# Verification Program Policies

Protecting the Public Health:

Helping Consumers Find Information About Verified Online Pharmacies that Sell Affordable Medications

**Rev. April 16, 2018**

# PharmacyChecker Verification Program Policies

# 16-01 Pharmacist Consultation

## Pharmacist Consultation

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| **PharmacyChecker 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 members ("Members") must meet in order to comply with PharmacyChecker Verification Program Standards related to patient counseling by a pharmacist.

**SCOPE:**

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

**RESPONSIBILITY:**

Members 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. Members 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, members must ensure that patients have access to a competent and licensed pharmacist in a timely manner but not to exceed 72 hours.

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

5. Members must ensure that patients can leave messages at all times, including after hours. Members 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 Members 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. A Member'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 Members 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 Member's SOP must include the competency standards assessed, frequency of assessment and methods used to evaluate competency of each pharmacist providing patient counseling.

12. Member websites must:

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

13. Member 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. |

# Medications Requiring Special Dispensing Considerations (MRSDC)

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| **PharmacyChecker Verification Program** | |
| **Policy No:** 16-02 | **Version No:** 2.0 |
| **Date Written:** May 2016 | **Date Revised:** February 2018 |
| **Effective Date:** April 16, 2018 | **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 Members. |

## PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program members ("Members") 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 Members that market, sell, process and / or dispense medications requiring special dispensing considerations **internationally.**

Members 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.

Member 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:

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

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

Members 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

Members 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 Members
- 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 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 Members.*
8. The PIC is responsible for ensuring staff are trained on the SOPs for MRSDC and documenting the training.

*Specialty Medications:*

Members 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. Members 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 |
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| 1.0 | N/A **Version 1.0 was drafted to replace** #11-007 “Banned Drugs”<br><br>**Note: It was announced but not implemented due to clarifications required by Members** | New SOP |
| 2.0 | April 16, 2018 | New SOP |

# Refrigerated Medications: Shipping Requirements

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| **PharmacyChecker Verification Program** | |
| **Policy No:** 16-03 | **Version No:** 2.0 |
| **Date Written:** 2010 | **Date Revised:** February 2018 |
| **Effective Date**: April 16, 2018 | **Replaces Version No:** 10-008 (revised Jan. 2011) |

## PURPOSE:

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

## SCOPE:

This policy applies to all Members that dispense refrigerated products. Only PharmacyChecker verified dispensing pharmacies located in Canada, United Kingdom, or the United States are permitted to dispense refrigerated products 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.woolcool.com/wp-content/uploads/2014/07/MHRA-Refrigerated-medicinal-products-what-pharmacists-need-to-know.pdf

## 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.

**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.

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

**GENERAL INFORMATION:**

- The manufacturer's labeling of many medications, including insulin, contains optimal storage conditions between 2ºC and 8ºC.
- 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.

- 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:**

1. 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.

2. Members 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 member 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 member uses a temperature indicator within the packaging to ensure the product does not exceed temperatures noted in the manufacturer labeling; **and**

- The member provides clear information to the consumer regarding 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- up to and including delivery/ receipt by the consumer**.

3. Members shipping refrigerated medications shall develop a Standard Operating Procedure (SOP) for packaging and shipping such medications.

4. Members may use more than one method depending on the product(s). The method used must not deviate from the manufacturers' labeling.
5. 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;

    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

    c. corrective actions and documentation requirements for temperature excursions outside predetermined temperature conditions.

6. 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.

7. Selection of a shipping container and/or box will be based on factors such as duration of transit, the size of the shipment and the ambient or outside temperatures experienced are important in deciding what type of packaging is required. Within a shipping container, the packaging configuration, which provides the primary means of environmental control for the medication, must ensure that the medication remains within the acceptable temperature range.

8. The SOP must also take into account the nature of the medication, local conditions, modes of transport and any seasonal variations experienced, as well as describe any special handling precautions.

9. The SOP must include 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 labelled 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.

10. The shipping container with medications requiring refrigeration must contain 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. 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:


12. 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). Validation that the shipping method retains the required storage conditions and will not deviate during the shipping process may be available from the commercial courier. Alternatively, Members may perform its own validation process to ensure that packing and shipping method retains the cold chain supply.

