



### Healthcare Questionnaire

These are the questions that merchants are required to answer when applying for LegitScript Healthcare Certification.

#### **Business Information**

- What is your primary motivation to become LegitScript-certified?
- Does your business process card-not-present (CNP) transactions? CNP transactions are transactions in which the physical card is not present. This is sometimes also referred to as "mobile order/telephone order," or "MOTO."
- Please provide the name of each bank or payment provider through which your company has a merchant account.
- Please provide any merchant billing descriptor(s) your company uses. A
  merchant billing descriptor is the name your company shows up as on credit
  card statements.
- How long has your company been in business?
- How would you describe your company? (You will select one or more preset options in the questionnaire.)
- Please provide a short description of your business model.
- If your business opened a new location, closed a location, changed its business name or phone number, or changed its corporate registration within the last five years, please list all previous locations, business names, phone numbers, and corporate registrations.
- If you have a National Provider Identifier (NPI), please list it.

#### Licensure or Registration

If your business currently holds, plans to obtain, or cancelled, or has lost any additional accreditation besides LegitScript certification, please provide a list and the status of each additional accreditation. Examples: VIPPS, .Pharmacy, VAWD, PCAB, URAC, etc. For each accreditation that you have lost, please clarify why.



### LegitScript is trusted, used, recognized, or recommended by:

- Visa
- Mastercard
- Google
- Facebook
- Amazon
- And major global payment service providers!

- Please upload a spreadsheet (from the provided template) with an overview of licensing or registration info that may include:
  - All jurisdictions your company ships, distributes, or provides services to. Please include all states, territories, provinces, and international jurisdictions as applicable.
  - All corporate registrations held by your company. Please include corporate registration numbers for all jurisdictions in which your company holds a corporate registration.
  - For telemedicine providers, please include all physician, pharmacy, and pharmacist licensure as applicable.
  - If applicable: all pharmacy and pharmacist licensure. Please include each pharmacy's name, address, and resident and non-resident license number with expiration dates. Also include each pharmacy's corresponding PIC and the PIC's licensure information with expiration dates.
  - If applicable: all wholesaler licensure information for wholesalers that supply drugs to your company. Please submit license numbers for these wholesalers that show they are licensed to supply drugs to the jurisdiction in which your company is located.
  - If applicable: DEA registration number (or equivalent controlled substances registration in other jurisdictions).
  - If applicable: all physician licensure. Please include each physician's name, all jurisdictions the physician provides consultations in on behalf of your company, resident and non-resident licensure numbers and expiration dates.
  - If applicable: all wholesaler licensure information owned by your company. Please include each facility's name, address, and resident and non-resident license numbers with expiration dates. Also, please include your DEA number, and indicate whether your company is VAWD accredited.
- If you ever had a license, certification, or accreditation application denied, please describe the circumstances.

#### Validity of Prescriptions (for pharmacies only)

- How can prescribers submit new prescriptions to your pharmacy?
- How can patients deliver new prescription orders to your pharmacy?
- How are patients able to receive their prescription medications from your pharmacy?



LegitScript
Certification helps
ensure that you can
fully participate in
online advertising,
e-commerce, and
payment processing
programs.

# Compounding Addendum (for compounding pharmacies only)

- Please estimate what percentage of your total prescription volume consists of non-sterile compounded medication.
- Please estimate what percentage of your total prescription volume consists of sterile compounded medication.
- If your pharmacy does sterile compounding, do you strictly comply with all USP 797 standards?
- If your pharmacy does non-sterile compounding, do you comply with all USP 795 standards?
- Does your pharmacy have written standard operating procedures (SOPs) in place for all compounding activities that are reviewed annually?
- Please provide a list of your top 10 sterile and top 10 non-sterile compounds that you prepare, as applicable, and the indication that each is most commonly used for.
- If the pharmacy uses published information or stability studies to establish the preparations' beyond-use dating, what sources are used?
- Please provide examples of the quality assurance and continuous quality improvement programs that you have in place to ensure the integrity of your compounded products.
- If your pharmacy contracts with an independent lab for analyzing sterility and potency of compounds, which lab do you use and how frequently do you have batches tested for potency and/or sterility?
- What steps does your pharmacy take if a batch of medication is found to have sub-therapeutic potency or is not sterile?
- What methods are used to assess compounding competency, and is training documented (i.e., Gro-Med, broth samples, direct observation)? How often do you re-test your staff?
- Does your pharmacy prepare and ship non-patient-specific compounded prescription medications to another state?
- Please estimate what percentage of your prescription volume consists of nonpatient-specific prescription medication prepared for in-state practitioners/ clinics and what percentage of your prescription volume consists of nonpatien-specific prescription medications that are shipped out of state.
- Are you registered as a 503b outsourcing facility with the FDA?
- If your pharmacy contracts with another facility to compound products that are dispensed by your pharmacy, please provide the name, address, and license number of the compounding pharmacy with which you contract.



Some credit card networks, such as Visa, make certification mandatory for pharmacy merchants, with LegitScript being an industry-recognized certifier.

