

# **NABP .PHARMACY, LEGITSCRIPT AND ONLINE PHARMACY ACCREDITATION**

APRIL 2, 2021

PREPARED FOR

ALLIANCE FOR PHARMACY COMPOUNDING

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## **NABP .PHARMACY, LEGITSCRIPT AND ONLINE PHARMACY ACCREDITATION**

Over the last several decades, technology has increasingly become a driving force in the pharmacy profession. This is an outgrowth of consumers relying on the internet for many aspects of their daily lives. For example, instead of physically going to class, a student can take an online course. Instead of having a face-to-face encounter with a primary care physician, the encounter can be a real time internet encounter. As an example that is close to home to pharmacies, we are seeing the rise of online pharmacies ... in which patients can receive prescription drugs without ever stepping foot into a pharmacy.

And then COVID hit. Over a 12 month period, in virtually all aspects of daily American life COVID shoved the dependence on technology ahead 10 years. As just one example, CMS and state governmental agencies relaxed many restrictions previously imposed on telehealth. It is likely that most, if not all, of these relaxed restrictions will remain permanent following the pandemic. What this means for pharmacies is that the online business model is here to stay ... and it will grow in importance. As online pharmacies proliferate, the challenge for stakeholders in the pharmacy industry is to maintain quality control and legally compliant operations. A reputable online pharmacy has a valuable role to play in providing health care. Sadly, but not surprisingly, there will be a handful of pharmacies that will try to “game the system” as they enter into the online pharmacy space. The goal of pharmacy stakeholders is to uncover these questionable players and facilitate their departure from the online pharmacy space.

A tool in the pharmacy profession’s toolbox to maintain quality control and legally compliant operations in the online pharmacy space is accreditation. An important goal of accrediting online pharmacies is to distinguish legitimate online pharmacies (that have invested in the technology, qualified personnel and systems in order to maintain a legally compliant operation) from the “fly-by-night” online pharmacies that are only in the business to make quick money.

Here is where the challenge arises. As of today, there are two organizations that accredit (or certify) online pharmacies: (i) NABP .Pharmacy and (ii) LegitScript. Both of these organizations unnecessarily make it difficult for online compounding pharmacies to become accredited. Specifically, both organizations will normally not accredit an online pharmacy that has previously received an FDA Form 483 and/or an FDA Warning Letter. The challenge for online compounding pharmacies is that by virtue of engaging in compounding, they are vulnerable to an FDA inspection. While the FDA does not have jurisdiction over pharmacies that engage in the traditional practice of pharmacy, the FDA *will* assert jurisdiction over pharmacies that the FDA believes may have crossed the line over into manufacturing. If a pharmacy is engaged in more than a small amount of compounding, then the FDA may be inclined to look at the pharmacy’s operations to see if the pharmacy has “crossed that line.” This White Paper will discuss (i) the challenges facing compounding online pharmacies as they seek NABP .Pharmacy accreditation and/or LegitScript certification and (ii) steps to resolve these challenges.

### **NABP .Pharmacy**

#### **What is NABP .Pharmacy?**

NABP .Pharmacy is an accreditation for online pharmacies that allows accredited pharmacies to bear the .pharmacy domain name. This unique domain name lets the public know that the pharmacy is a legitimate business and provides other benefits when advertising and accepting online credit card payments. NABP .Pharmacy accreditation is obtained through the NABP. Applicants must submit an application, pay required fees, and meet regulatory standards for pharmacy licensure.

### **What does it mean when an online pharmacy obtains accreditation from NABP .Pharmacy?**

An online pharmacy that bears a .pharmacy domain demonstrates authenticity to consumers and helps to combat the growing number of rogue websites offering unlicensed pharmacy services.<sup>1</sup> After being reviewed and approved by NABP, a pharmacy receives a .pharmacy active domain name, is added to the verified website list, and is able to use the .pharmacy domain name like a .com or .biz website. Obtaining digital pharmacy accreditation from NABP .Pharmacy automatically allows pharmacies to advertise with Google, Yahoo!, Bing, Snapchat, and Twitter. Further, Mastercard and Visa will consider an accredited pharmacy as a legitimate merchant and allow for “card-not-present” transactions because NABP .Pharmacy verification is a trusted third-party verification program.