13. 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<br><br>Amended (1) to clarify that only PharmacyChecker verified 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) |

# Maximum Three Months' Supply Dispensed Internationally

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| **PharmacyChecker 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 members ("Members") 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 Members 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.

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

Members 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:**

Members 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. **Members 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.**

Online Pharmacy Members:

1. Members 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 Members requires the online pharmacy to process the prescription order prior to international dispensing by another pharmacy, the Member 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.

Dispensing Pharmacy Members:

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

2. 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.

3. The pharmacist must ensure that no prescription with a quantity exceeding a three months' supply is dispensed internationally; <u>unless</u>
    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). |

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| 3.0 | November 30, 2016 | 90-day changed to three months throughout document<br>Exceptions for exceeding a three months' supply updated to include options for dispensing sealed manufacturer packages of medication:<br>• sealed manufacturer packaging of #100 tablets / capsules<br>• 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<br>• 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 Marketing/Dispensing Indian Pharmaceutical Products Internationally

## Marketing/Dispensing Indian Pharmaceutical Products Internationally

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| **PharmacyChecker Verification Program** | |
| **Policy No:** 16-05 | **Version No:** 1.0 |
| **Date Written:** August 2016 | **Date Revised:** N/A |
| **Effective Date:** April 10, 2017 | **Replaces Version No:** 12-002 and strikes 4.9.3 of PharmacyChecker Inspection Program |

**PURPOSE:**

This policy amends and outlines the requirements for PharmacyChecker (PC) Verification Program members ("Members") regarding compliance with PharmacyChecker Verification Program Standards and Agreement related to dispensing Indian pharmaceutical products internationally, as outlined below. Indian pharmaceutical products that fall outside of these parameters may not be marketed, processed and / or dispensed internationally by Members.

**SCOPE:**

This policy applies to Members that market, process and / or dispense Indian pharmaceutical products internationally.

**RESPONSIBILITY:**

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

Members that market, process and / or dispense Indian pharmaceutical products internationally are responsible for compliance with the requirements outlined below.

**RATIONAL:**

PC requires Members to sell prescription drugs manufactured under current Good Manufacturing Practices (GMP), and provide a safe international mail-order pharmacy service. PC Policy Marketing / Dispensing Indian Pharmaceutical Products Internationally is based on:

1) a 2012 report that suggests a higher incidence of substandard drugs sold in India by smaller Indian drug manufacturers compared to the largest Indian manufacturers, specifically those whose products are known to meet exceedingly high international standards;

2) PC's understanding that products manufactured in plants with approval by the U.S. Food and Drug Administration, United Kingdom Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Agency, European Medicines Agency, and/or equivalent drug regulatory authorities are more reliable than those without such approvals; and

3) PC's understanding that ethically promoted global pharmaceutical company products marketed through their branded divisions are the highest quality products available for sale in India.

**DEFINITIONS:**

**Indian Pharmaceutical Product**: products approved for sale in Indian pharmacies.

**Ethically promoted pharmaceutical products**: pharmaceutical products approved for sale in India that have been manufactured by First-Tier Indian manufacturers (defined below) and that are marketed under a brand name directly promoted through the company's branded division.

**First-tier Indian manufacturer**: a pharmaceutical company based in India that:

- has a global presence in at least one of the following markets: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States; **and** products approved for sale in at least one of the aforementioned countries or

- is registered with a drug regulatory authority of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa and United Kingdom, United States.

**Global pharmaceutical company**: for the purposes of this policy, is a pharmaceutical company that is based in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, United States , that has products approved for sale in the aforementioned countries **and** sells pharmaceutical products internationally to one or more of the aforementioned countries.

**REQUIREMENTS:**

1. Members marketing, processing and / or dispensing pharmaceuticals approved for sale in India must ensure the products are:
    a. Ethically promoted pharmaceutical products manufactured by first-tier Indian manufacturers and global pharmaceutical companies, **and/or**

    b. Products manufactured in plants registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States.

2. The PIC is responsible for:
    a. confirming the pedigree of all medications the pharmacy dispenses;

    b. maintaining a list that *at a minimum* must include:

        i. manufacturers confirmed by the pharmacy to be first Tier Indian manufacturers;
        ii. name of each pharmaceutical confirmed by the pharmacy to be ethically promoted; and
        iii. wholesalers confirmed by the pharmacy to be trusted sources of first Tier Indian manufacturer's ethically promoted products

c. developing and maintaining an SOP for purchasing and dispensing Indian pharmaceuticals in accordance with this policy; and

d. ensuring staff are trained on the SOPs for purchasing and dispensing Indian pharmaceuticals and documenting the training.

