PharmacyChecker.com

International Pharmacy Verification Program Policies

Protecting the Public Health Across the Globe: Helping patient-consumers, their caregivers and healthcare providers find information about safe online pharmacies that sell affordable medicines.

Rev. May 2025

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16-01 Pharmacist Consultation

PharmacyChecker International Pharmacy Verification Program	
Policy No: 16-01	**Version No:** 2.0
Date Written: May 2016	**Date Revised:** February 15, 2018
Effective Date: April 16, 2018	**Replaces Version No:** 1.0

PURPOSE:

This policy identifies the requirements that PharmacyChecker (PC) Verification Program Accredited Pharmacies ("accredited pharmacies") must meet in order to comply with PharmacyChecker Verification Program Standards related to patient counseling by a pharmacist.

SCOPE:

This policy applies to all accredited pharmacies that market, sell, process and / or dispense, prescription medications. It identifies the practice standards that accredited pharmacies must meet pertaining to patient counseling by a pharmacist.

RESPONSIBILITY:

Accredited pharmacies are responsible for ensuring their website clearly provides information regarding pharmacist consultation, including a phone number a patient may use to request pharmacist consultation.

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") 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.

REQUIREMENTS:

1. Online Pharmacy must have a working reliable telephone number that allows for clear communication without interference (i.e. a landline not subject to dropped calls, static, etc.) that is answered by pharmacy staff fluent in English during the business hours published by the online pharmacy.

2. Accredited pharmacies must ensure that customer service representatives, call center representatives, pharmacy staff, etc. responsible for answering the online pharmacy telephone appropriately identify the name of the online pharmacy and identify themselves to consumer when answering calls and/or returning consumer calls.

3. In the event the pharmacy uses a call center or after-hours messaging service, or answering machine, accredited pharmacies must ensure that patients have access to a competent and licensed pharmacist in a timely manner but not to exceed 72 hours.

4. Accredited pharmacies must ensure that patients have telephone access to connect with a pharmacist for consultation; if live chat or a messaging service is used, the accredited pharmacy must have a process for ensuring timely receipt of the message by the pharmacist.

5. Accredited pharmacies must ensure that patients can leave messages at all times, including after hours. Accredited pharmacies must have a process for ensuring all messages are returned as soon as possible, but not exceeding 72 hours from the time the message is left by the consumer.

6. The PIC is responsible to ensure that its website and others that are accredited pharmacies and take orders filled by the PIC, explicitly states the hours that pharmacist consultation is available, which, at a minimum, must be available during normal business hours.

7. An accredited pharmacy's SOP must include the requirements of the pharmacist related to patient consultation. These duties, include but are not limited to:

    a. Making appropriate recommendations regarding medication therapy management and adherence;
    b. Obtaining a medication profile, allergy and pertinent medical history from the patient seeking consultation;
    c. Evaluating the patient's medication profile, in conjunction with applicable allergies and disease states, in order to determine appropriate interventions and/or referrals;
    d. Ensuring the patient understands the counseling points explained;
    e. Establishing contact with the patient's provider in the event a referral or intervention in therapy is needed;
    f. Performing a full review of the information obtained from the patient looking for issues pertaining to non-compliance, inappropriate therapies or prescribing practices; over/underutilization, and interactions with other pharmaceuticals, allergies, disease-states, or supplements; and
    g. Recording pertinent information related to the information obtained from the patient and the counseling performed into the patient's profile or the pharmacy's counseling log.

8. The pharmacist performing patient counseling must be licensed and able to perform all requirements under this policy, in addition to the requirements in their own country, state, or relevant jurisdiction.

9. The pharmacist performing patient counseling must be able to competently, clearly, and concisely deliver sound advice within their scope of practice. If communication issues arise, due to language differences, or the consulting pharmacist is unable to help the patient directly, the accredited pharmacies must have a process to refer the patient to another licensed pharmacist or appropriate healthcare professional.

10. The PIC must ensure competency of the pharmacist performing counseling. Documentation of competency assessment for each pharmacist must be kept on file.

11. The accredited pharmacy's SOP must include the competency standards assessed,

frequency of assessment and methods used to evaluate competency of each pharmacist providing patient counseling.

12. Accredited pharmacy websites must:

    a. clearly provide information regarding pharmacist consultation; and
    b. provide a phone number a patient may use to request pharmacist consultation.

13. Accredited pharmacies must provide PharmacyChecker with SOP for patient counseling, the pharmacy's counseling log, and related pharmacist competency assessment documentation upon request.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP
2.0	April 16, 2018	Amended to clarify that the pharmacy must have a reliable working telephone number that is answered during the published business hours by staff that are fluent in English.

16-02 Medications Requiring Special Dispensing Considerations

PharmacyChecker International Pharmacy Verification Program	
Policy No: 16-02	**Version No:** 3.0
Date Written: May 2016	**Date Revised:** January 2020
Effective Date: April 1, 2020	**Replaces Policy No:** N/A **Version 1.0 was drafted to replace** #11-007 "Banned Drugs" It was announced but not implemented due to clarifications required by accredited pharmacies.

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program Accredited Pharmacies ("accredited pharmacies") regarding compliance with PharmacyChecker Verification Program standards related to selling, marketing, processing, and /or dispensing medications requiring special dispensing considerations, as defined by this policy, including but not limited to medications identified by U.S.-FDA Risk Evaluation and Mitigation Strategies (REMS) program.

SCOPE:

This policy outlines requirements for the website, pharmacy, and pharmacist(s) related to dispensing medications requiring special dispensing considerations, as defined by this policy.

This policy applies to all accredited pharmacies that market, sell, process and / or dispense medications requiring special dispensing considerations **internationally.**

Accredited pharmacies that dispense MRSDC internationally must adhere to the strictest applicable requirements for safety and monitoring recommendations. This means a dispensing pharmacy must adhere to the applicable black box warning and suggested monitoring required from the jurisdiction where the pharmacy resides unless the jurisdiction where the medication will be dispensed to is stricter. (For example, the U.S. FDA requires black box warnings in medication package inserts and has strict requirements for medications identified as REMS and REMS w/ETASU, pharmacies dispensing to consumers in the U.S. would follow the U.S. FDA requirements (i.e. black box warning, REMS and ETASU)

Dispensing to Consumer in the U.S.

Accredited pharmacies must adhere to the requirements defined in the U.S., including but not limited to medications identified as requiring Risk Evaluation Mitigation Strategies (REMS) by the U.S. FDA, when marketing, selling, processing and/or dispensing to consumers in the U.S., as outlined below

RESPONSIBILITY:

Accredited pharmacies are responsible for ensuring medications are dispensed safely, and according to standards of practice and regulatory requirements.

Accredited pharmacies marketing, selling, processing, procuring, storing, and dispensing prescriptions for MRSDC, must meet additional safety criteria and standards identified within this policy.

Accredited pharmacies are responsible for ensuring:

- all pharmacists are trained and competent to dispense these medications; and
- all staff, including call center staff, are trained to recognize these medications and the requirement for pharmacist intervention / consultation

Accredited pharmacies must ensure that their website(s) clearly provides pertinent information and required disclaimers regarding these medications, as outlined below.