### **Does NABP .Pharmacy reject an application for accreditation when the pharmacy has received an FDA Form 483?**

The NABP .Pharmacy Verified Websites Program application includes vetting by the NABP prior to approval of domain registration.<sup>2</sup> The vetting ensures that applicants meet all applicable Program Standards, including regulatory standards and valid prescription requirements. Applicants must demonstrate licensure in good standing and compliance with the laws of the jurisdiction in which they are based as well as all jurisdictions where they conduct business.

Despite the NABP acknowledgement in a June 2020 Resolution that the FDA Form 483 “is not a citation or notice of violation of any law or rule,”<sup>3</sup> entities applying for NABP .Pharmacy accreditation can have an application denied if they have an open Form 483 or an open FDA Warning Letter.<sup>4</sup>

If a pharmacy or its affiliate is subject to an FDA Form 483 and seeks eligibility to apply for a .pharmacy domain name, the pharmacy needs to:

- (a) Hold a “close-out” letter or a status of “Closed” on the FDA’s Registered Outsourcing Facilities page;

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<sup>1</sup> [.Pharmacy Verified Websites | National Association of Boards of Pharmacy \(nabp.pharmacy\)](#)

<sup>2</sup> [Program Eligibility and Policies | .Pharmacy Verified Websites | NABP](#)

<sup>3</sup> [State Pharmacy Boards’ Responses to FDA Form 483 Observations \(Resolution 116-1-20\) - National Association of Boards of Pharmacy \(nabp.pharmacy\)](#)

<sup>4</sup> [Program Eligibility and Policies | .Pharmacy Verified Websites | NABP](#)

- (b) Obtain Drug Distributor accreditation, if eligible, through the NABP; or
- (c) If requested by the NABP, complete a Verified Pharmacy Program (“VPP”) inspection, that will be reviewed by the NABP to determine if the pharmacy currently complies with all NABP .Pharmacy Program Standards.

While the NABP will not automatically reject an applicant for receiving a Form 483 from the FDA, it will require the applicant to undergo additional vetting or accreditation prior to receiving a .pharmacy domain.

### **Does NABP .Pharmacy reject an application for accreditation when the pharmacy has received an FDA Warning Letter?**

If a pharmacy or its affiliate is subject to an FDA Warning Letter and seeks eligibility to apply for a .pharmacy domain name, the pharmacy needs to:

- (a) Hold a “close-out” letter or a status of “Closed” on the FDA’s Registered Outsourcing Facilities page; or
- (b) Obtain Drug Distributor accreditation if eligible, through NABP.<sup>5</sup>

While the NABP will not automatically reject an applicant for receiving a Warning Letter from the FDA, it will require the applicant to obtain drug distributor accreditation prior to receiving a .pharmacy domain. If a pharmacy receives a warning letter, as compared to a Form 483 notice, there are less avenues to obtain the NABP .Pharmacy accreditation.

### **What is the difference between (i) NABP compounding accreditation and (ii) NABP NABP .Pharmacy accreditation?**

The NABP Compounding Pharmacy Accreditation is focused on an applicant’s ability to comply with the United States Pharmacopeia (USP) standards <795>, <797>, and <800>.<sup>6</sup> The Compounding Pharmacy Accreditation is for U.S. licensed pharmacies that actively compound as part of their pharmacy business and:

- Follow the Federal Food, Drug, and Cosmetic Act section 503A requirements;
- Follow USP requirements;
- Compound patient-specific preparations pursuant to prescriptions;
- Primarily compound for human patients; and
- Have successfully completed the NABP prerequisite Verified Pharmacy Program (VPP) inspection and been deemed eligible to apply for Compounding Pharmacy Accreditation.<sup>7</sup>