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

**ATTACHMENTS:**

Appendix I: Indian Pharmaceutical Products

**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<br><br>4.9.3 Products manufactured in plants inspected for cGMP by PharmacyChecker or a third-party inspector acceptable to PharmacyChecker.<br><br>Lists the countries that acceded to the EU prior to 2002.<br><br>Adds guidance for determining global pharmaceutical company, First-Tier Indian Manufacturers and ethically promoted products. |

## Appendix I: Indian Pharmaceutical Products

The following table can be used to determine whether a pharmaceutical product approved for sale in India is compliant (meaning one that is an ethically promoted pharmaceutical by First-Tier Manufacturers and global pharmaceutical companies).

| Manufacturer | | | Yes | No |
|---|---|---|---|---|
| 1.0 | Is the manufacturer a global pharmaceutical company? | Go to 1.1 | | |
| 1.1 | Does the manufacturer have a global presence in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States? | If Yes, go to 1.2<br><br>If No, go to 2.0 | | |
| 1.2 | Does the manufacturer have products approved for sale in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States? | If Yes, go to 1.3<br><br>If No, go to 2.0 | | |
| 1.3 | Are the products approved for sale in 1.2 manufactured in plants registered with the U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate, United Kingdom Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Agency, European Medicines Agency, and/or other equivalent agencies, subject to PC's approval. | If Yes, the manufacturer meets standard 4.9 as a global manufacturer go to 3.0<br><br>If No, go to 2.0 | | |
| 2.0 | Is the manufacturer a First-Tier Indian Manufacturer? | Go to 2.1 | | |
| 2.1 | Is the Indian manufacturing plant registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States? | If Yes, the manufacturer meets standard 4.9 as a First-Tier Indian manufacturer, go to 3.0<br><br>If No, go to 2.2 | | |
| 2.2 | Does the Indian Manufacturing plant have global presence in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States? | If Yes go to 2.3<br><br>If No, the manufacturer does **NOT** meet standard 4.9 as a First-Tier First Tier Indian manufacturer | | |

| | | | | |
|---|---|---|---|---|
| 2.3 | Does the Indian manufacturer have products approved for sale in at least one of the following top tier countries Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom or United States? | If Yes, the manufacturer meets standard 4.9 as a First-Tier Indian manufacturer, go to 2.0<br><br>If No, the manufacturer does **NOT** meet standard 4.9 as a First-Tier First Tier Indian manufacturer | | |
| **Pharmaceutical Product** | | | **Yes** | **No** |
| 3.0 | Is the medication manufactured in a plant registered with regulatory authorities of one of the following: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Japan, Liechtenstein, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland South Africa, United Kingdom, and United States? | If Yes, the medication meets standard 4.9<br><br>If No, go to 3.1 | | |
| 3.1 | Is the medication ethically promoted through the First-Tier Indian manufacturer's branded division? | Go to 3.2 | | |
| 3.2 | Does the First-Tier Indian manufacturer market the medication under a brand name? | If Yes, the medication is a branded-generic, go to 3.3<br>If No, the medication does not meet standard 4.9 | | |
| 3.3 | Is the 'branded generic' marketed through the branded division of the First-Tier Indian manufacturer? | If Yes, the medication meets standard 4.9<br>If No, the medication does not meet standard 4.9 | | |

# 17-01 Shared Pharmacy Services: Agreements Between Members

| Shared Pharmacy Services: Agreements Between Members | |
|---|---|
| **PharmacyChecker Verification Program** | |
| **Policy No:** 17-01 | **Version No:** 1.0 |
| **Date Written:** August 2017 | **Date Revised:** N/A |
| **Effective Date:** April 16, 2018 | **Replaces**: Form 1003, Form 1004, and Pharmacist Certification Letter |

## PURPOSE:

This policy outlines the requirements for PharmacyChecker (PC) Verification Program members ("members") regarding compliance with the PharmacyChecker Verification Program agreement, standards and policies related to 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 both online pharmacy members that refer prescription orders to dispensing pharmacies and dispensing pharmacy members that dispense prescription orders referred from online pharmacy members.