REFERENCES:

- U.S. FDA labeling (i.e. package insert): https://www.accessdata.fda.gov/scripts/cder/daf/
- U.S. FDA REMS: http://www.accessdata.fda.gov/scripts/cder/rems/
- U.S. FDA's Guide to Drug Safety Terms: https://www.fda.gov/downloads/forconsumers/consumerupdates/ucm107976.pdf
- PharmacyChecker Policy 16-03, Temperature Sensitive Medications: Shipping Requirements
- PharmacyChecker Policy 17-01; Shared Pharmacy Services Agreements Between Accredited pharmacies
- Drug Information Resources for a Pharmacist, such as Lexicomp Online, DailyMed, etc.

DEFINITIONS:

***Blackbox Warning* Medications:** a warning regarding serious or life-threatening risks required by the U.S. FDA to be included in the approved labeling of a prescription medication. The warning is required to be prominently displayed within a black box.

Medications Requiring Special Dispensing Considerations ("MRSDC"): medications requiring additional actions by a pharmacist to ensure safe delivery and use. Such medications include intravenous use medications, specialty medications, REMS medications, *Blackbox warning* medications and/or other medications with special considerations outlined by the approved U.S. labeling.

Specialty Medications: are prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis and multiple sclerosis, which may require administration by or in the presence of a healthcare provider, and generally require close therapeutic monitoring and patient follow-up, such as periodic laboratory tests (i.e. liver function tests).

Risk Evaluation and Mitigation Strategies ("REMS"): are a collection of requirements related to individual medications that were developed to ensure that the benefit of a medication outweighs its risk.

The Food and Drug Administration Amendments Act (FDAAA 2007) mandates that the US FDA require manufacturers to submit Risk Evaluation and Mitigation Strategies (REMS) when deemed necessary. Although the provisions are directed toward manufacturers, requirements for pharmacies and pharmacists exist within various REMS programs, including communication to

the prescriber, enrollment of the prescriber in a special program, enrollment of the patient in a special program, specialized Medication Guides to communicate risks, or special tests (i.e., pregnancy tests) prior to dispensing.

REQUIRMENTS:

General:

1. 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 consulting with the prescriber when in the pharmacist's professional judgement, it is necessary.

2. The pharmacist processing and/or dispensing a prescription for a MRSDC is responsible to ensure that medication is not contraindicated for the patient and consulting with the prescriber when in the pharmacist's professional judgement, it is necessary.

3. The pharmacy shall develop SOPs related to processing and dispensing MRSDCs.

4. The PIC must review all applicable U.S.-FDA mandated REMS requirements and approved U.S. labeling information during the development of SOPs related to MRSDC.

5. The PIC developing SOPs for MRSDC medications must also consider the following:

    a. Does the medication need to be infused or administered by a practitioner?
    b. Is close follow-up of the patient required for safe use?
    c. Does the medication need to be shipped in a refrigerated state?
    d. Are practitioners, pharmacists and / or patients required to meet special requirements or register in special programs in order for the medication to be dispensed in the United States?

6. The PIC must ensure the SOP includes packaging and shipping requirements in accordance with PC Policy 16-03: Temperature Sensitive Medications: Shipping Requirements, if the medication is temperature sensitive.
7. The SOP must clearly delineate the responsibilities regarding requirements and roles for processing and dispensing MRSDC between the partner pharmacy and the dispensing pharmacy, in accordance with PharmacyChecker policy *17-01 Shared Pharmacy Services Agreements Between Accredited Companies.*
8. The PIC is responsible for ensuring staff are trained on the SOPs for MRSDC and documenting the training.

Intravenous and Specialty Medications:

Accredited pharmacies are responsible for ensuring the pharmacy's website clearly publishes 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."

The pharmacist processing and/or dispensing a prescription for a medication that cannot be self-administered or can only be self-administered under the supervision of a healthcare provider is responsible to ensure that a disclaimer is included within the package. The disclaimer must read as follows:

"This medication requires special monitoring or administration in a clinical setting or training by a healthcare professional prior to self-administration. Contact your provider prior to use."

Black Box Warnings:

The pharmacist processing and/or dispensing a prescription for which the U.S. FDA has required a *blackbox warning* 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.

The pharmacist shall document all communications with the provider regarding clinical interventions in accordance with the pharmacy's SOP, but at a minimum on the prescription or within the patient's medication profile.

The pharmacist processing and/or dispensing a prescription for which the U.S. FDA has required a *blackbox warning* 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.

US-FDA REMS Program:

The U.S. FDA requires additional criteria known as "Elements to Assure Safe Use" (ETASU) for certain REMS medications. These medications may require restricted distribution channels as well as provider, pharmacy and patient registration ensuring monitoring. Accredited pharmacies located outside the U.S. are prohibited from dispensing REMS medications with 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.

The pharmacist processing and/or dispensing a prescription that has been identified by U.S. FDA as a REMS medication shall 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.

The pharmacist processing and/or dispensing a prescription that has been identified by U.S. FDA as a REMS medication dispensed for administration by a healthcare professional in a clinical setting (i.e. clinic, infusion center, dialysis center), only need to

be distributed at the time of first dispensing, unless the medication guide has materially changed, or the patient or patient's agent requests a medication guide.

The pharmacist processing and/or dispensing a prescription medication that requires administration by a healthcare provider that has been identified by U.S. FDA as a REMS medication is responsible for ensuring REMS medications are not shipped directly to the patient unless prescriber authorization has been received and documented.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0	N/A **Version 1.0 was drafted to replace** #11-007 "Banned Drugs" **Note: It was announced but not implemented due to clarifications required by accredited pharmacies**	New SOP
2.0	April 16, 2018	New SOP
3.0	April 1, 2020	Addition of Intravenous medications to policy

16-03 Refrigerated Medications: Shipping Requirements

PharmacyChecker International Pharmacy Verification Program	
Policy No: 16-03	**Version No:** 3.0
Date Written: 2010	**Date Revised:** April 15, 2018
Effective Date: June 15, 2018	**Replaces Version No:** Version 2.0

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Accredited Pharmacies ("accredited pharmacies") regarding compliance with PharmacyChecker Verification Program Standards related to ensuring that the cold chain supply is maintained throughout the shipping process if dispensing refrigerated medications.

SCOPE:

This policy applies to all accredited pharmacies that dispense refrigerated medications. Only PharmacyChecker accredited dispensing pharmacies located in Canada, United Kingdom, or the United States are permitted to dispense refrigerated medications to consumers in the U.S.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with PharmacyChecker Verification Program Standards and Pharmacy Standards Agreement.

REFERENCES:

United States Pharmacopeia (USP) Chapter <1079>, Good Storage & Shipping Practices, https://pharmacy.ks.gov/docs/default-source/default-document-library/ups-36-good-storage-and-shipping-practices.pdf

Health Canada, Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069), http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069-eng.php

MHRA – Refrigerated Products: What Pharmacists Need to Know, https://www.pharmaceutical-journal.com/learning/learning-article/refrigerated-medicinal-products-what-pharmacists-need-to-know/10036090.article

DEFINITIONS:

Cold chain supply: the transportation of refrigerated products along a supply chain through thermal and refrigerated packaging methods and the logistical planning to protect the integrity of these shipments.