- If you compound products to be sold over-the-counter, please provide a list.
- If there have been any product recalls or negative patient outcomes related to your compounded products that were reported to your pharmacy in the past year, please describe the incident, as well as any corrective action your pharmacy took.
- If your pharmacy has a policy and procedure for handling patient-reported adverse drug events related to compounded products, please attach it.
- Do you have a process in place to identify all patients that received a recalled medication or API (active pharmaceutical ingredient)?
- If you have been inspected by the FDA, DEA, or other federal regulating body within the past five years, please provide details regarding the visit and any findings they had. Please include any actions you took in response to the audit and any written follow-up or corrective action documentation that you submitted to the auditing entity.
- If you are a 503A compounding pharmacy, are you ensuring that you are only compounding using bulk drug substances that are a components of FDAapproved drug products, the subject of an applicable USP or NF monograph or on the 503A bulk drug substance list?

# Patient Services (for pharmacies and telemedicine providers)

- For pharmacies and telemedicine providers with an internet presence: Does your website display accurate names and contact information for the dispensing pharmacy, pharmacist, or physician(s) engaged in providing medical care?
- For telemedicine providers only: Do you offer a method for patients to contact the physician who prescribed the drug?
- For pharmacies and telemedicine providers: Please upload an image of a sample patient's prescription label showing the pharmacy's contact information.
- For telemedicine providers only: Are the identity and credentials of the prescribing physician disclosed to the patient prior to the provision of care?
- For telemedicine providers only: Please upload a spreadsheet (from the provided template) to help us understand how your telemedicine practice complies with applicable laws and regulations.
  - List every jurisdiction where you provide telemedicine services, including both individual US states and/or countries, as applicable.



Without certification from a recognized entity like
LegitScript, many banks, advertising programs, social media platforms, and e-commerce websites will terminate your account.

- Cite laws and regulations and explain how your telemedicine services comply with the specific laws and regulations of each jurisdiction as they relate to, including but not limited to:
  - Establishing patient-practitioner relationship
  - Patient identification
  - Patient consent
  - Online prescribing
  - Medical records / HIPAA
- If you offer your customers a mobile app, please list all corresponding app store links.

#### **Controlled Substances**

 If your company dispenses, administers, distributes, or manufactures controlled substances, please describe how your company's operating procedures address and minimize the diversion of controlled substances.

#### **Audits and Inspections**

Please upload any available audits or inspections for your company by pharmacy and drug safety regulators, including but not limited to, Boards of Pharmacy, Medical Boards, FDA, DEA, Joint Commission, DNV, etc. for the last five years. Please include any actions you took in response to the audit and any written follow-up or corrective action documentation that you submitted to the auditing entity.

#### **Prior Discipline**

If your company, officers, or employees, including any manufacturer, wholesaler, pharmacy, its pharmacists, and any medical practitioner associated with your company, has been the subject of disciplinary action within the last five years, please describe the events related to the discipline and any corrective actions that have been put in place. Also, please upload any relevant documents. Disciplinary action is defined as any adverse or potentially adverse government or regulatory action related to an applicant's license(s); the dispensing, prescribing, promotion, or distribution of drugs; or the company or its officers. Disciplinary action shall be interpreted broadly and includes suspensions, probationary statuses, reprimands, warning letters, consent agreements, and any other similar regulatory communication from any regulatory agency.



If your company has been subject to any fine or reprimand with regard to financial transaction within the last five years, including fines from the payments industry (e.g., Visa GBPP or Mastercard BRAM fines), or fines from regulators with regard to financial transactions (e.g., wire fraud), please describe the events related to the fine or reprimand and any corrective actions that have been put in place. Please also upload any relevant documents.

#### **Location Information**

If your company directly imports medication, please give a representative sample of the medications that are directly imported. Please also include the name, address and website for the company that supplies the medications.

#### Affiliate Information

- If your pharmacy acts as the contracted dispensing pharmacy for any other company, please provide the name, address, and website for each company.
- Please provide a list of your principals and officers.
- Please list all domain names that are owned or operated by your company or any of its principals. Please note: Failure to provide all domain names will result in a delay of your application.
- Please list all websites you would like to be considered for LegitScript Certification. Note: certification fees are assessed per website. The LegitScript Certification Team will reach out to you if billing adjustments are required.

#### **Domain Name Registration**

- Do any of your domain names use a privacy-protected domain name registration? If so, please remove the privacy protection and make all domain name registrations transparent to avoid processing delays of your application.
- Please list the names and URLs of any entities that produce content for your website.
- If your business has any agreements where a party is compensated for referring business to your company, please provide the name of the party or affiliate network, and a URL if applicable. Example: Your company is associated with an affiliate marketing network.



#### **Transparency**

- If your primary website is currently under construction or in a stage of development in which you anticipate significant changes in the near future, please describe when you anticipate the changes to be completed and when LegitScript will be able to review a version of this website before it is published. Please note: LegitScript cannot certify a website that is under construction or in an unfinished form, and this will delay the application process.
- If your website features an area where a patient or other user must sign in, please provide any necessary credentials LegitScript will need to access it.

#### Privacy

- Does your website transmit protected health information, as defined by HIPAA?
- If your Privacy Statement is available online, please provide a link to this document.

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