## 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 PharmacyChecker Agreements.

Online pharmacy members must ensure that prescription orders are only referred to dispensing pharmacies that are approved in the PharmacyChecker Verification Program. **Members found to be referring orders to a non-PharmacyChecker approved pharmacy are subject to immediate termination from the Verification Program.**

All members who refer or accept referrals of prescription medication orders are responsible for documenting the relationship between each member, in accordance with the PharmacyChecker Verification Program agreement, standards, and policies.

Members must ensure that PharmacyChecker confirms, in writing, the receipt of required forms documenting the shared services relationship, in accordance with this policy, prior to referring/ accepting referrals of prescription orders.

## DEFINITIONS:

Company: The online pharmacy or PC Member Group that contracts with a dispensing pharmacy to dispense prescription orders. Online Pharmacy / PC Member Group may also contract with consultant pharmacist(s) to review and authenticate prescription medication orders.

PC Member Group: the company operating prescription drug-marketing websites that contract with dispensing pharmacies to dispense prescription orders. PC Member Group may also contract with consultant pharmacist to review and authenticate prescription orders.

PC Member Group Websites: the websites owned and operated by PC Member Group.

Dispensing Pharmacy: a licensed pharmacy that dispenses prescription orders. Dispensing Pharmacies may operate their own online pharmacy (i.e. website) or contract with online pharmacy / PC Member Group to dispense prescription orders on their behalf.

Consultant Pharmacist: a pharmacist licensed in the jurisdiction in which they practice, who is an employee of or contractor to online pharmacy / PC Member Group.

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 Agreement: agreement between verified members that documents the responsibilities for reviewing, processing and dispensing of prescription medication orders for each pharmacist.

**REQUIREMENTS:**

1. Before participating in shared services, members must ensure that all requirements outlined below have been met and PharmacyChecker has confirmed in writing receipt of all necessary forms/documents.

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

3. Prescription medication orders must be reviewed and dispensed by licensed pharmacists. Upon request, a copy of the pharmacist's license must be submitted to PharmacyChecker.

4. Members must have a written contract/agreement that outlines the services provided and the responsibilities of each member in complying with PharmacyChecker agreements, standards, and policies related to marketing, selling, processing and/or dispensing prescription medications. The contract/agreement between the pharmacies must document the responsibilities of each member 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 of the pharmacist(s) involved in shared services.

5. Members must 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 members. The database must be secure and cannot be duplicated, downloaded, or removed from the original platform.

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

7. Members must maintain Standard Operating Procedures (SOPs) that include at least the following:
    a. the responsibilities of each member 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. Each member referring and/or receiving prescription medication orders must document the shared service agreement by completing a PharmacyChecker required form: refer to Appendix I Online Pharmacy Shared Services Agreement Form, and Appendix II Dispensing Pharmacy Shared Services Agreement Form.

    **Note:** forms must be completed even if the pharmacy owns/operates the website and prescription medications orders are only referred to the dispensing pharmacy that owns/ operates the website.

9. A separate shared services agreement form must be completed to document each shared service agreement (i.e. if the online pharmacy works with more than one dispensing pharmacy, a form is required to be completed and signed by the PIC of each dispensing pharmacy, and a copy emailed to PharmacyChecker *directly* from each pharmacy). The PIC must include (i.e. Cc) the contact for the online partner on the email submission of the form to PharmacyChecker.

10. Shared services agreement forms must be completed, signed, scanned, and emailed as attachments to PharmacyChecker, and confirmed by PharmacyChecker (i.e. email confirmation from PharmacyChecker) prior to prescription medication orders being referred to the dispensing pharmacy.

11. Shared service agreement forms must be updated annually, or sooner as necessary (i.e. member is required to inform PharmacyChecker if/when the contract/agreement is terminated and shared service between the members has ceased, or when a new contract/agreement between members is executed.)

12. Online Pharmacies, including PC Member Groups, are responsible for providing PharmacyChecker with information for each dispensing pharmacy that they refer prescription medication orders to, or otherwise utilize in processing and dispensing prescription orders by completing the Online Pharmacy Shared Services Agreement Form for each dispensing pharmacy: refer to Appendix I.

