Program as wholesale pharmacies, unless the pharmacy only dispenses medications approved for sale in Singapore.

6.3 If a licensed wholesaler that supplies prescription medications to PharmacyChecker accredited Singaporean pharmacies that dispense medications approved for sale in other

approved countries, the wholesaler must be accredited in the PharmacyChecker Verification Program as a wholesale pharmacy and must provide PharmacyChecker with the following:

- A. A letter, signed by the owner of the wholesale pharmacy certifying:
 - 1. that they export prescription products to the Singaporean Pharmacy; and
 - 2. that they only export products to the Singaporean Pharmacy that are approved for sale in the domestic market where the wholesale pharmacy resides;
- B. An export license with contact information for verification.

d. Pharmacies Operating in Free Trade Zones (POFTZs) and Wholesale Suppliers

6.4 Pharmacies Operating in Free Trade Zones (POFTZ) must only purchase prescription medications from licensed wholesale suppliers that are also accredited in the PharmacyChecker Verification Program as wholesale pharmacies.

6.5 Each licensed wholesaler supplying medications to PharmacyChecker accredited POFTZ must be accredited in the PharmacyChecker Verification Program as wholesale pharmacy and provide PharmacyChecker with the following:

- A. A letter, signed by the owner of the wholesale pharmacy certifying:
 - 1. that they export prescription products to the Singaporean Pharmacy; and
 - 2. that they only export products to the Singaporean Pharmacy that are approved for sale in the domestic market where the wholesale pharmacy resides;
- B. An export license with contact information for verification.

Section VII: Controlled Substances

7.0 If located **outside** the U.S, neither the pharmacy nor its owners, directors, employees, and/or any person associated with it, including through ownership in other companies, may market, sell, process and/or dispense prescription orders for controlled substances, as defined by U.S. law, [federal](#) and/or state, to patients in the U.S.

7.1 Pharmacies located **within** the U.S. that market, sell, process and/or dispense prescription orders for controlled substances via the internet, pharmacy must adhere to the prescription requirements for online pharmacies ([21 CFR 1306.09](#)) and must ensure that prescription orders will only be referred to a dispensing pharmacy that possesses a valid U.S. DEA registration. for controlled substances, as defined by U.S. law, [federal](#) and/or state, to patients in the U.S.

7.2 Pharmacies located **within** the U.S. that market, sell, process and/or dispense prescription orders for schedule II controlled substances via the internet must publish on the

pharmacy website homepage or on a page prominently linked to from the homepage a disclosure statement attesting to comply with the requirements of the [Ryan Haight Online Pharmacy Act](#).

The disclosure statement must also include the following information:

- Name and address of the pharmacy as it appears on the pharmacy's DEA certificate.
- Pharmacy's telephone number and email address.
- Name, professional degree, and states of licensure of Pharmacist-in-Charge, and phone number of the Pharmacist-in-Charge.
- List of states in which the pharmacy is licensed to dispense controlled substances.
- DEA certification that the pharmacy is registered as an online pharmacy to deliver, distribute, and dispense by means of the Internet controlled substances.
- 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.
- Statement: "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. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309 of the Controlled Substances Act (21 U.S.C. 829)."

7.3 Pharmacy, its owners, directors, employees, and/or any person associated with it, including through ownership in other companies, may neither affiliate with nor refer customers to non-U.S. companies that market, sell, process and/or dispense prescription orders for controlled substances, as defined by U.S. law, [federal](#) and/or state, to patients in the U.S.

7.4 Pharmacy must ensure that a method for identifying controlled substances, as defined by U.S. law, [federal](#) and/or state, is developed and documented in the pharmacy's SOP.

7.5 If located **outside** the U.S and the pharmacy markets controlled substances, as defined by U.S. law, [federal](#) and/or state, on its website, pharmacy must create a disclaimer statement alerting consumers that controlled substances, as defined by U.S. law, [federal](#) and/or state, cannot be dispensed to patients in the U.S. The pharmacy must clearly apply the disclaimer statement on all pages that the controlled substance, as defined by US law, federal and/or state, is listed /marketed on its website.

7.6 Pharmacy must ensure that staff are trained to correctly identify controlled substances, as defined by U.S. law, [federal](#) and/or state, and to answer questions regarding the restriction on marketing and dispensing of controlled substances, as defined by U.S. law, [federal](#) and/or state, to patients in the U.S.

Section VIII: Generic Marketing Claims

8.0 Pharmacy may not publish and/or provide false or misleading information regarding generic medications and must ensure its websites and all information the pharmacy provides to patients (e.g. invoices, patient counseling, pamphlets, etc.) contain truthful and accurate information regarding marketing claims about generic medications.

