Amazon Business (AB) Professional Healthcare (PHC) Seller Policy

1. What is the Amazon Business Professional Healthcare Program?

a. Overview

The Amazon Business (AB) Professional Healthcare (PHC) program offers products that are labeled as Prescription (Rx) and professional-use only medical devices to licensed professional healthcare customers with AB accounts. Products offered, listed, and distributed in the PHC program may only be sold by approved Selling Partners. Rx medical devices will only be sold to appropriately licensed healthcare customers who have AB accounts. Any licensed eligible practitioner may apply for a license review, to authorize purchasing Rx medical devices offered within the PHC program. AB account registration and license verification are free. For more information and latest requirements for customer eligibility, visit the PHC Customer Help Page.

The PHC program is currently available in all states within the United States. This document is a short overview of program requirements for Seller participation, sale, and distribution of Rx medical devices within the program. It is not an exhaustive set of Amazon policies, which are found on Seller Central.

b. Third Party (3P) Seller PHC Program

The Amazon 3P or Seller PHC program is administered through Seller Central and is accessible by invitation only. Sellers participating in this program manage account setup, catalog, marketing, orders, shipments, and website pricing on Amazon. In this program, Sellers are to list prescription (Rx) and professional-use only

medical device offers on Amazon's Marketplace, where customers can discover products and place orders. Sellers in the PHC program will utilize Merchant Fulfillment Network (MFN) to distribute Rx medical devices. MFN distribution is maintained and completed by the Seller, not by Amazon. Fulfillment by Amazon (FBA) is not available for this PHC program. As a Seller, manufacturers and suppliers are required to meet the terms outlined in the online Amazon Services Business Solutions Agreement, be approved as a Business Seller, and must be licensed by the appropriate states to sell Rx medical devices. For more information on PHC Seller distribution requirements, please reach out to your Account Manager or contact us through Seller Support services Seller Central.

c. What products are eligible?

Eligible medical devices are defined as select Class I and Class II devices that are not life-sustaining devices or long-term implantable devices. Class III life-saving devices (i.e., ventilators and defibrillators) that require tracking, per 21 C.F.R. 821, are eligible. See 102359 – PROFESSIONAL HEALTHCARE (PHC) PROCESS – SERIAL NUMBER TRACK AND TRACE. Products outside the scope of this program include over the counter devices (OTC), drugs, drug/device combination products, drug delivery devices, and biological products (therapeutic biologicals and vaccines). Refrigerated and frozen medical devices and test kits are in-scope for MFN, if the Seller has the warehousing and fulfillment capabilities for cold-chain. It is the responsibility of the Seller (per the applicable terms and conditions) to understand the scope of products currently allowed and refrain from listing such items at this time.

For more information on the information about OTC and prescription (Rx) and professional-use only medical devices, view Seller Central. Additionally, view the Food and Drug Administration's (FDA's) website to find more information regarding Medical Device Classification, OTC Devices, Drugs, Combination Products, and Medical Device Tracking.

Products identified as prescription (Rx) and professional-use only medical devices are not eligible for Fulfillment by Amazon (FBA). FDA Regulations prevent unlicensed Fulfillment Centers (FCs) from storing prescription medical devices. If you believe that your product has been incorrectly classified as a prescription medical device, please contact seller support through "contact us" to start an appeal.

Examples of permitted listings for sellers participating in the PHC program include the following:

- Products that require a prescription or a medical professional's supervision or direction for their use
- Products that are labeled for professional-use only or not for retail sale
- Products that have been classified by the FDA, such as medical devices that require FDA clearance or approval that have not been cleared or approved by the FDA, for over-the-counter use such as:
    - Acupuncture/intradermal needles
    - Anesthetic vaporizers
    - Asthma inhalers
    - Bacteriostatic water
    - Cancer tests (see examples of cancer tests below)
    - Cardiac monitor
    - Cavity varnish (see examples of cavity varnish below)
    - Chin-up strip
    - Circumcision devices
    - Contact lens cases (unless cleared for over-the-counter use)
    - Contact lenses, including both cosmetic and corrective lenses