13. The PIC of each dispensing pharmacy is responsible for providing PharmacyChecker with information for each PharmacyChecker verified website it accepts prescription orders from by completing the Dispensing Pharmacy Shared Services Agreement Form: refer to Appendix II.

14. Members must file each Shared Services Agreement form by emailing PharmacyChecker, forms@pharmacychecker.com. The email must also include the representative from the online pharmacy and the PIC of the dispensing pharmacy, where applicable.

**ATTACHMENTS:**

Appendix I: Online Pharmacy Shared Services Agreement Form

Appendix II: Dispensing Pharmacy Shared Services Agreement Form

**HISTORY:**

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

PharmacyChecker.com, LLC
333 Mamaroneck Avenue
White Plains, NY 10605
p: 718.554.3067
f: 718.715.1033

# Online Pharmacy: Shared Services Agreement Form

Online pharmacy members, including PC Member Groups, are required to file a form for each dispensing pharmacy to which their website refers prescription orders or otherwise utilizes for prescription medication order processing. Sections I – III of the form must be completed and signed prior to submitting to PharmacyChecker.

**Note**: Forms must be updated annually, or sooner as necessary (i.e. member is required to inform PharmacyChecker if/when the agreement is terminated and shared service between the members has ceased, and/or when a newly formed shared service contract/agreement between members is executed.) Completed forms must be emailed as attachments to forms@pharmacychecker.com.

## Section I: General Information

Shared services agreement between **[ONLINE PHARMACY]** and **[DISPENSING PHARMACY]**

**Member Info: (**list PC Member ID and URL for each Company website)

| **Dispensing Pharmacy** | **Pharmacist-in-Charge (PIC)** | **PC Member ID #** |
|---|---|---|
| | | |
| **Name: Company / PC Member Group** | **Online Pharmacy Member _[URL"http://www]_____** | **PC Member ID #** |
| | | |
| | | |
| | | |

(add additional rows or attach a separate sheet of paper as needed)

## Section II: Authorized Agent Certification

I, the undersigned, am an authorized agent of **[COMPANY] .**
I hereby certify that:
1) I have read and agree that **[COMPANY]** will comply with and be bound by the PharmacyChecker Membership Agreement and the Seal Agreement.

2) **[COMPANY]** 's website(s) (listed in section I above) refers prescription medication orders to **[DISPENSING PHARMACY]** located at _____[PHARMACY ADDRESS]_____.
If at any time our Company ceases referring prescription medication orders to the above mentioned dispensing pharmacy, I will immediately notify PharmacyChecker.

_____

Signature Authorized Agent for Company Print Name Date

**Section III: Prescription Processing Agreement Between Pharmacies**

I, the undersigned, am an authorized agent of **[COMPANY] .**
I hereby certify that all prescription medication orders referred to **[DISPENSING PHARMACY]** from **[COMPANY]'s** Website(s) (noted above in section I) are reviewed/processed by a pharmacist in accordance with PharmacyChecker policy 17-01, as noted in A to D below:

**A. Reviewed for Authentication by: (check one)**

1. ☐ a Pharmacist (employed by/contracted by) the online pharmacy / PC member group, if selected, complete pharmacist info below prior to moving to B; OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website, if selected, go directly to B below

_____

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

**B. Review for Appropriateness by: (check one)**

1. ☐ a Pharmacist (employed by/contracted by) the online pharmacy / PC member group, if selected, complete pharmacist info below (or notate "same as above") prior to moving to C; OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website, if selected, go directly to C below

_____

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows as needed)

**C. Prescriber Consultation by: (check one)**

1. ☐ a Pharmacist (employed by/contracted by) the online pharmacy / PC member group, if selected, complete pharmacist info below (or notate "same as above" prior to moving to D); OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website, if selected, go directly to D below

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

**D. Patient Consultation by: (check one)**

1. ☐ a Pharmacist (employed by/contracted by) the online pharmacy / PC member group (if selected, complete pharmacist info below (or notate same as above) prior to moving to required signature below); OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website (if selected, go directly to required signature below)

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

Signature Authorized Agent for Company Print Name Date

Signature of Pharmacist Print Name Date
employed by/contracted by) the
online pharmacy / PC member group
(if #1 was selected in A, B, C, and/or D above)

PharmacyChecker.com, LLC
333 Mamaroneck Avenue
White Plains, NY 10605
p: 718.554.3067
f: 718.715.1033

# Dispensing Pharmacy: Shared Services Agreement Form

Dispensing Pharmacy Members are required to file a form for each PharmacyChecker-approved Online pharmacy, for which their pharmacy dispenses prescription orders. Sections I – III of this form must be completed and signed prior to submitting to PC. (Note: if Dispensing Pharmacy fulfills orders for multiple websites that are administered by a single management company, they may opt to list those websites in a single document).