8.1 Pharmacy may not refer to generic drugs as, or imply them to be, “identical to” or “exactly the same as” their brand name counterparts, but can be described as “comparable,” “equivalent,” “bioequivalent,” or “similar.”

Section IX: Generic Substitution

9.0 Except where required by law, the pharmacy may not substitute a generic prescription drug if the customer has ordered a brand name drug without the consent of the customer when dispensing a prescription internationally.

Section X: Maximum Three Months’ Supply Dispensed Internationally

10.0 Pharmacy may not market, sell, process and/or dispense internationally prescription orders for erectile dysfunction medications, exceeding a three months’ supply under any circumstances, in accordance with PharmacyChecker policy 16-04, *Maximum Three Months’ Supply Dispensed Internationally*.

10.1 For all other prescription medications, pharmacy may not market, sell, process and/or dispense internationally prescription orders exceeding a three months’ supply unless an exception, as defined by and in accordance with PharmacyChecker Policy 16-04, is met and documented prior to processing or referring the prescription to the dispensing pharmacy. (Standard 10.1 does not apply to erectile dysfunction medications, for which there is no exception; refer to: Standard 10.0 above.)

Section XI: Requirements for Medications with Special Considerations

a. Dispensing Refrigerated Medications

11.0 The pharmacy must comply with PharmacyChecker policy 16-03 *Refrigerated Medications: Shipping Requirements*, if marketing, selling, processing and/or dispensing medications requiring refrigerated storage. Only **dispensing pharmacies** located in Canada, the United Kingdom or the United States may dispense temperature sensitive medications to consumers in the U.S.

11.1 If the **dispensing pharmacy** markets, sells, processes and/or dispenses medications requiring refrigerated storage, the pharmacy must provide signed and dated documentation to

online pharmacy and PharmacyChecker that confirms the pharmacy complies with the requirements of PharmacyChecker policy *16-03 Refrigerated Medications: Shipping Requirements*.

11.2 If the **online pharmacy** markets, sells and/or processes prescription orders for medications requiring refrigerated storage, pharmacy must receive documentation from the Pharmacist-in-Charge of each pharmacy to which they link or refer prescription orders, that the pharmacy complies with PharmacyChecker policy 16-03, *Temperature Sensitive Medications: Shipping Requirements*.

11.3 If the **dispensing pharmacy** markets, sells, processes and/or dispenses medications requiring refrigerated storage, the pharmacy must ensure that the shipping container with medications requiring refrigeration contains a temperature indicator with clear directions to the recipient for the evaluation of monitoring indicators and steps to take in the event of an excursion.

11.4 If the **dispensing pharmacy** markets, sells, processes and/or dispenses medications requiring refrigerated storage, the pharmacy must ensure the exterior of the shipping container is properly labeled to alert the patient to open and refrigerate the contents immediately upon receipt.

b. Dispensing Medications Requiring Special Dispensing Considerations

11.5 If the pharmacy markets, sells, processes and/or dispenses medications requiring special dispensing considerations internationally, the pharmacy must adhere to the strictest applicable requirements for safety and monitoring recommendations, in accordance with PharmacyChecker policy *16-02 Medications Requiring Special Dispensing Considerations (MRSDC)*, which at a minimum requires:

11.6 If the pharmacy markets, sells, processes and/or dispenses medications requiring special dispensing considerations internationally, the pharmacist processing and/or dispensing a prescription for a MRSDC is responsible to ensure that all required clinical monitoring, such as laboratory tests, etc., have been performed and are within acceptable parameters, prior to dispensing and to consult with the prescriber when in the pharmacist's professional judgement, it is necessary;

11.7 If the pharmacy markets, sells, processes and/or dispenses internationally, medications requiring special dispensing considerations internationally, the pharmacist processing and/or dispensing a prescription for a MRSDC is responsible to ensure that medication is not contraindicated for the patient it is being dispensed and consulting with the prescriber when in the pharmacist's professional judgement, it is necessary;

11.8 If the pharmacy processes and/or dispenses internationally a prescription for a medication that the U.S. FDA has required a *blackbox warning*, the pharmacist is responsible to ensure that the patient receives a copy of the current version of approved U.S. labeling (i.e. package insert) and/or company sponsored patient information disclosing the *blackbox warning* information.

11.9 If located **outside** the U.S, pharmacy must not market, sell, process or dispense internationally medications identified by the US FDA as REMS medications with additional “Elements to Assure Safe Use” (ETASU) requirements related to dispensing, such as restricted distribution or pharmacy registration, as international pharmacies are not recognized as participants by the U.S. FDA.

11.10 The pharmacist processing and/or dispensing internationally a medication that has been identified by the U.S. FDA as a REMS medication must ensure that the patient receives a copy of the most current version of the U.S. FDA approved Medication Guide (MedGuide) each time the medication is dispensed.

