Mailing Prescription Medications to Patients

This document was prepared by the National Family Planning & Reproductive Health Association (NFPRHA) in consultation with subject matter expert Sally Rafie, PharmD, BCPS, APH, NCMP, FCCP, FCPhA of <u>Birth Control Pharmacist</u>. It outlines considerations for health centers that are exploring the feasibility and permissibility of mailing medications to patients. It is intended for informational purposes only. It is not intended to provide legal or medical advice to any entity or individual, nor intended as a solicitation or endorsement of a specific product.

State Laws and Regulations

Generally, health centers may provide medications to their patients within their state and local service area in person or by mail. Especially against the backdrop of the COVID-19 pandemic, mailing medications to meet community health needs likely will be viewed favorably by many state boards of medicine and pharmacy. Not only can the practice limit the need for unnecessary in-person visits and potential exposures to COVID-19, but it also can minimize logistical barriers to access, especially for patients with limited transportation and unpredictable schedules and those residing in areas with unmet needs.

DEFINITIONS

PATIENT

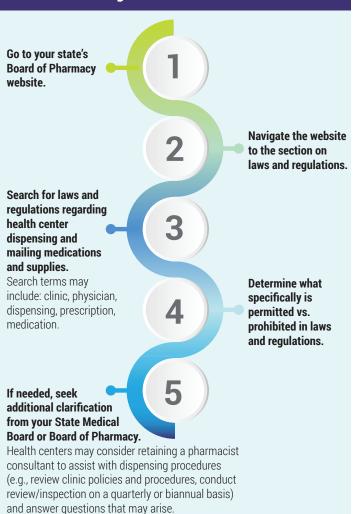
An individual with a recent health center encounter. When using medications purchased through the 340B Drug Pricing Program, the health center must have provided an established patient with a service consistent with its 340B qualifying grant, either in person or via audio-video or audio-only telehealth visit, to initiate the prescription and dispense a 340B-priced medication.¹

DISPENSING

Provision of medications to a patient pursuant to a prescription from a health care provider or provision of medications directly to a patient by the health care provider.

PRESCRIPTION

Transmission order (e.g., written, oral, electronic) for a patient issued by a health care provider within their scope of practice.



How to Check Pharmacy Laws on Dispensing and Mailing Medications in Your State

¹ Refills on qualifying prescriptions are eligible for 340B pricing.

State Laws and Regulations

Can medications be mailed to patients within the state?

Health centers first will need to determine the laws and regulations pertaining to mailing medications to their patients within the state. As part of this first exploratory step, health centers need to confirm the following:

- Is a special license required from the Board of Pharmacy to dispense medications by mail? Some states do not require a pharmacy license for on-site dispensing but do call for a pharmacy license to mail medications; others require a separate mail-order pharmacy license. Additionally, some states require health centers to have a pharmacy license if ordering medications from a drug wholesaler.
- What types of medications are health centers allowed and/or prohibited (e.g., controlled substances) to mail to established patients?
- What, if any, restrictions exist related to the quantities of medications that can be mailed (i.e., 30-day supply, 90day supply)?
- What are labeling requirements (e.g., patient name, medication name, directions) for medications that are mailed to patients?
 - How, if at all, do these requirements differ from medications dispensed on-site?
- What, if any, requirements exist for having a phone number where patients may reach a health care professional for counseling or questions?

Are there emergency provisions during public health emergencies (e.g., COVID-19 pandemic)?

Health centers should check their state medical board and pharmacy board websites for announcements regarding emergency regulations, noting whether emergency provisions are in place for federal and/or state-declared emergencies and effective dates.

Can medications be mailed to patients outside the state?

In addition to all the above considerations related to mailing medications within the originating state, health centers will want to determine the laws and regulations in place in any destination state.