- Continuous, Variable and Bilevel Positive Airway Pressure (CPAP, VPAP, BiPAP) devices and certain accessories (see examples of Continuous, Variable and Bilevel Positive Airway Pressure (CPAP, VPAP, BiPAP) devices and their accessories below)
- Cranial electrotherapy stimulators
- Defibrillators (unless approved or cleared for over-the-counter use – see examples of defibrillators below)
- Prescription dental devices, such as (see examples of denture relining, repairing, or rebasing resin below):
    - Dental burs
    - Dental X-ray units
    - Denture relining, repairing, or rebasing resin
    - Dental handpiece or dental drill
- Electronic stethoscopes
- Electrosurgical cutting and coagulation devices
- Fetal Dopplers
- Home HIV test kits
- Hypodermic needles and insulin injectors, such as:
    - Monoject Safety Syringes
- Infant heel warmers
- Implantable devices, such as pacemakers
- Infusion pumps and their accessories (with exception of batteries, which are permitted)
- Infusion set
- Insulin pumps (see examples of insulin pumps below)
- Laser combs
- Mandibular advancement devices (see examples of mandibular advancement devices below)
- Mesotherapy products
- Nebulizers and their accessories, such as holding chambers
- Oral cavity abrasive polishing agents (see examples of oral cavity abrasive polishing agents below)
- Oxygen concentrators, compressors, conservers, generators, condensers and their accessories, such as:
    - Hyperbaric chambers
- Penis enlargement devices (see examples of penis enlargement devices below)
- Pinhole eyewear that makes unapproved medical claims
- Prescription eyewear
- Polar Care Cold Therapy System products manufactured by Breg, Inc.
- Pulse oximeters (in order to be listed and sold by sellers outside of the PHC program, pulse oximeters must be either (a) clearly labeled and consistently marketed as “for sports or aviation use only” or "not for medical use," or (b) cleared by the FDA for OTC purchase and marketed accordingly)
- Radiesse
- Resin tooth bonding agents (see examples of resin tooth bonding agents below)
- Seizure bite sticks
- Skin glue
- Surgical kits
- Surgical sutures
- Ultra sound therapy and ultra sound pain relief devices
- Vaginal pessary devices
- Ventilator machines

- VITROS Immunodiagnostic, Integrated, and Chemistry Systems

Below are examples of prescription (Rx) and professional-use only medical devices that may only be listed by Sellers participating in the PHC program.

- Cancer tests:
  - PSA Prostate Specific Antigen
  - High-Sensitivity CRP Home Test Kit
  - Cervical Cancer Test
- Cavity varnish:
  - Ascent F-Coat
  - Copal Varnish with Fluoride
  - Fluoridex
  - GC Fuji Varnish
  - GLUMA Desensitizer PowerGel
  - MI Varnish
  - NUPRO
  - Pulpdent Fluoride Varnish
  - Vanish Varnish
- Continuous, Variable, and Bilevel Positive Airway Pressure (CPAP, VPAP, BiPAP) devices and their accessories:
  - BiPAP Plus
  - CPAP Masks
  - DeVilbiss IntelliPAP
  - iDPAP Celestia CPAP Machine
  - Polaris EX CPAP
  - Respironics REMstar
  - RPM Bilevel CPAP System
- Denture relining, repairing, or rebasing resin:
  - Coe Comfort
  - Coe-Soft
  - Coe-Soft LC
- Defibrillators (not approved for over-the-counter use):
  - HeartStart OnSite AED
  - HeartStart FRx AED
  - HeartStart MRx
  - Lifeline AED
  - Medtronic LIFEPAK
  - MRL LifeQuest AED
  - Welch Allyn AED 20
  - ZOLL AED Pro
- Insulin pumps:
  - Animas Infusion Set
  - Contact Detach Infusion Set
  - GenStrip Blood Glucose Test Strips sold by Shasta Technologies LLC
  - Medtronic Minimed Paradigm Revel 523
  - One Touch Ping Glucose Management System
- Mandibular advancement devices:
  - Airflow Pressure Transducer