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<sup>5</sup> *Id.*

<sup>6</sup> [Compounding Pharmacy Accreditation | National Association of Boards of Pharmacy \(nabp.pharmacy\)](https://www.nabp.pharmacy/Compounding-Pharmacy-Accreditation)

<sup>7</sup> *Id.*

By comparison, the NABP .Pharmacy verification is available to a wide variety of pharmaceutical businesses or entities, not just compounding pharmacies. The NABP .Pharmacy verification is available to the following entities if they “offer prescription drugs or prescription drug-related products, services, or information via the internet:”

- Pharmacies (both Human and Veterinary);
- PBMs;
- Schools or Colleges of Pharmacy;
- Continuing Pharmacy Education Providers;
- Wholesale Drug Distributors;
- Pharmaceutical Manufacturers;
- Resource
  - Advocacy or Consumer Education Groups;
  - Drug Information or Pharmacy Referral Sites;
  - Pharmacy Associations;
- Professional
  - Medical Professionals Sites;
  - Pharmacy Consultants;
- Pharmacy Automation Distributors; or
- Boards of Pharmacy and Regulatory Agencies.<sup>8</sup>

### LegitScript

#### **What is LegitScript?**

LegitScript is an accreditation agency that provides services, including compliance and monitoring for health care product merchants and internet pharmacies. LegitScript currently offers accreditation for: (1) health care merchants; (2) pharmacies; (3) telemedicine providers; (4) eyewear merchants; and (5) addiction treatment providers. As part of its routine business practice, LegitScript maintains a database that includes information on whether health care products have been found to contain active pharmaceutical ingredients or have unsafe or misleading information.

#### **What does it mean when an online pharmacy obtains certification from LegitScript?**

LegitScript offers certification that is an indicator to the public that the laws and regulations required for pharmacy licensure are being followed. LegitScript certification is often required by many companies before a pharmacy may become a participating member. For example, certain credit card companies (i.e., Visa and Mastercard) require certification for all pharmacy merchants.

LegitScript is the leading third-party certification expert in complex health care sectors. Many of the world’s leading companies require or recognize LegitScript certification programs in the

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<sup>8</sup> [Program Eligibility and Policies | .Pharmacy Verified Websites | NABP](#)

health care and addiction treatment spaces—including Visa, Google, Bing, Facebook, and Amazon.<sup>9</sup>

### **Does Legit Script reject an application for certification when the pharmacy has received an FDA Form 483?**

There is no specific language on the LegitScript website or in the *LegitScript Healthcare Merchant Certification Terms and Conditions* (“Terms and Conditions”) that specifically states that LegitScript will reject an application for credentialing from an online pharmacy when the pharmacy has an FDA Form 483 pending. However, the Terms and Conditions permit LegitScript, in its “sole discretion,” to “grant, deny, or revoke Applicant’s certification application or certification status for any reason and at any time.”<sup>10</sup>

One of the factors that LegitScript considers when reviewing an applicant is whether the applicant has been subject to Disciplinary Actions. Disciplinary Actions include “suspensions, probationary statuses, reprimands, warning letters, consent agreements, and any communication from any medical board, Board of Pharmacy or other regulatory agency or organization, regardless of jurisdiction.”<sup>11</sup> An FDA Form 483 is likely considered by LegitScript as a Disciplinary Action under the definition of a “reprimand” and/or “communication from ... [a] regulatory agency or organization.”

### **Does LegitScript reject an application for credentialing when the pharmacy has a Warning Letter?**

See previous subsection. An FDA Warning Letter clearly falls within the definition of a Disciplinary Action as a “warning letter.”

## **VIPPS**

### **What is “VIPPS?” How does it relate to NABP .Pharmacy and LegitScript?**

Verified Internet Pharmacy Practice Sites (“VIPPS”) was the precursor to the Digital Pharmacy Accreditation offered by the NABP<sup>12</sup> and a former competing service to LegitScript. VIPPS is no longer an active service.