Refrigerated medication: a medication for which the manufacturing labeling requires storage conditions between 2ºC and 8ºC.

Temperature indicator: a device that monitors temperatures during shipping and storage and provides visual evidence of exposure to unacceptable temperature levels, protecting product quality throughout the entire shipping and handling process.

Demonstration shipment: a shipping container/package sent to address specified by PharmacyChecker to ensure the shipping method retains the required refrigerated (2ºC - 8ºC) condition.

GENERAL INFORMATION:

- Medications must be shipped and stored in a manner that ensures the products will be maintained within an acceptable temperature range as defined in the approved labeling. The manufacturer's labeling of many medications, including insulin, contains optimal storage condition between 2ºC and 8ºC.

- Packaging and shipping method may not risk exposure to temperatures outside a medication's recommended storage conditions.

- The manufacturer's storage requirements must be maintained through all stages of the medication distribution process, including shipping.

- The manufacturer's labeling of some medications (e.g. CombiPatch; Nuvaring) contain information permitting storage at room temperature for a specified time frame after dispensing to the patient.

- The shipping process and containers must be designed to prevent damage and maintain the integrity and quality of the medication(s) until receipt and storage by the patient.

REQUIRMENTS:

9. In accordance with PharmacyChecker Verification Program standard 11.0, only dispensing pharmacies located in Canada, the United Kingdom, or the United States may dispense refrigerated medications to consumers in the U.S.

10. Accredited pharmacies dispensing refrigerated medications must ensure cold chain supply of the product throughout the processing/dispensing and shipping processes.

Note: If the manufacturer's labeling includes information permitting storage at room temperature for a specified time frame after dispensing, the product may be shipped without maintaining cold chain supply if:

- The manufacturer's timeframe for storage at room temperature exceeds 4 months from the date the product is removed from the refrigerator for dispensing;

- The accredited pharmacy places a notation with the room temperature expiration date on the product;

- The refrigerated medication being dispensed has an expiration date exceeding the modified date that will be applied by the pharmacy; The accredited pharmacy clearly communicates to the consumer the storage and directions for discarding based on the room temperature expiration date applied to the product by the pharmacy at dispensing

Note: Although the manufacturer's labeling for some products (e.g. Lantus) provide for room temperature storage and an amended expiration date (i.e. 28 days) upon first use, this information pertains to the product when in-use by the patient ONLY. **Therefore, the pharmacy must ensure cold chain supply is maintained throughout the process including delivery/receipt by the consumer**.

11. The manufacturer's labeling on the storage and shipping needs of each medication must be adhered to. (See above regarding requirements that must be met for refrigerated products that the manufacturer's labeling permits room temperature storage at dispensing.) In the absence of manufacturer's labeling, information from peer-reviewed journal articles or other reputable sources must be utilized to develop the SOP.

12. Selection of a shipping container and packaging will be based on factors such as duration of transit, the size of the shipment and the ambient or outside temperatures experienced during transit. The packaging selected by the pharmacy must ensure refrigerated storage temperature (2ºC - 8ºC) throughout the processing and shipping including receipt by the consumer.

13. The shipping container with medications requiring refrigeration must include:

    a. a temperature indicator(s) with a temperature accuracy of +/-1 ºC and irreversible indication type to ensure product stays within acceptable range (2ºC - 8ºC) and is not subject to freezing.
        a. The use of two separate temperature indicators, one for monitoring temperature below 2ºC and one for monitoring temperatures above 8ºC may be required. (e.g. ShockWatch - WarmMark and ColdMark temperature indicators)
        b. The temperature indicator(s) used shall be mounted directly on to the medication when placed inside the product shipment.
    b. clear directions to the recipient for the evaluation of monitoring indicators and steps to take in the event of an excursion.

14. The exterior of the shipping container must be properly labeled to alert the patient to open and refrigerate the contents immediately upon receipt. The label must be securely affixed and indelible.

    Example labeling includes:

15. Packaging and shipping method must be qualified to ensure that appropriate conditions are maintained under probable extremes of ambient temperature and should also account for possible unforeseen delays which may occur in shipping/transportation (for example, shipment delays at international mail facilities).

16. The shipping method must require signature from recipient unless exception is made by recipient due to extenuating circumstances.

17. Validation that the shipping method retains the required refrigerated (2ºC - 8ºC) storage condition and will not deviate during the shipping process may be available from the commercial courier. Alternatively, accredited pharmacies may perform their own validation process to ensure that packing and shipping method retains the cold chain supply.

18. Accredited pharmacies will be subject to shipment method audits and mystery shopping and, prior to shipping refrigerated medications and at least annually thereafter, be expected to send a demonstration shipment for each shipping method to an address specified by PharmacyChecker upon request to ensure that each shipping method being utilized retains the required refrigerated (2ºC - 8ºC) condition. Upon the effective date of this policy, accredited pharmacies shall not ship refrigerated medications until demonstration shipment(s) has/have been verified by PharmacyChecker.

19. Accredited pharmacies are responsible for ensuring the pharmacy's website clearly publishes a notification that is placed on the same page with and above the listing where the refrigerated medication is sold. The notification must read as follows:

    > *"This product requires special packaging to maintain its integrity during the shipping process. DO NOT USE THIS MEDICATION if the attached temperature indicator shows that the medication was exposed to temperatures below 2 degrees or above 8 degrees celsius, and contact the pharmacy immediately."*

20. Accredited pharmacies shipping refrigerated medications must have and submit to PharmacyChecker a Standard Operating Procedure (SOP) for packaging and shipping such medications. The SOP must include:

    a. a list of refrigerated medications dispensed/shipped, including a notation for medications that will be shipped at room temperature based on manufacturer's labeling; (Accredited pharmacies must notify PharmacyChecker upon any additions or changes made to the list of refrigerated products dispensed or

shipped)

b. the required temperature, packaging and shipping method for each medication, including instructions for applying a room temperature expiration date to

products that will be shipped outside of cold chain supply process; and a corrective action plan and documentation requirements for temperature excursions outside predetermined temperature condition.

c. description of any special handling precautions and take into account the nature of the medication, local conditions, modes of transport and any seasonal variations experienced.

d. information regarding cold packs placed in shipping containers used to transport medications, including:

    a. the type, size and number of packs should correspond to the shipping duration and temperature needed;

    b. the location of the packs should ensure that the entire shipment of the product is maintained within the labeled storage conditions; and

    c. adequate barrier materials should be used to prevent contact between the packs and the products, if the packs are at a temperature outside the range acceptable for product storage.

21. The SOP may include more than one shipping method depending on the product(s). The shipping method used must not deviate from the manufacturers' labeling.