11.11 Online pharmacy must clearly publish on the pharmacy’s website a disclaimer that is placed above/with the first listing where the medication is sold. The disclaimer must read as follows:

“Ask your healthcare provider for guidance before ordering this medication from an online pharmacy. This medication requires prescriber approval prior to mailing directly to a patient as it may require administration in a clinical setting or special monitoring by a healthcare practitioner.”

Section XII: Pharmacy Disclosure Requirements

a. Disclosure of Pharmacy Location

12.0 Pharmacy must ensure information it provides regarding the pharmacy’s location is not false or misleading (i.e. a claim to sell medication from Canadian pharmacies only when pharmacies in countries other than Canada fill prescription orders).

12.1 If the pharmacy’s website processes prescription medication orders for international dispensing, pharmacy must ensure that all countries/regions from which drugs may be dispensed are listed on its website on every page discussing how or from where drugs are dispensed and must include at a minimum the homepage and FAQ page or may also include a link to a page which clearly publishes this information.

12.2 If marketing and/or selling prescription medication orders internationally, pharmacy must ensure that its website lists the specific country/region or, if applicable, the list of potential countries/regions, from which a drug will be dispensed, either before or on the

checkout page, but always prior to the placement of an order. This information must appear above or to the side of an action button (e.g. “Add to Cart”, “Checkout”, or “Proceed”) required to proceed with an order and before charging a customer for a prescription product, the pharmacy must inform the customer of the location of the pharmacy dispensing /shipping the prescription product.

a. Website Transparency and Disclosures

12.3 Pharmacy must not engage in practices or extend offers on its website that deceive or defraud patients as to any material detail regarding the practice, its staff, prescription drugs, or financial transactions.

12.4 Pharmacy must ensure that information does not include false or misleading claims about prescription drug source, safety or efficacy.

12.5 Pharmacy must ensure that information posted on its website does not include false or misleading claims about the legality of importation of prescription medications for personal use.

12.6 Pharmacy must ensure that information including but not limited to the homepage, about us page, and FAQ page, does not include false or misleading claims about the online pharmacy operations.

12.7 Pharmacy’s website must publish a phone number at which a customer can contact the pharmacy for assistance.

12.8 Pharmacy’s website must publish a mailing address at which a customer can contact pharmacy for assistance.

Section XIII: Privacy and Confidentiality

13.0 Pharmacy must ensure that patients’ personal information is not shared with third parties other than to process and dispense prescription orders, and/or to comply with PharmacyChecker Program standards and/or with government requirements.

13.1 Pharmacy must publish on its website a privacy policy stipulating that customers’ personal or financial information will not be shared, except where necessary to process and dispense prescriptions orders, to comply with PharmacyChecker Program standards or with government requirements.

13.2 If pharmacy requires or permits the online transmission of personal and financial data via its website, pages on which such information is transmitted must employ Secure Socket Layer or equivalent technology and must be in accordance with the laws of the website’s host country/region.

Section XIV: Pharmacist Consultation

14.0 Pharmacy must provide the patient who has placed an order with ways to directly contact a pharmacist for consultation, in accordance with PharmacyChecker policy 16-01, *Pharmacist Consultation*, which at a minimum requires the following:

14.1 The Pharmacist-in-Charge of the **dispensing pharmacy** is responsible to ensure that patient(s) have access to a pharmacist for consultation, the pharmacist performing the counseling is competent, the pharmacy's Standard Operating Procedures (SOPs) cover patient counseling and documentation requirements of PharmacyChecker policy 16-01 are met.

14.2 Pharmacy must clearly publish on its website that a pharmacist consultation with a licensed pharmacist is available for customers who have questions about medications.

14.3 Pharmacy must ensure that patients have access to a competent and licensed pharmacist in a timely manner, within 72 hours of the patient making a request for patient counseling.

Section XV: Pharmacy Inspection

(Standards 15.0 to 15.3 do not apply to **Online Pharmacy**)

15.0 Pharmacy must maintain license(s) and where required be inspected by the governing regulatory authority.

15.1 If a **dispensing pharmacy** located in India, Turkey, Barbados, Mauritius, or Singapore, the dispensing pharmacy must demonstrate compliance with PharmacyChecker standards and polices by a satisfactory inspection performed by PharmacyChecker.

15.2 If a **dispensing pharmacy** located in India, Turkey, Barbados, Mauritius, or Singapore, the dispensing pharmacy must comply with PharmacyChecker's International Pharmacy Inspection Program and Standards.