NABP now offers the “Verified Pharmacy Program” (“VPP”).<sup>13</sup> According to the NABP website, NABP’s VPP program is the most widely recognized multistate, uniform inspection program accepted by state boards of pharmacy across the nation. For pharmacies seeking nonresident licensure, VPP allows state boards of pharmacy to access an NABP pharmacy’s licensure details, VPP inspection report, inspection responses, and other important data through

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<sup>9</sup> LegitScript Certification, LegitScript.com, available at <https://www.legitscript.com/service/certification/>.

<sup>10</sup> *Id.* § IX(h).

<sup>11</sup> *Id.* § IV(d).

<sup>12</sup> [National Association of Boards of Pharmacy Accreditation Application \(nabp.net\)](https://www.nabp.net)

<sup>13</sup> [Verified Pharmacy Program](https://www.nabp.net), NABP.

the use of a secure information sharing network. NABP Compounding Pharmacy Accreditation requires an applicant pharmacy to undergo a VPP inspection.

### **Telemedicine, Telepharmacy and Online Pharmacy Sales**

#### **Distinction among telemedicine, telepharmacy, and online pharmacy sales.**

Telemedicine is the practice of allowing health care professionals to evaluate, diagnose, and treat patients at a distance using telecommunications technology.<sup>14</sup> Telepharmacy is the telemedicine version of pharmacy practice.

Telepharmacy works just like a traditional pharmacy except that the pharmacist supervises technicians, verifies prescriptions, and counsels patients from a remote location. When telepharmacy is practiced, regardless of whether it is in a retail independent setting, a health system, a hospital, etc., there is a pharmacist dedicated to overseeing the operations of the telepharmacy from a host pharmacy. When a patient visits a telepharmacy, he has a nearly identical experience as he does with a traditional pharmacy. The patient visits a brick-and-mortar location, talks to pharmacy technicians, and has immediate access to a pharmacist if he has questions or needs a consultation. Pharmacists practicing telepharmacy can be available in-person at the telepharmacy location for clinical services or appointments.

The process for filling a prescription at a telepharmacy is as follows:

1. A physician prescribes medication for a patient;
2. The patient visits a local brick and mortar telepharmacy;
3. A pharmacy technician fills the prescription with the pharmacist verifying from the host location; and
4. The patient has a private video consultation with the pharmacist, if needed.

An internet pharmacy, also colloquially known as an “online pharmacy,” ships medication directly to patients. The process of filling a prescription by an internet pharmacy is as follows:

1. A physician prescribes medication for a patient;
2. The patient submits the prescription online to the internet pharmacy;
3. The patient has a phone call with a pharmacist, if necessary; and
4. The prescription is delivered to the patient in the mail.<sup>15</sup>

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<sup>14</sup> [“What is Telemedicine,”](#) Chiron.

<sup>15</sup> [The Difference Between Telepharmacy and Internet Pharmacy,](#) Telepharm, Aug. 22, 2019.

When a patient speaks with a pharmacist, the pharmacist is located in one of the internet pharmacy's locations where pharmacists spend their days fielding calls from patients in a queue-based format. Generally speaking, an internet pharmacy is a pharmacy that has transitioned into the "call center" model.

In short, telepharmacy (i) keeps local pharmacies in communities, but (ii) allows pharmacists to expand their reach. From a health, safety and fraud perspective, telepharmacies are generally safer and experience less fraud than online internet pharmacies. Internet pharmacies are a big business that do not have a brick-and-mortar presence in communities. They have also been known to be a popular avenue for the unlicensed sale of medications. On the other hand, when legally operated, internet pharmacies provide a high level of convenience for patients.

### **FDA Form 483**

**An FDA Form 483 documents the inspector's observations. It is not a citation or notice of any rule.**

FDA Form 483 contains the following language: "[Listed observations] are inspectional observations; and do not represent a final agency determination regarding your compliance."

On June 3, 2020, the NABP passed Resolution 116-1-20 that states in part: "FDA Form 483 ... documents the inspector's observations and is not a citation or notice of violation of any law or rule."