22. The PIC shall document the source of all information used in developing the SOP, such as manufacturer recommendation, journal articles, studies to demonstrate adequacy of the packing/shipping method, validation and trial shipping data.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP

2.0	April 16, 2018	Title Change **From** Temperature Sensitive Medications: Shipping Requirements **To** Refrigerated Medications: Shipping Requirements Amended (1) to clarify that only PharmacyChecker accredited dispensing pharmacies located in Canada, United Kingdom or the United States may dispense temperature sensitive products to consumers in the U.S. and (2) provide guidance regarding room temperature storage of refrigerated medications at dispensing (based on manufacturer's labeling)
3.0	June 15, 2018	Amended (1) to clarify all SOP requirements for shipping refrigerated medications, and (2) addition of new shipment method requirements for refrigerated medication including: 2ºC - 8ºC condition throughout processing and shipping up to receipt by consumer, inclusion of temperature indicator to monitor for freezing, signature of consumer upon delivery, published website notification and demonstration shipment.

16-04 Maximum Three Months' Supply Dispensed Internationally

PharmacyChecker International Pharmacy Verification Program	
Policy No: 16-04	**Version No:** 3.0
Date Written: June 17, 2016	**Date Revised:** October 5, 2016
Effective Date: November 30, 2016	**Replaces Version No:** 16-04 version 2.0

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program Accredited Pharmacies ("accredited pharmacies") regarding compliance with PharmacyChecker Verification Program Standards (the "Standards") related to ensuring that medications dispensed internationally do not exceed a three months' supply, unless medically necessary or an exception as defined by this policy is met.

SCOPE:

This policy applies to all accredited pharmacies that market, sell, process and / or dispense medications internationally. This policy outlines requirements for the website, pharmacy, and pharmacist(s) related to our standards that limit the international dispensing of medication to a three months' supply, unless medically necessary or an exception as defined by this policy is met. The policy does not affect domestic dispensing.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with the Standards as they apply to dispensing pharmacies.

Accredited pharmacies must ensure that online pharmacies do not exceed marketing limitation and clearly provide pertinent information and required disclaimers regarding these medications, as outlined below.

Accredited pharmacies participating in the PC Listing Program must ensure that listings comply with this policy as well as PC Listing Program Policy 14-002: *Price Submission Guidelines for Popular Medications*.

DEFINITIONS:

Days' Supply: the number of days that the supply of dispensed medication will last. For the purposes of this policy, the days' supply is calculated based on the recommended daily dose / administration schedule as noted in the manufacturer package insert. The pharmacist must use professional judgement in processing / dispensing prescriptions outside the recommended dose / administration schedule and the reason for doing so shall be documented.

Medically necessary: a decision by the prescriber, exercising prudent clinical judgment, that the care warrants the patient to require a greater than a three months' supply of medication at a time for the purpose of treating an illness, injury, disease or its symptoms. The prescriber's decision must be:

a. in accordance with the generally accepted standards of medical practice; and
b. clinically appropriate for the patient's illness, injury or disease.

REQUIREMENTS:

Accredited pharmacies may not market, process and / or dispense a supply exceeding a three months' supply maximum for erectile dysfunction medications, such as Viagra, Cialis, under any circumstances. Accredited pharmacies **found to be marketing and / or dispensing greater than a three months' supply of erectile dysfunction medications are subject to immediate discipline, up to and including termination from the Program.**

Accredited Online Pharmacies:

1. Accredited pharmacies processing and/ or referring prescription orders to other pharmacies must ensure that the online pharmacy has an SOP regarding a three months' maximum supply dispensed internationally. The SOP must:
    a. prohibit exceeding a three months' supply maximum for erectile dysfunction medications, such as Viagra, Cialis, and Levitra under any circumstances;
    b. include the requirements, as defined by this policy, for exceeding a three months' supply based on manufacturer packaging;
    c. include the requirements, as defined in this policy, for exceeding a three months' supply if medically necessary;
    d. include a definition of medically necessary, as defined in this policy; and
    e. clearly delineate the responsibilities between the online pharmacy and the dispensing pharmacy regarding requirements and roles for processing and dispensing prescriptions internationally, in accordance with this policy.

2. If the agreement between accredited pharmacies requires the online pharmacy to process the prescription order prior to international dispensing by another pharmacy, the accredited pharmacy must ensure that no prescription with a quantity exceeding a three months' supply is transmitted to another pharmacy for dispensing; unless
    a. Based on the manufacturer packaging of the medication:
        i. The medication will be dispensed in the sealed manufacturer package of #100 tablets / capsules;
        ii. The medication will be dispensed with a combination of smaller sealed manufacturer packages and the pharmacist calculates the quantity as close to the maximum three months' supply as possible based on package size
        iii. The medication is only available in one package size that exceeds a three months' supply and the medication will be dispensed in the sealed manufacturer package.

OR

    b. It is medically necessary, as defined above, to exceed a three months' supply demonstrated by:
        i. the prescriber was contacted; and
        ii. the prescriber indicates a medically necessary reason to exceed a three months' supply; and
        iii. the pharmacist documents this information on the prescription or within the patient's medication profile.

Accredited Dispensing Pharmacies:

The PIC of the dispensing pharmacy must ensure that the pharmacy has an SOP regarding the 90-day maximum supply dispensed internationally.

1. The SOP must:
    a. prohibit exceeding a three months' supply maximum for lifestyle medications, such as Viagra, Cialis, under any circumstances;
    b. include the requirements, as defined by this policy, for exceeding a three months' supply based on manufacturer packaging
    c. include the requirements, as defined in this policy, for exceeding a three months' supply if medically necessary;
    d. include a definition of medically necessary, as defined in this policy; and

    e. clearly delineate the responsibilities between the online pharmacy and the dispensing pharmacy regarding requirements and roles for processing and dispensing prescriptions internationally, in accordance with this policy.

2. The pharmacist must ensure that no prescription with a quantity exceeding a three months' supply is dispensed internationally; unless
    a. Based on the manufacturer packaging of the medication:
        i. The medication will be dispensed in the sealed manufacturer package(s) of #100 tablets / capsules; or
        ii. The medication will be dispensed with a combination of smaller sealed manufacturer packages and the pharmacist calculates the quantity as close to the maximum three months' supply as possible based on package size;
        iii. The medication is only available in one package size that exceeds a three months' supply and the medication will be dispensed in the sealed manufacturer package.

    OR

    b. It is medically necessary, as defined above, to exceed a three months' supply demonstrated by:
        iv. the prescriber was contacted; and
        v. the prescriber indicates a medically necessary reason to exceed a three months' supply; and
        vi. the pharmacist documents this information on the prescription or within the patient's medication profile.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0		New SOP

2.0		Updated to include exception for U.S. and Canadian pharmacy dispensing a three months' supply internationally with sealed manufacturer bottle(s) of #100 tablets / capsules (except for erectile dysfunction medications).

3.0	November 30, 2016	90- day changed to three months throughout document Exceptions for exceeding a three months' supply updated to include options for dispensing sealed manufacturer packages of medication: • sealed manufacturer packaging of #100 tablets / capsules • a combination of smaller sealed manufacturer packages calculating the quantity as close to the maximum three months' supply as possible based on package size; and • smallest available manufacturer sealed packaging when the medication is not available in smaller package sizes and the available package exceeds a three months' supply

16-05 Distributing & Dispensing Pharmaceutical Products Internationally

PharmacyChecker International Pharmacy Verification Program	
Policy No: 16-05	**Version No:** 3.0
Date Written: August 2016	**Date Revised:** May 2025
Effective Date: September 1, 2025	**Replaces Version No:** 2.0

PURPOSE:

This policy details the requirements of dispensing pharmacies and wholesalers in their compliance with the PharmacyChecker (PC) International Pharmacy Verification Program (IPVP) Accreditation Standards and Agreement related to dispensing and distributing pharmaceutical products internationally. Pharmaceutical products that fall outside of the parameters listed below may not be marketed, processed, distributed, and/or dispensed internationally by accredited pharmacies.