- What are the licensure requirements for the health center if mailing medications to another state? Some states require that health centers have a pharmacy license or separate mail order pharmacy license. Health centers should check laws for all states where they are planning to mail medications.
- What, if any, are the licensure considerations for the prescribing clinician in the destination state (e.g., does the clinician need to be licensed in the destination state)?
- How do health centers proceed when regulations in two different states do not align (e.g., the state where the health center is located has different labeling requirements than the state to which the medication is being mailed)? This often depends on where the health center is licensed and whether it is licensed in multiple states (more common in metropolitan areas). Questions such as this are best answered in consultation with a pharmacist consultant or attorney with expertise in pharmacy law.



Operational Considerations

Health Plan & Self-Pay Payment Policies

The feasibility and sustainability of a health center mailing medications to patients hinges on whether (and the extent to which) payers provide reimbursement for medications sent by mail and associated costs (e.g., postage). Once a health center determines the regulatory feasibility of mailing medications, it will want to identify the extent to which it will be reimbursed for the service and whether negotiations with specific payers are warranted.

- Determine health plan-specific policies and restrictions regarding mailing medications to patients for all contracted payers, including:
 - Medicaid fee-for-service
 - Medicaid managed care
 - Commercial health plans
 - What, if any, incentives exist to encourage patients to use contracted mail-order services?
 - Note: No restrictions on mailing medications in the 340B program.
- How might payer reimbursement policies differ for medications that are mailed instead of dispensed on-site?

Logistical Considerations

Some medications must be stored in a specific, consistent environment. Failure to do this not only may make the medication less effective, but also may have harmful effects for the patient. As a result, when mailing medications, it is critical for health centers to ensure that medications are delivered safely and intact.

- Ensure medications remain at the appropriate temperature range during transit.
 - How might unstable temperatures impact the feasibility of mailing certain medications or supplies by mail?
- What special packaging and labeling might the health center use to ensure medications remain within the appropriate temperature range?

- To what extent might each payer reimburse for postage? Though not common, this is an expense that health centers may address through negotiation and advocacy.
- How might these policies and restrictions vary for mailing medications to plan enrollees residing out-of-state (e.g., students)?
- How will the health center handle patient payments/ copayments for medications that are mailed versus dispensed on site?
 - Will the health center use the same schedule of discounts/sliding fee scale for mailed medications as it does for those that are dispensed on site? Of note, when using a Title X Family Planning Services Fee Schedule, health centers may not charge the patient a different rate/amount for medications that are mailed instead of dispensed on-site.
 - To what extent will patients be asked to cover postage expenses?
 - How will the health center collect patients' payments/ contributions for mailed medications?

FOR EXAMPLE:

Most contraceptives should be kept at room temperature during transit.

- The target temperature is 20° 25°C (68° 77°F) with an acceptable temperature range of 15° - 30°C (59° - 86°F).
 - Of note, despite being stored in the refrigerator in the clinic, the generic NuvaRing product may be kept at room temperature for up to 4 months.
- Do not refrigerate, freeze, or expose contraceptives to excessive heat.

EXAMPLE CONTINUED:

Antibiotics for sexually transmitted infection (STI) management² should be stored at room temperature and away from excess heat and moisture.

- The target temperature is 20° 25°C (68° 77°F) with an acceptable temperature range of 15° - 30°C (59°F - 86°F).
- Protect from light by dispensing in a tight, light-resistant container.

Shipment & Delivery

Health centers will need to evaluate the most appropriate option for shipment.

- Health centers may consider costs, timeliness, and delivery options with various shipping vendors. In addition to the USPS, vendors include UPS, FedEx, and local courier companies. Finally, health centers may consider providing local deliveries themselves (e.g., clinic staff members use a health center vehicle to deliver medications within a 5-mile radius three times a week).
- How long will it take for the carrier to deliver the package?
 - To what extent do these timeframes impact the feasibility of mailing certain medications or supplies by mail?
- Is the carrier able to confirm that the patient received the package? Does the health center receive confirmation that the medication was delivered and received by the patient? While the patient signature requirement was suspended during the pandemic, this may be required by contracted payers.
 - Options to obtain confirmation include delivery signature confirmation from shipping vendor or direct confirmation to the health center (e.g., scanning QR code on medication paperwork, replying to email, replying to text message).
 - What other feedback loops may be needed to confirm the patient received their medication?