**The FDA has no obligation to officially "close out" a 483. After issuing a 483, the FDA can elect not to take any further action.**

The FDA Form 483 lists observations made by the FDA during an inspection. The observations are inspectional only, and do not represent a final agency determination regarding compliance. Following an inspection, the FDA prepares an Establishment Inspection Report ("EIR") of inspection findings. When the inspection is closed, a copy of the final EIR is provided to the pharmacy if no enforcement action is taken.

The inspection is considered closed under the criteria of 21 CFR § 20.64(d)(3):

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, **when a final decision has been made not to take such action** or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney,

or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

Based on the language of the regulation, there is no timeline in which the FDA must make a final decision. A final decision can be pending indefinitely.

**Even though the FDA has no obligation to officially close out a Form 483, there is a mechanism for the FDA to do so.**

See the above discussion. Following an inspection and the issuance of the FDA Form 483, the FDA will prepare an EIR. The EIR may indicate that the agency has made a final decision not to take any further action.

### **Warning Letter**

**An FDA Warning Letter documents the FDA’s observations and conclusions, and requests that remedial steps be taken by the pharmacy. It is not a citation or notice of violation of any rule.**

According to Advisory Actions, 4-1 [FDA Regulatory Procedures Manual](#), March 2020:

“The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency’s principal means of achieving prompt voluntary compliance with the Federal Food, Drug, and Cosmetic Act (the Act).

...

A Warning Letter is informal and advisory. It communicates the agency’s position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.”

**The FDA has no obligation to officially “close out” a Warning Letter. After issuing a Warning Letter, the FDA can simply elect not to take any further action.**

Advisory Actions, 4-1 FDA Regulatory Procedures Manual, March 2020 stands for the proposition that because of the nature of the warning letter as an informal and advisory letter that seeks to achieve voluntary compliance, the FDA can simply elect to not take any further action.

**Even though the FDA has no obligation to officially close out a Warning Letter, there is a mechanism for the FDA to do so.**

The Procedures for addressing a Warning Letter are outlined in the FDA Regulatory Procedures Manual 4-1-8.

Generally, following the issuance of a Warning Letter, the pharmacy that was inspected will have an opportunity to respond. The response may include a discussion of corrective steps taken or a discussion of the pharmacy's disagreement with the Warning Letters findings. The FDA sends a courtesy acknowledgement response after a Response to a Warning Letter is received. When the FDA has verified that the corrective steps detailed in the Response have actually been performed, it will issue a "Warning Letter Close-Out Letter." The verification is normally accomplished through subsequent inspections.

The Close-Out Letter is available for warning letters issued on or after September 1, 2009. Issuance of this letter constitutes a finding that the violations that had previously been identified in the Warning Letter have been addressed by the pharmacy.

### **Steps That Compounding Online Pharmacies Can Take**

The key is for pharmacy stakeholders to educate NABP and LegitScript that receipt by an online pharmacy of an FDA Form 483 and/or an FDA Warning Letter should not be a factor in whether the pharmacy qualifies for (i) NABP .Pharmacy accreditation or (ii) LegitScript certification. The argument to be made by stakeholders is that neither a Form 483, nor a Warning Letter, constitutes a violation. Rather, the (i) Form 483 sets out inspectional observations and (ii) Warning Letter sets out the FDA's observations and conclusions. Form 483 and the Warning Letter are not dispositive of whether the pharmacy's actions are proper or improper. Further, it is difficult and time consuming to "close out" a Form 483 and a Warning Letter. And the FDA may simply decide to take no action to close out the Form 483 and Warning Letter. Said another way, the FDA may decide to leave these two documents open indefinitely.

The educational steps that stakeholders can take may include:

- Sharing this White Paper with the NABP and LegitScript.
- Using this White Paper for background information, writing letters to the NABP and LegitScript.
- Posting information and arguments on multiple websites.
- Conducting multiple webinars/Zoom programs on this topic.
- Scheduling face-to-face meetings with the NABP and LegitScript.