  - Dymedix Reusable Airflow/Snore Sensor
  - Nose Breathe Mouthpiece for Heavy Snorer
  - Quiet Night Sleep Appliance
  - Removable Acrylic Herbst
  - Snore Guard
  - Snore Guard Advance
  - Snore Hook Discluder
  - Snore Sat Recorder
  - Snore-Aid Max
- Oral cavity abrasive polishing agents:
  - Butler Calci-Flor Prophylaxis Paste
  - GC MI Paste
  - GC MI Paste Plus
  - Gelato Prophylaxis Paste
  - Enamel Pro
  - Mi Paste
  - MI Paste Plus
  - PREVENTECH Prophylaxis Paste with Fluoride
  - VOCO Paste
- Penis enlargement devices:
  - Bathmate Penis Enlargement Pump
  - Bathmate Hydropump Hercules
- Resin tooth bonding agents:
  - Ascent Bond Universal Adhesive System
  - Beautibond Multi
  - Beautibond Multi PR Plus
  - Cimara and Cimara Zircon
  - GC Fuji Bond LC
  - SilJet System

d. Seller Requirements

Sellers, in accordance with the Seller terms and conditions must provide genuine, new, unexpired, and unadulterated products labeled for the geographic region (US). When filling out the product templates, Sellers must provide accurate information about the product for correct classification and publishing. Sellers are further required to provide proof of licensure to sell prescription (Rx) and professional-use only medical devices in states that require State Board of Pharmacy registration. To be able to sell and ship prescription (Rx) and professional-use only medical devices, Amazon currently requires Sellers to be licensed in the following states: Alaska, Arizona, California, Connecticut, District of Columbia, Georgia, Idaho, Iowa, Louisiana, Maryland, Michigan, Montana, Nevada, New Hampshire, New Jersey, New York, North Dakota, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and Wisconsin. If a Seller is unable to provide proof of licensure in these states, then they will be blocked from selling Rx medical devices to customers residing in that state. Manufacturers of Rx medical devices are required to provide FDA registration. Wholesalers are required to provide invoices that indicate the manufacturer that is sourcing products. Manufacturers and wholesalers are required to provide confirmation that they are not on a debarment list.

Please see Seller Central for more information.

2. Onboarding Process

a. Onboarding

The PHC program is currently invitation only. Sellers will onboard their products through Seller Central and by coordinating with their Seller Account Manager. To list products in PHC, approved Sellers will be ungated to allow for new PHC ASIN Creation. Your Seller Account Manager will provide instructions on how to fill out the PHC flat file to properly classify products.

b. Item Creation

Accurate information for item upload and creation is critical to the correct publishing application for these products. Because the categories support over-the-counter (OTC) products (products that consumers and general business customers can purchase) and prescription (Rx) and professional-use only medical devices (products that require a license to purchase), Amazon requires Seller input for the correct publication of these items. Item set-up begins with the Seller flat file.
The template requires the Sellers to answer a series of questions related to the product's labeling and intended use in order to properly publish the item. The main "FDA" attributes are as follows:

- FDA Indication of Use
- Manufacturer Label
- Manufacturer Instructions For Use

Depending on the nature of the product, the Seller should provide the correct designation for each of the three attributes, and choices will range from "professional" vs "consumer" or "OTC" vs "Rx only". Designating at least one of the attributes as "prescription," "professional," or "Rx only" will drive item restriction on Amazon.com, so that only licensed healthcare customers will be able to access this product and add the product to the cart. Accurate input and review at this step is critical, and should be reviewed by the Seller's Quality or Regulatory Affairs team for correct interpretation and designation of the attribute values. Incorrect information will ultimately lead to long delays in item publishing and potential violation of Amazon terms for supplying or listing products. Filling out correct information in these fields at item submission is required and is the responsibility of each Seller. All product information provided by Sellers (including information provided for these attributes) constitutes "Your Product information" under the Amazon Services Business Solutions Agreement. Further questions and clarification should be discussed with your Seller Account Manager.

Please see Seller Central for more information.

c. Unique Device Identifier (UDI)

Amazon can support Global Trade Item Number (GTIN), GTIN-12 and GTIN -14 UDIs in the Product ID field. Seller flat files do not yet accommodate Health Industry Bar Code (HIBC) UDI type in the Product ID field. Entry of UDI is optional, however strongly encouraged if applicable.

- Fill in the appropriate UDI number or identifier in the "Product ID" column on the PHC flat file and select "GTIN" for the Product ID Type.
- Ensure the correct UDI is entered for the correct UOM (unit of measure) and case pack configuration. Errors in this step will cause incorrect matching of the SKU to the appropriate ASIN (Amazon Stocking Identification Number) in the Amazon catalog. Currently, Amazon sets up a unique ASIN for each UDI

and UOM. Thus, each UOM configuration for a manufacturer part number will have a unique ASIN and a unique UDI.