SCOPE:

This policy applies to Tier 2 accredited dispensing pharmacies and wholesalers (collectively, "accredited pharmacies"), which are those pharmacies and wholesalers located in countries or trade zones without advanced regulatory authorities, that market, process, distribute and/or dispense pharmaceutical products internationally.

Dispensing pharmacies and wholesalers with a Tier 2 designation – such as those located in India, Turkey, and Mauritius – are responsible for compliance with and subject to IPVP scrutiny against the requirements outlined in this policy.

Dispensing pharmacies and wholesalers located in jurisdictions known to have the most advanced systems of pharmaceutical and pharmacy regulations, referred to by PharmacyChecker as Tier 1 Pharmacies, are not subject to further scrutiny by the IPVP team against this policy.

RESPONSIBILITY:

The pharmacist-in-charge, pharmacist manager, or equivalent name for the lead pharmacist of a dispensing pharmacy (PIC) is responsible for compliance with PharmacyChecker Standards and Policies as they apply to Tier 2 dispensing pharmacies.

The wholesale manager is responsible for compliance with PharmacyChecker Standards and Policies as they apply to Tier 2 wholesalers.

RATIONALE:

PharmacyChecker requires all accredited dispensing pharmacies to only dispense prescription drugs manufactured under Current Good Manufacturing Practice (CGMP) regulations distributed from accredited wholesalers, thereby ensuring a safe international mail-order pharmacy service. PharmacyChecker Policy 16-05 Distributing & Dispensing Pharmaceutical Products Internationally is based on:

1. PC's understanding that subpar inspections of active pharmaceutical

ingredient (API) manufacturing facilities, located in countries with weaker pharmaceutical regulations, are a growing problem often associated with India and China, the world's largest producers of pharmaceutical ingredients;
2. Reporting that suggests Turkey, China, Mexico, the UK, and India are the five countries from which "the highest volume of counterfeited, diverted, and adulterated pharmaceuticals originate";
3. Reporting that suggests a higher incidence of substandard drugs sold in India by smaller Indian drug manufacturers as compared to the largest Indian manufacturers, specifically those whose products are known to meet exceedingly high international standards;
4. PC's understanding that products manufactured in plants with approval by regulatory authorities, such as the U.S. Food and Drug Administration, United Kingdom Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Administration, European Medicines Agency, and/or equivalent drug regulatory authorities, are more reliable than those without such approvals. As such, PharmacyChecker considers the following in maintaining its proprietary lists of Advanced Regulatory Authorities (ARAs) and Approved Global Manufacturers (AGMs):
    a. The emerging list of World Health Organization's Listed Authorities (referred to as WLAs) that have Medicines listed as a product stream, a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized, thereby replacing the procurement-oriented concept of stringent regulatory authorities (SRAs). This list also includes several of the regulatory authorities' functions, which consist of regulatory GMP inspection and licensing establishments.
        i. As of May 2024, that list includes Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia (Czech Republic), Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, the Republic of Korea, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United States of America.
        ii. As of May 2024, that list includes the regional regulatory system, the European Medicines Regulatory Network.
        iii. As of December 2024, the WHO has released a list of national regulatory authorities that have not quite reached WLA status. The list includes medicines approved by the Turkish Medicines and Medical Devices Agency (TİTCK), reaching a maturity level of 3, meaning "stable, well-functioning and integrated regulatory systems."
    b. According to Section 802 of the Federal Food, Drug, and Cosmetic

Act (FDCA) codified into Title 21, Chapter 9, Subchapter VIII—Imports and Exports, of the United States Code (21 U.S.C. § 382), a drug is considered eligible for export should it possess valid marketing authorization by the appropriate authority. The FDCA includes a list of eligible countries and territories for the export of a drug or medical device.

   i. That list includes Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association).

5. PC's understanding that ethically promoted global pharmaceutical company products are the highest quality products available for sale internationally.

DEFINITIONS:

Advanced Regulatory Authority (ARA): a health regulatory authority recognized as operating under the most advanced systems of pharmaceutical and pharmacy regulations. Refer to Appendix I.

Tier 2 pharmacies: PharmacyChecker-accredited pharmacies and wholesalers that fill, dispense and/or distribute medication from a country or trade zone without the oversight of an Advanced Regulatory Authority.

Approved Global Manufacturer (AGM): a pharmaceutical company with (1) product(s) approved by at least one Advanced Regulatory Authority (ARA) and/or (2) manufacturer site(s) registered with at least one ARA.

Ethically promoted pharmaceutical products: pharmaceutical products manufactured, marketed, and directly promoted by an Approved Global Manufacturer. Refer to Appendix II.

REQUIREMENTS:

1. Tier 2 accredited dispensing pharmacies marketing, processing, and/or dispensing pharmaceuticals approved for sale in their country of residence must ensure that such products are ethically promoted pharmaceutical products manufactured by approved global manufacturers.
2. Tier 2 accredited wholesalers must distribute to Tier 2 accredited dispensing pharmacies in the PharmacyChecker Network only pharmaceuticals approved for sale in their country of residence that are ethically promoted pharmaceutical products manufactured by approved global manufacturers.
3. Dispensing pharmacy PICs and wholesaler manager responsibilities are detailed below:

   The dispensing pharmacy PIC is responsible for:

   a. confirming the pedigree of all medications the pharmacy dispenses, maintaining

at a minimum the following:

i. copies of licenses for all wholesalers from which the pharmacy has purchased drug products;
ii. a system and documentation required to establish a complete chain of custody from the drug manufacturer to the accredited pharmacy.
iii. **Note:** Per the effective date of this policy, PharmacyChecker accredited pharmacies may not dispense medications internationally procured from any wholesaler that cannot furnish the items listed above upon request.

b. maintaining a list that *at a minimum* must include:
    i. manufacturers confirmed by the pharmacy to be Approved Global Manufacturers;
    ii. name of each pharmaceutical product confirmed by the pharmacy to be ethically promoted; and
    iii. wholesalers confirmed by the pharmacy to be trusted sources of ethically promoted products.
c. developing and maintaining a standard operating procedure (SOP) for purchasing and dispensing pharmaceuticals in accordance with this policy; and
d. ensuring staff are trained on the SOPs for purchasing and dispensing pharmaceuticals and documenting the training.

