

Healthcare Certification Application Checklist: Spain

We are excited to offer telemedicine providers in Spain the opportunity to participate in LegitScript's Healthcare Certification program, now recognized by Google. Achieving this Certification demonstrates your commitment to compliance and transparency, opening up new advertising opportunities for your services.

Please review the checklist below to help prepare for the application process. As you navigate through the checklist, remember that we are here to help and support you. We highly encourage you to review our [Certification Standards](#), [Terms & Conditions](#), and program [FAQs](#) for a comprehensive understanding of our requirements.

If you have any questions about the certification process or need further assistance, our team is here to help you make this as easy as possible. Please do not hesitate to reach out to us at certification@legitscript.com.

Thank you for choosing LegitScript—we look forward to partnering with you every step of the way on your path to certification!

Licensure and Registration

- ☐ Ensure that your active [business registration](#) information is accurately reflected on the LegitScript [Licensure Template](#).
 - ☐ If you provide direct telemedicine services as a Physician or Nurse, please ensure that you fill out the medical provider name, license number, and credential as can be found on the [State Registry of Health Professionals](#) (Consulta Pública de Profesionales Sanitarios), or [CODEM Register of Members](#) (Registro de colegiados) if applicable, on the "Prescribers" tab in the LegitScript [Licensure Template](#).
 - ☐ If your business involves the prescribing of medication in-person or via telemedicine, please include your business' autonomous authorization code in the business registration section of

the [Licensure Template](#), or any other relevant information that will enable us to verify your business is licensed as a [Health Center](#) (Centros de salud).

- ☐ If your entity is a pharmacy, please fill out the “Pharmacy” tab of the [Licensure Template](#). When completing this section, please indicate the specific Autonomous Community College of Pharmacists (Colegios Oficiales de Farmacéuticos) your license was issued by.
- ☐ If your entity is a pharmacy, please ensure that all pharmacist information is clearly provided in the “Pharmacy” tab of the [Licensure Template](#), such as the name, membership number, locality, or school of your respective pharmacists.
- ☐ If your entity is a pharmacy engaged in distance selling (venta a distancia), please notate as such and disclose what autonomous community (comunidad autónoma) your pharmacy holds distance selling licensure in under the “Pharmacy” tab of the [Licensure Template](#).

Telemedicine

- ☐ If you offer telemedicine services, please fill out the “International Applicants” tab within our [Telemedicine Compliance Spreadsheet](#). Make sure to specify if your telehealth providers are located in Spain or in any other jurisdiction outside of Spain in this document.
- ☐ If you offer telemedicine services, please ensure that you are adhering to all requirements related to providing telemedicine issued by relevant regulatory authorities.
- ☐ If you offer telemedicine consultations with prescribing doctors or nurses, please ensure that you are compliant with all relevant regulations pertaining to medical providers prescribing via online consultations. This includes [the Spanish Code of Medical Ethics](#) (Código de Deontología Médica), and ensuring telemedicine consultations meet the same standards as face-to-face care.
 - ☐ If you utilize providers located outside of Spain to serve Spanish patients, please ensure you explain your compliance with the regulations in the respective country your providers are physically located in in the telemedicine compliance spreadsheet.

Pharmacy

- ☐ If you offer pharmacy or medication compounding services, please ensure that you are adhering to all pharmacy and/or compounding requirements issued by relevant regulatory authorities.
 - ☐ If your business compounds medications, please fill out all applicable sections of the [Compounding Addendum](#). Please mark any areas in the compounding addendum that are specific to the US as N/A.
 - ☐ Please be prepared to provide copies of any relevant audits or inspections of your pharmacy conducted by the autonomous community in which you operate.

Partner Requirements

- ☐ Did you know all “partners” are required to be certified through LegitScript?
 - ☐ Partners are defined as organizations essential to supporting the applicant’s continuum of care, such as partner pharmacies responsible for the fulfillment of prescription medication to patients. You can learn more about Affiliates and Partners within LegitScript’s [Certification Standards](#).
- ☐ Have you searched and verified your partner’s LegitScript certification status [here](#)? Is your partner classified as “Certified”? If yes, great! Please be ready to present evidence of the partnership.
 - ☐ If not, please confirm they are ready and willing to apply for their own certification.
 - ☐ Pharmacies and medical providers partnered with applying merchants who are not LegitScript-certified must submit their own application for LegitScript certification within sixty days after the applicant’s own certification, should they achieve it. Please note that the outcome of their compliance review may affect your own certification, if there is an active partnership. For more information surrounding the healthcare application process, see [here](#).