15.3 If a **dispensing pharmacy** located in India, Turkey, Barbados, Mauritius, or Singapore, pharmacy must:

- a. be inspected by PharmacyChecker; and
- b. pay PharmacyChecker non-refundable inspection fee and costs associated with the inspection, such as travel and accommodations.

D. Terms and Definitions

Affiliating Pharmacy: Prescription drug selling websites and/or licensed dispensing pharmacies sharing the responsibilities of the dispensing process by contractual agreement (i.e. shared services).

Applicant: A company that has submitted an application for accreditation in the PharmacyChecker Verification Program and is under evaluation by PharmacyChecker staff to demonstrate compliance with PharmacyChecker standards.

Best Practices: superseding the regulatory requirements and standards of care for pharmacies that process and dispense medications. To ensure adherence with program requirements, best practices will be determined through professional assessment and expert interpretation of the established program standards and policies determined by a qualified PharmacyChecker staff.

Dispensing: The process of a pharmacist providing a patient with a medication pursuant to a valid prescription. Dispensing includes all steps that occur from receipt of the prescription to the medication being delivered to the patient.

Dispensing Pharmacy: A company, which is licensed to sell pharmaceuticals, that dispenses medications to individual patients pursuant to a lawful, valid prescription.

International Dispensing Pharmacy: A pharmacy licensed to operate in the country/region in which it resides that dispenses prescription medication internationally to consumers through the mail. An international pharmacy can also serve consumers where it operates.

International Prescription Dispensary: An international pharmacy that only dispenses prescription medication to consumers in other countries. These pharmacies are generally located in free trade zones.

Accredited Company: A pharmacy and/or website that is accredited by PharmacyChecker as meeting and/or continually complying with PharmacyChecker's standards.

Mystery shopping: A methodology used to determine compliance with standards and policies, confirm quality of services rendered and to obtain key information about targeted products and/or practices.

Online Pharmacy: A company that markets and sells lawfully-manufactured prescription medications over the Internet, dispensed by mail to patients by its own pharmacy, or by referring prescriptions to other dispensing pharmacies.

Outsourcing Facility (503B): an entity that is registered with the US FDA and licensed to operate per the state in which it resides, as applicable and ships prescription medications that dispenses non-patient specific compounded medications prepared under GMP standards to pharmacies and institutions

Pharmacist-in-Charge: A pharmacist manager and/or equivalent name for head of a pharmacy.

Pharmacy's Website: a website owned and/or operated by an online pharmacy, dispensing pharmacy and/or wholesale pharmacy that is used to market, sell, process and/or dispense prescription medications via the Internet.

Physical Pharmacy: A licensed space used for dispensing prescription medication.

Remote Medical Consultation ("Prescribing") Services: remote consultation services that directly or indirectly generate prescriptions for patients who are not physically examined in person by the prescribing practitioner.

Standard of Care: the minimum requirements set forth to execute pharmacy practice.

Valid Prescription: a prescription issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established:

- a) The patient has a legitimate medical complaint;
- b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice explicitly permitted under federal or state laws or regulations; and
- c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.

Veterinary Pharmacy: A licensed pharmacy that dispenses medications for use by animals.

Wholesale Pharmacy: A company that sells and/or distributes prescription medications to authorized pharmacies, hospitals and/or licensed prescribers.

U.S. DEA: The United States Drug Enforcement Agency. For more information refer to:
<https://www.dea.gov/index.shtml>

U.S. FDA: The United States Food and Drug Administration. For more information refer to:
<https://www.fda.gov/>

*Note: Some entities may be a combination of the above definitions and could have a presence domestically, internationally, locally, as well as online.

E: Additional Information

Please refer to the [PharmacyChecker.com](https://www.pharmacychecker.com) website for additional information about the Verification Program. The [PharmacyChecker Verification Program](#) page contains links to pdf documents, such as:

PharmacyChecker Verification Program Guidance Policies

16-01 Pharmacist Consultation

16-03 Temperature Sensitive Medications: Shipping Requirements

16-04 Maximum Three Months' Supply Dispensed Internationally

16-05 Marketing/Dispensing Indian Pharmaceutical Products Internationally

17-01 Shared Pharmacy Services: Agreements Between Accredited Companies

17-02 Valid Prescription Requirement

PharmacyChecker Verification Program Agreements

Verification Program Accreditation Agreement

Verification Program Seal Agreement

PharmacyChecker Inspection Program

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Revenues are derived from fees generated from the Verification Program, pharmacy listings, and advertising.

PUBLIC COMMENT

PharmacyChecker welcomes input from any interested party (e.g., consumer groups, retailers, healthcare professionals, academic and commercial researchers, manufacturers, government agencies, trade groups, etc.) on its evaluations and reporting. Comments and questions should be submitted electronically to shivam.patel@pharmacychecker.com.