The wholesale manager is responsible for:

e. confirming the pedigree of all medications the wholesaler distributes to accredited dispensing pharmacies, maintaining *at a minimum* the following:
    i. a system and documentation required to establish a complete chain of custody from the drug manufacturer to the accredited dispensing pharmacy.
    ii. **Note:** Per the effective date of this policy, PharmacyChecker-accredited wholesalers may not distribute medications to PharmacyChecker-accredited dispensing pharmacies procured from a non-AGM or any manufacturer that cannot furnish the items listed above upon request.
f. maintaining a list that *at a minimum* must include:
    i. all manufacturer names with which the wholesaler maintains a business relationship;
    ii. name of each distributed pharmaceutical product tied to the manufacturer;
    iii. names of each PharmacyChecker-accredited dispensing pharmacy to which the wholesaler exports and/or distributes product.
        - PharmacyChecker may request a signed letter by the wholesale owner, certifying that wholesaler exports and distributes to the accredited dispensing pharmacies only ethically promoted pharmaceutical products in compliance with PharmacyChecker Policy 16-05 Distributing & Dispensing Pharmaceutical Products Internationally
g. developing and maintaining a standard operating procedure (SOP) for purchasing and distributing pharmaceuticals in accordance with this policy; and
h. ensuring staff are trained on the SOPs for purchasing and distributing

pharmaceuticals and documenting the training.

4. The SOP must be reviewed and updated periodically to reflect the addition or deletion of manufacturer(s) and/or product(s).

ATTACHMENTS:

Appendix I: Advanced Regulatory Authorities

Appendix II: Ethically Promoted Pharmaceutical Products from Approved Global Manufacturers

HISTORY:

Version Number	Date Effective	Description of Change
1.0	April 10, 2017	New SOP- amends and replaces Policy 12-02 and strikes 4.9.3 from the PharmacyChecker Inspection Program 4.9.3 Products manufactured in plants inspected for cGMP by PharmacyChecker or a third-party inspector acceptable to PharmacyChecker. Lists the countries that acceded to the EU prior to 2002. Adds guidance for determining global pharmaceutical company, First-Tier Indian Manufacturers and ethically promoted products.
2.0	September 15, 2020	Addition of requirement 2a. for a system and documentation required to establish a complete chain of custody from the drug manufacturer to the accredited pharmacy.
3.0	September 1st, 2025	Updates Policy 16-05 title Includes wholesale distributors Strikes 'Indian' to expand vigilance to not just India, but other countries without advanced regulatory authorities Strikes out Definitions, 4.9.1, and 4.9.2 from the PharmacyChecker Inspection Program Updates Rationale for Policy 16-05, including details about WLA and FDCA countries Updates Definitions to remove Indian Pharmaceutical Product, First-tier Indian manufacturer, Global pharmaceutical company; update Ethically promoted pharmaceutical product; and add Advanced Regulatory Authority, Tier 1 pharmacies, and Approved Global Manufacturer Updates Requirements Changes Appendix I to list Advanced Regulatory Authorities Includes Appendix II to change from a table to a flow diagram to help with decision making in compliance with Policy 16-05

Appendix I: Advanced Regulatory Authorities

An Advanced Regulatory Authority (ARA) is a health regulatory authority recognized as operating under the most advanced systems of pharmaceutical and pharmacy regulations.

PharmacyChecker considers the below health authorities as Advanced Regulatory Authorities. Tier 1 pharmacies are located in countries with ARAs. Tier 2 pharmacies are located in countries that do not achieve the ARA designation.

In evaluating pharmaceutical products against Policy 16-05, the PC IPVP staff will prioritize crosschecking the following regulatory agency databases:

- Food and Drug Administration (FDA) (United States of America)
- Health Canada - Therapeutic Products Directorate (TPD) (Canada)
- Medicines and Healthcare products Regulatory Agency (MHRA) (United Kingdom)
- European Medicines Agency
- Therapeutic Goods Administration (Australia)
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe) (New Zealand)
- Swiss Agency for Therapeutic Products (Swissmedic) (Switzerland)
- South African Health Products Regulatory Authority (SAHPRA) (South Africa)

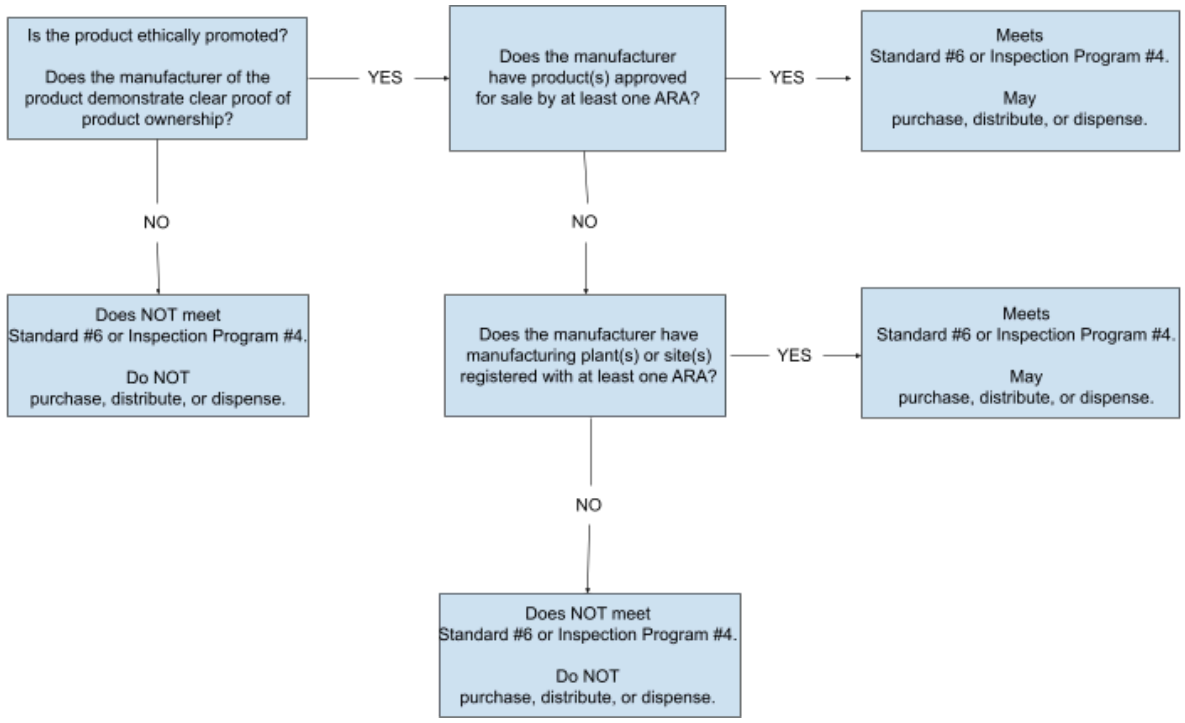
The following are also ARAs that would fulfill the manufacturer requirements of Policy 16-05.