Antivirals for HIV pre-exposure prophylaxis (PrEP) should be kept in their original light-resistant container and at room temperature during transit.

 The target temperature is 20° - 25°C (68° - 77°F) with an acceptable temperature range of 15° - 30°C (59°F - 86°F).

Another set of important considerations relate to the patient's delivery preferences, including any concerns they might have related to privacy and confidentiality. As part of this process, the health center will want to determine the following:

- What is the patient's preferred mailing address? This may be different from their permanent (i.e., home) address.
- Does the patient need or prefer discreet packaging for the delivery so that the source of and/or contents of the package are indiscernible?
- In cases where the patient is not available to accept the delivery:
 - Should the carrier leave the package?
 - Should the carrier allow another person to accept the delivery?
- It's also important for the health center to discuss what options are available through their courier/delivery carrier.
- How will the health center communicate delivery timeframes to patients? Consider communicating timeframes for patients in need of time-sensitive medications (e.g., STI treatment, emergency contraception) and offer the option to pick up their medications at the health center's physical location or a local pharmacy to ensure timely access.

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² In states where expedited partner therapy (EPT) is permissible or potentially allowable (subject to additional actions or policies), health centers may dispense 340B-priced medications for EPT if the patient meets the 340B patient definition at their (in-person or telehealth) visit and tests positive for an STI (or is eligible for syndromic treatment, per the health center's clinical protocols). The rationale is that EPT is a treatment for the patient because it prevents reinfection. A health center's use of 340B drugs for EPT should be included in its 340B policies and procedures. Health centers may check the legal status of EPT and prescription requirements in their state here.

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🧈 Follow Up

As with medications dispensed on site, it is important for patients to have an appropriately licensed provider to answer questions.

• What phone number(s) should be enclosed in the event the patient has questions or concerns?



Documentation

How will the health center document patient preference and consent for mail delivery of medications in the patient's health record?

- How will the health center document specific preferences for obtaining time-sensitive medications (e.g., STI treatment, emergency contraception) in the patient's health record?
- How, if at all, will the process for completing the health center's dispensing record be different for medications to be mailed to patients (as compared to medications dispensed on-site)?
- How will the health center document the permissibility of mailing 340B-priced medications in its 340B Policy & Procedure Manual? The health center will want to include documentation on how it will ensure that the patient receiving the 340B-priced medication by mail meets the 340B patient definition and this eligibility is documented in the patient's medical record.³

Additional Resources

Some medications have additional restrictions on their use (i.e., distribution, prescribing, dispensing, administration, patient education). Notable examples for health centers include medication abortion and controlled substances.

Resources on Mailing Medication Abortion

Mifepristone continues to have a UD Food & Drug Administration (FDA)-imposed **Risk Evaluation and Mitigation Strategy** with restrictions on distribution (i.e., only certified prescribers can order and stock the drug), prescribing (i.e., prescribers must be certified by completing a prescriber agreement form), dispensing (i.e., the drug only can be dispensed in person or by mail by certified prescribers from health centers, medical offices, and hospitals, as well as partner mail order pharmacies), and patient education (i.e., patient agreement form). Further, some states have pending legislation that would prohibit mailing medication for medication abortion.

 Pharmacy and Clinical Collaboration for Medication Abortion - <u>https://birthcontrolpharm.files.wordpress.</u> com/2021/08/clinic-pharmacy-collab-for-mab.pdf

Resources on Mailing Controlled Substances

Drug Enforcement Administration (DEA) Diversion Control Division COVID-19 Information - <u>https://www.deadiversion.</u> usdoj.gov/coronavirus.html



For more information, contact Elizabeth Jones, Senior Director of Service Delivery Improvement, at ejones@nfprha.org.

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³ If a health center is selected for a 340B audit by the Health Resources and Services Administration (HRSA), much of the audit will take place through chart reviews. As a result, health centers should ensure that all patients' charts accurately and thoroughly reflect how the 340B patient definition is met.