Forms must be updated annually, or sooner as necessary (i.e. member is required to inform PharmacyChecker if/when the agreement is terminated and shared service between the members has ceased, and/or when a newly formed shared service contract/agreement between members is executed. Completed forms must be emailed as attachments to forms@pharmacychecker.com

## Section I: General Information

Dispensing process shared services agreement between **[DISPENSING PHARMACY]** and **[COMPANY]**

**Info: (**list PC Member ID and URL for each Company website)

| **Dispensing Pharmacy** | **Pharmacist-in-Charge (PIC)** | **PC Member ID #** |
|---|---|---|
| | | |
| **Name: Company / PC Member Group** | **Online Pharmacy Member _[URL"http://www]_____** | **PC Member ID #** |
| | | |
| | | |
| | | |

(add additional rows or attach a separate sheet of paper as needed)

## Section II: Pharmacist Certification

I, the undersigned, am the Pharmacist-in-Charge of **[DISPENSING PHARMACY]** located at _____[PHARMACY ADDRESS] _____.

I hereby certify that:

1) I have read and agree that Company will comply with and be bound by the PharmacyChecker Membership Agreement and the Seal Agreement.
2) **[DISPENSING PHARMACY]** dispenses prescription medication orders initiated or generated by **[COMPANY]'s** Website(s) via websites noted above in Section I.

If at any time my pharmacy ceases dispensing prescription medication orders from the above-mentioned website(s), I will immediately notify PharmacyChecker.com.

Signature PIC for Dispensing Pharmacy Print Name Date

## Section III: Prescription Processing Agreement Between Pharmacies

I, the undersigned, am the Pharmacist-in-Charge of **[DISPENSING PHARMACY]**

I hereby certify that all prescription medication orders referred from **[COMPANY]'s** Website(s) (noted above in section I) are reviewed/processed by a pharmacist in accordance with PharmacyChecker standards and polices, as noted in A to D below.

### A. Reviewed for Authentication by: (check one)

1. ☐ a Pharmacist (employed by / contracted by) the online pharmacy/PC member group
   if selected, go directly to B below; OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website
   (if selected, complete pharmacist info below prior to moving to B)

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

### B. Review for Appropriateness by: (check one)

1. ☐ a Pharmacist (employed by / contracted by) the online pharmacy/PC member group
   (if selected, go directly to C below); OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website
   (if selected, complete pharmacist info below (or notate same as above) prior to moving to C)

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows as needed)

### C. Prescriber Consultation by: (check one)

1. ☐ a Pharmacist (employed by / contracted by) the online pharmacy/PC member group
   (if selected, go directly to D below); OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that owns/operates the website
(if selected, complete pharmacist info below (or notate same as above) prior to moving to D)

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

**D. Patient Consultation by:**

1. ☐ a Pharmacist (employed by / contracted by) the online pharmacy/PC member group
(if selected, go directly to required signature below); OR

2. ☐ a Pharmacist employed by Dispensing Pharmacy that own/operates the website
(if selected, complete pharmacist info below (or notate same as above) prior to moving to required signature below)

Print Name of Licensed Pharmacist License # By: Pharmacy Regulatory Authority
(add additional rows or attach a separate sheet of paper as needed)

Signature PIC for Dispensing Pharmacy Print Name Date

# Valid Prescription Requirement

| | |
|---|---|
| **PharmacyChecker 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 members ("Members") regarding compliance with PharmacyChecker Verification Program agreements, and standards related to the "valid" prescription requirement.

## SCOPE:

This policy applies to Members 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 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.

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 Member 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 Member'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 remote medical consultation ("prescribing") services to patients in another country/region, except where expressly permitted by law in that country/region.

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 Member 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 Member'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 Members*.

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 |
| | | |