- Austrian Agency for Health and Food Safety (AGES) (Austria)
- Federal Agency for Medicines and Health Products (FAMHP) (Belgium)
- Bulgarian Drug Agency (Bulgaria)
- Agency for Medicinal Products and Medical Devices of Croatia (HALMED) (Croatia)
- Ministry of Health — Pharmaceutical Services (Cyprus)
- State Institute for Drug Control (SUKL) (Czech Republic)
- Danish Medicines Agency (Denmark)
- State Agency of Medicines (Estonia)
- Finnish Medicines Agency (FIMEA) (Finland)
- National Agency for the Safety of Medicine and Health Products (ANSM) (France)
- Federal Institute for Drugs and Medical Devices (BfArM) (Germany)
- Paul Ehrlich Institute (PEI) (Germany)
- National Organization for Medicines (Greece)
- National Centre for Public Health and Pharmacy (NNK) (Hungary)
- Icelandic Medicines Agency (Iceland)
- Health Products Regulatory Authority (HPRA) (Ireland)
- Italian Medicines Agency (AIFA) (Italy)
- Israel Ministry of Health (Israel)
- Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency (PDMA) (Japan)
- State Agency of Medicines (Latvia)
- Office of Health / Department of Pharmaceuticals (Liechtenstein)
- State Medicines Control Agency (VVKT) (Lithuania)
- Ministry of Health and Social Security (Luxembourg)

- Malta Medicines Authority (MMA) (Malta)
- Medicines Evaluation Board (Netherlands)
- Health and Youth Care Inspectorate, Ministry of Health, Welfare and Sport (Netherlands)
- Norwegian Medical Products Agency (Norway)
- Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Poland)
- Chief Pharmaceutical Inspectorate (Poland)
- National Authority of Medicines and Health Products (Infarmed) (Portugal)
- National Authority of Medicines and Medical Devices of Romania (Romania)
- Health Sciences Authority (HSA) (Singapore)
- State Institute for Drug Control (SUKL) (Slovakia)
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) (Slovenia)
- Ministry of Food and Drug Safety (MFDS) (South Korea)
- Spanish Agency of Medicines and Medical Devices (AEMPS) (Spain)
- Swedish Medical Products Agency (Sweden)

Appendix II: Ethically Promoted Pharmaceutical Products from Approved Global Manufacturers

The following flow chart can be used to determine whether a pharmaceutical product distributed or sold by a Tier 2 accredited dispensing pharmacy or wholesaler is compliant with Policy 16-05 Distributing & Dispensing Pharmaceutical Products Internationally.



17-01 Shared Pharmacy Services Declaration Between Accredited Companies

PharmacyChecker International Pharmacy Verification Program	
Policy No: 17-01	**Version No:** 3.0
Date Written: August 2017	**Date Revised:** August 2, 2024
Effective Date: April 16, 2018	**Replaces**: Online Pharmacy & Dispensing Pharmacy Shared Services Agreement forms (Appendices I & II); Form 1003, Form 1004, and Pharmacist Certification Letter

PURPOSE:
This policy outlines the requirements for PharmacyChecker (PC) International Pharmacy Verification Program (IPVP) Accredited Pharmacies ("accredited pharmacies") regarding compliance with the PharmacyChecker International Pharmacy Verification Program Agreement, Standards, and Policies related to all online pharmacies (i.e., websites) that refer prescription medication orders to dispensing pharmacies and safe prescription processing and dispensing of medications.

SCOPE:
This policy applies to accredited online pharmacies that refer prescription orders to accredited dispensing pharmacies and accredited dispensing pharmacies that dispense prescription orders referred from accredited online pharmacies.

RESPONSIBILITY:
All accredited pharmacies, online and dispensing, who refer or accept referrals of prescription medication orders are responsible for documenting the relationship between each accredited pharmacy, in accordance with the PC IPVP Agreement, Standards, and Policies.

Online pharmacies must ensure that prescription orders are only referred to dispensing pharmacies that are accredited in the PC IPVP.

Online pharmacies found to be referring orders to a dispensing pharmacy that is not in the PharmacyChecker network and therefore do not meet PC IPVP standards are subject to immediate revocation of PharmacyChecker Accreditation.

The pharmacist-in-charge, pharmacist manager, or equivalent name for the lead pharmacist of a dispensing pharmacy (PIC) is responsible for compliance with PharmacyChecker Standards and Guidance Policies as they apply to all PharmacyChecker-accredited dispensing pharmacies.

DEFINITIONS:

Online Pharmacy: a website or prescription service group that markets prescription drugs directly to consumers online. Online pharmacies may operate their own dispensing pharmacy or contract with a dispensing pharmacy to fill orders on their behalf.

Dispensing Pharmacy: a licensed pharmacy that dispenses prescription orders. Dispensing pharmacies may operate their own online pharmacy or contract with an online pharmacy to market prescription orders on their behalf.

Pharmacist: a pharmacist licensed by the relevant regulatory authority where they reside who is 1) an employee of a dispensing pharmacy, or 2) an employee of or contractor to an online pharmacy.

Reviewed for Authenticity: a review performed by a licensed pharmacist verifying the prescription is a valid prescription, issued by a licensed medical practitioner within the prescriber's scope of practice.

Reviewed for Appropriateness: a Prospective Drug Utilization Review (DUR) performed by a licensed Pharmacist. DUR includes, but is not limited to:

- reviewing the available medication history of the patient for consistency of treatment; and
- assessment of therapeutic appropriateness, by making a reasonable effort to identify:
  - over-utilization or under-utilization; therapeutic duplication;
  - drug-disease contraindication; drug-drug interaction;
  - drug-food interaction;
  - incorrect drug dosage or duration of drug treatment;
  - drug-allergy interactions; misuse;
  - any significant change in drug, dose, or directions; or
  - any age-related contraindications.

The prescriber is contacted when clinically significant interactions are noted or in the pharmacist's professional opinion follow-up with the prescriber is required.

Shared Service Declaration: a declaration response issued to PharmacyChecker that documents the responsibilities of each accredited pharmacy related to the reviewing, processing, and dispensing of prescription medication orders in addition to providing patient and prescriber consultation.

REQUIREMENTS:
Before engaging in shared services, all accredited pharmacies must meet the requirements detailed below, having written confirmation that PharmacyChecker has approved the required Shared Services Declaration in accordance with this policy.

1. PharmacyChecker-accredited online pharmacies (i.e. websites that receive/process prescription medication orders) must only refer orders for dispensing and shipping to PharmacyChecker-accredited dispensing pharmacies.

2. Prescription medication orders **must** be reviewed for authenticity and appropriateness and dispensed by licensed pharmacists at PharmacyChecker-accredited dispensing pharmacies.

3. Copies of license(s) of all pharmacist(s) who work at PC-accredited online pharmacies and dispensing pharmacies must be submitted to PharmacyChecker.

4. Accredited pharmacies must declare the services provided and the responsibilities of each accredited pharmacy in compliance with PharmacyChecker Agreements, Standards, and Policies related to marketing, selling, processing and/or dispensing prescription medications through the required Shared Services Declaration. The declaration must document the responsibilities of each accredited pharmacy related to prescription processing, including, but not limited to, the responsibilities for prescription authentication, Drug Utilization Review (DUR), patient and/or prescriber consultation, as well as a list of the name(s), and license number(s) of the pharmacist(s) involved in shared services.

Note: Online pharmacy may also contract with consultant pharmacist(s) to review and authenticate prescription medication orders and provide patient/prescriber consultation ***in addition to*** the declared accredited dispensing pharmacy partnership.

5. Accredited pharmacies, online and dispensing, must share a common electronic file or technology ("database") that allows access to information necessary to perform the duties outlined in this shared pharmacy services policy. The database must be secure and cannot be duplicated, downloaded, or removed from the original platform.