Legal Compliance

- ☐ Make sure your website’s language and product offerings follow national laws and regulations with regard to medicines and/or health services.
 - ☐ Advertising of prescription-only medications on websites or social media is prohibited under [Real Decreto 1416/1994](#).
 - ☐ If your business prescribes or dispenses medications that have not received prior authorization from the AEMPS or the European Commission, please be prepared to demonstrate how your prescribing or dispensing of these unapproved substances follows one of the special situations outlined in [Real Decreto 1015/2009](#).
 - ☐ If your business offers non-drug health products like personal care products, cosmetic products, or homeopathic medicinal products, please be prepared to demonstrate these products are authorized to be sold in Spain, such as demonstrating personal care products have received [marketing authorization](#) or that the manufacturer of the cosmetic products offered by your business has been certified by the [AEMPS](#).
 - ☐ Has your business or one of your principals been subject to discipline within the last five years? Has your business had any licenses or certifications that were lost, revoked, or not renewed? Has your business had to recall products?
 - ☐ Please provide evidence/documentation detailing this discipline, and to support any disciplinary action resolutions. You may wish to reference LegitScript’s [Terms & Conditions](#) for examples of Disciplinary Action.

Patient Services

- ☐ Have you ensured your products and services are up-to-date with regulatory requirements?
 - ☐ Websites must make the following information accessible to users of their website as outlined by the [LSSI-CE](#), including your:
 - ☐ Corporate Entity Name
 - ☐ Physical Address
 - ☐ Contact Methods
 - ☐ Tax Identification Number (NIF/CIF)
 - ☐ Regulatory & Registration Data (Details of registration in the Commercial Registry (Registro Mercantil) or any other applicable public registry)
 - ☐ Professional Designations (professional association (colegio profesional)), collegiate number, and applicable ethical rules for your regulated profession)
- ☐ Have you confirmed that all website and social media advertising is in compliance with Spanish General, Physician, and Medicine Advertising regulations like [Ley 34/1988](#), [Ley 3/1991](#), [Real Decreto Legislativo 1/2015](#), [Real Decreto 1416/1994](#), and [Ley 44/2003](#)? These regulations outline various requirements for advertising healthcare products and services such as:
 - ☐ Prohibiting Acts of Deception, such as providing misleading or false information regarding the existence, nature, or characteristics of goods and services;
 - ☐ Ensuring all advertisements and promotions regarding healthcare providers is accurate and scientifically sound, and that the provider is properly identified in any advertisement; and
 - ☐ Prohibiting the advertisement of prescription drugs, as well as promoting medicines in various ways such as promoting medicines for athletic performance enhancement, stating a medicine has received health authorization, or making claims regarding medicines in relation to diseases like cancer, tuberculosis, and sexually transmitted diseases.

Transparency

- ☐ Is your website still under development/expecting updates? Please be prepared to provide LegitScript with a staging site or wireframes/screenshots and the expected timeframe of completion.
- ☐ If applicable, please create a test patient account and provide us with a username and password to access your patient/client portal.
- ☐ Please be prepared to provide us with a list of all jurisdictions your business serves, including any jurisdictions outside of Spain.

Affiliates

- ☐ Ensure affiliates or affiliations with your business are compliant and operating legally. This includes, but is not limited to: co-owned businesses of the business' owners or principals, supplying wholesalers or distributors, partner pharmacies/provider networks, and marketing or promotional partners.
 - ☐ Common barriers can include affiliations with entities offering unapproved medicines, and website/social media advertising featuring impermissible claims or ingredients.
- ☐ Please be reminded that all [applicable](#) in-scope business models utilized/promoted on the submitted domain must be approved by LegitScript, per our [Terms & Conditions](#).
- ☐ Does your platform promote/link to a third-party telemedicine provider partner or partner pharmacy? If so, the promoted URL is subject to the partner requirements listed within the "Partner Requirements" section of this document.

Questions? Email our team at certification@legitscript.com