- Do not add any additional barcode labels like ASIN labels to an item package that has a UDI label. Do not cover the UDI barcode label with other stickers or labels.
  If you have a UDI that is not in GTIN-14 format, leave both the "Product ID" and "Product ID Type" fields blank.

3. Product Requirements

a. Labeling Requirements

All medical devices must be labeled in English with the following information:

- The name and place of business of manufacturer, packer, or distributor, including the street address, city, state, and zip code;
- Directions for use, including:
  - Statements of all purposes for which, and conditions under which, the device can be used;
  - Quantity of dose for each use and standard quantities for persons of different ages and physical conditions;
  - Frequency of administration;
  - Duration of application;
  - Time of administration in relation to other factors;
  - Route or method of application; and
  - Any preparation necessary for use.
- Prescription medical devices must include an Rx statement, i.e., "Caution: Federal law restricts this device to sale by or on the order of a (Insert name of physician, dentist or other licensed practitioner").

For more information, see the U.S. Food and Drug Administration's Guidance on Labeling

b. Expiration dated products

All units shipped to a customer via Direct Fulfillment are required to have at least 180 days of dating before expiration.

c. Marketing Requirements

The requirements below apply to all product marketing materials, including the product detail page, product packaging, and any instructional materials or package inserts included with the product.

- Medical devices must not make false or misleading statements.
- Medical devices must use the claims "FDA cleared" or "FDA approved" appropriately (for more information, see Is It Really 'FDA Approved?').
- Medical devices must not use the FDA logo (for more information, see Is It Really 'FDA Approved?').

4. Frequently Asked Questions

All sellers are prohibited from listing products that improperly claim to be "FDA cleared," "FDA approved" or products that include the FDA logo in associated images (for more information, see: Is It Really 'FDA Approved?' and FDA Logo Policy).

Q. I would like to be a Seller of Rx Medical products, am I automatically approved for the program because I'm FDA registered?
A. No, you would not be automatically approved by Amazon to sell Class I and II Rx medical devices. The sale and distribution of medical devices is governed at the state level. Please check with your legal and regulatory contact to ensure your company maintains licenses with the states that require them. You will need to provide proof of active licensure to participate in the PHC program. Sellers must also meet minimum business requirements (breadth of products, fulfillment capabilities, etc.) to be approved for the PHC program.

Q. Are products classified as "exempt" by the FDA okay to sell to general business customers and consumers?
A. You are responsible for determining whether a product in your catalog is appropriate for sale to consumers and general business customers based on the product's label, instructions and indication of use. For questions or disputes, please provide a copy of your 510(k) or other applicable product documentation as well as justification for the unrestricted classification.

Q: My products don't show up on the site at all, even though I received an ASIN (Amazon Standard Identification Number) list from Amazon confirming the products were created in the catalog. What's wrong with them?
A: If your products were designated as "restricted to licensed healthcare professionals only" by the attributes you provided, your product will only publish to the Amazon Business experience[i]. In order to search and view these products, you will need to log in using an Amazon Business account ID. If your products are still not visible, it is likely the ASIN was set up incorrectly and caught by a restricted product rule. Please contact your Seller Account Manager for this particular issue.

Q: Does Amazon currently allow for FBA distribution for Rx medical devices?
A: No, products identified as Rx medical devices are not eligible for Fulfillment by Amazon (FBA). If Amazon receives Rx medical devices as FBA, products will be destroyed at the Selling Partner's expense.

Q: Why is my product not eligible for FBA?
A: Direct seller to the help page regarding Medical Devices and accessories. This help page should be reviewed prior to creating new ASINs.

Q: My product was incorrectly identified as an Rx medical device. What is the process for updating my product as a non-Rx medical device?
A: If you believe that your product has been incorrectly classified as a prescription (Rx) and professional-use only medical device, please contact your seller support and ask them to submit a seller appeals ticket. Please provide your 510(k) product information, indications for use (IFU), and product packaging images (6 sides).

[i] As of July 2017- detail page and search experience may vary over time.