6. Each accredited pharmacy is responsible for maintaining confidentiality and integrity of patient information.

7. Accredited pharmacies must maintain Standard Operating Procedures (SOPs) that include at least the following:

   a. the responsibilities of each accredited pharmacy related to prescription processing, including, but not limited to, prescription authentication, Drug Utilization Review (DUR), patient and/or prescriber consultation; and

   b. procedures to be followed to protect the confidentiality and integrity of patient information.

8. Shared Services Declaration must be completed and approved by PharmacyChecker (i.e. email approval from PharmacyChecker) prior to prescription medication orders being referred to the dispensing pharmacy.

9. Shared Services Declaration must be completed annually, or sooner as necessary (i.e., accredited pharmacy is required to inform PharmacyChecker if/when the shared service between the accredited pharmacy has ceased, or when a new shared service relationship between pharmacies

is executed.)

HISTORY:

Version	Date Effective	Description of Change
1.0	April 16, 2018	New SOP
2.0	July 22, 2022	Ensuring prescription fulfillment responsibility by dispensing pharmacies is documented.
3.0	September 1, 2024	Implementing separate declarations of services provided to ensure a shared understanding of responsibility among partner pharmacies.

17-02 Valid Prescription Requirement

PharmacyChecker International Pharmacy Verification Program	
Policy No: 17-02	**Version No:** 1.0
Date Written: August 2017	**Date Revised:** N/A
Effective Date: April 16, 2018	**Replaces Policy No:** N/A

PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program Accredited Pharmacies ("accredited pharmacies") regarding compliance with PharmacyChecker Verification Program agreements, and standards related to the "valid" prescription requirement.

SCOPE:

This policy applies to accredited pharmacies that market, process and/or dispense prescription medications. This policy outlines requirements for the website, pharmacy, and pharmacist(s) related to the requirement for a "valid" prescription.

RESPONSIBILITY:

The Pharmacist-in-Charge, pharmacist manager, or equivalent name for the lead pharmacist of a pharmacy, ("PIC") is responsible for compliance with the standards as they apply to dispensing pharmacies.

Pharmacies located outside the U.S. are prohibited from marketing, selling, processing and/or dispensing controlled substances, as defined under U.S. law, to consumers in the U.S.

Pharmacies located within the U.S. must dispense controlled substance in accordance with 21 CFR 1306 or relevant state law whichever is strictest.

DEFINITIONS:

A "valid" prescription is one 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 clearly permitted under the laws where the patient resides; and
c. A logical connection exists between the medical complaint, illness or disease, the medical history, and the physical examination and the drug prescribed.

In addition, a valid prescription must be 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)

Note: Re: missing or incorrect information: *

- the patient's address may be added to the prescription by the pharmacist without consulting the prescriber;
- all other clarification (e.g. missing or incorrect information) must be made only after consultation with the prescriber.

*U.S. pharmacies dispensing controlled substances must only make changes in accordance with federal and state law.

Reviewed for Appropriateness: a prospective Drug Utilization Review (DUR) performed by a licensed Pharmacist. DUR includes, but is not limited to:

- reviewing the available medication history of the patient for consistency of treatment; and
- assessment of therapeutic appropriateness, by making a reasonable effort to identify:
  - over-utilization or under-utilization; therapeutic duplication;
  - drug-disease contraindication; drug-drug interaction;
  - drug-food interaction;
  - incorrect drug dosage or duration of drug treatment;
  - drug-allergy interactions; misuse;
  - any significant change in drug, dose, or directions; or
  - any age-related contraindications.

Note: The prescriber must be contacted when clinically significant interactions are noted or in the pharmacist's professional opinion follow-up with the prescriber is required.

REFERENCES:

21 CFR 1308 Controlled Substance Schedules

21 CFR 1306.9 Prescription Requirements for Online Pharmacies

21 CFR 1306.12 CII: Refilling Prescriptions; Issuance of Multiple Prescriptions

21 CFR 1306.22 CIII-V: Refilling of Prescriptions

REQUIREMENTS:

1. Pharmacy may only process and/or dispense prescription orders upon receipt of a "valid" prescription, as defined above, issued by a medical practitioner licensed and authorized to

prescribe in the jurisdiction where the provider practices.

2. Pharmacy processing and / or dispensing prescription orders to patients in the U.S. must adhere to the requirement for a prescription based on U.S. requirements (i.e. if a medication requires a prescription in the U.S. the accredited pharmacy must not process and/or dispense the medication prior to receipt of a valid prescription, as defined above, despite the medication not requiring a prescription in the accredited pharmacy's jurisdiction).

3. Pharmacy must clearly communicate on their website that a valid prescription, as defined above, is required for the purchase of prescription medication.

4. Pharmacy may neither offer nor provide its own remote medical consultation ("online prescribing") services to patients in another country/region, except where clearly permitted under the laws where the patient resides.

5. Pharmacy located **outside** the U.S. may not accept and/or process prescription orders for patients ordering from the U.S. that have been obtained through a remote consultation (e.g. telemedicine practice), unless expressly permitted under U.S. federal and/or state laws or regulations.

6. Pharmacy located **within** the U.S. may accept and/or process prescription orders obtained through a telemedicine practice only where explicitly permitted under federal or state laws or regulations.

7. Pharmacy located **outside** the U.S may not market, sell, process and/or dispense prescription orders for controlled substances, as defined under U.S. law, to patients in the U.S.

8. Pharmacy located in the U.S. must hold a valid U.S. DEA Registration in good standing and if dispensing controlled substances via the internet must adhere to the requirements of Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (21 CFR 1306.09).

9. Pharmacy located in the U.S. must hold a valid State controlled substance registration in good standing as required by the pharmacy's jurisdiction, including applicable non-resident licensure and registration, where applicable.

10. Pharmacy marketing, selling, processing and/or dispensing prescription orders for patients in the U.S. must adhere to the controlled substance schedule as defined under U.S. law (i.e. the accredited pharmacy must not market, sell, process and / or dispense a prescription order for a medication that is a controlled substance in the U.S., despite the medication not being a controlled substance in the accredited pharmacy's jurisdiction).

11. Unless expressly authorized by law, pharmacy may not process and/or dispense prescription orders (including refills) for non-controlled prescription drugs, as defined by

U.S. law, more than one (1) year from the date written by the practitioner.

12. Pharmacy located in the U.S. that market, sell, process and / or dispense controlled substances must adhere to the requirements for date filled and allowable refills of 21 CFR 1306 and / or State law, whichever is stricter.

13. Pharmacy must ensure that all prescription medication orders that are processed through its website are directly dispensed and shipped by the licensed pharmacies approved in the PharmacyChecker Verification Program, in accordance with PharmacyChecker policy *17-01 Shared Pharmacy Services Agreements Between Accredited Companies*.

14. Prescription medication orders must be reviewed for appropriateness, as defined above, and dispensed by licensed pharmacists.

15. Pharmacy's Standard Operating Procedure (SOP) must include processes to determine validity of prescriptions received by the pharmacy and requirements for proper DUR by the pharmacist.

ATTACHMENTS:

N/A

HISTORY:

Version Number	Date Effective	Description of Change
1.0	April 16, 2018	New SOP