Regulatory Changes and Telehealth Pharmacy Practice

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ABSTRACT— Telehealth pharmacy matured rapidly during and after the COVID-19 public health emergency (PHE), and the rules that govern it have shifted almost as quickly. This manuscript synthesizes recent regulatory changes (2020–2025) that shape how pharmacists and pharmacist-prescribers deliver care at a distance, with emphasis on prescribing authorities, remote supply/dispensing, cross-border e-prescriptions, privacy/security, and reimbursement. Using a comparative policy analysis of primary sources from national regulators and boards, we map converging trends: (1) a move from broad pandemic flexibilities to targeted, risk-based safeguards (for example, the United Kingdom's 2025 distance-selling guidance and additional controls for high-risk medicines); (2) incremental normalization of telemedicine prescribing for controlled substances in the United States via extended flexibilities through 2025 and DEA proposals for "special registration"; (3) government-led infrastructures for e-prescriptions and summaries in the European Union; (4) codification of telemedicine rules in India that enable pharmacist-supported teleconsultation ecosystems; and (5) expanded emergency and electronic prescribing frameworks in Australia and the ongoing use of national model standards in Canada.

We translate these shifts into practice implications for community, hospital, and online pharmacy operations—covering clinical governance, documentation, identity and suitability checks, remote supervision, cross-jurisdiction workflows, and payer policy alignment. Finally, we propose a practicable compliance-by-design framework that pharmacies can operationalize now to remain lawful, safe, and equitable as telehealth pharmacy moves from extraordinary to ordinary care.

KEYWORDS

telepharmacy, telehealth prescribing, online pharmacy, controlled substances, e-prescription, regulatory compliance, HIPAA/GDPR, pharmacist prescribers, remote dispensing, health policy

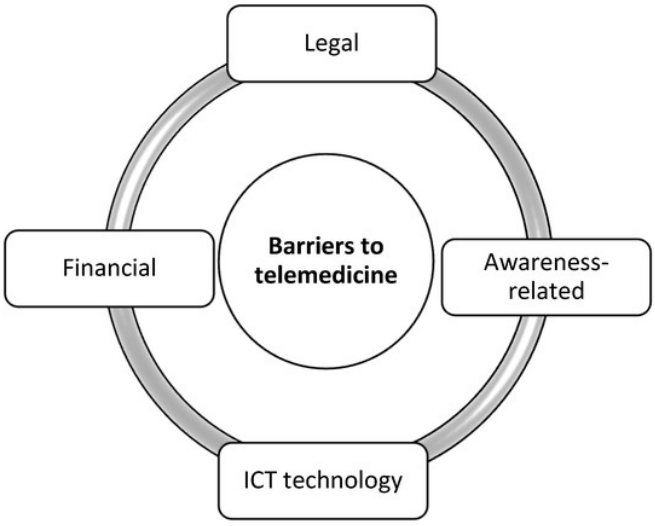

Fig.1 Telehealth Pharmacy Practice,Source([1])

INTRODUCTION

Telehealth pharmacy—encompassing remote clinical services by pharmacists, electronic prescribing, and the distance sale/supply of medicines—moved from niche to mainstream in just a few years. Pandemic-era permissions accelerated adoption, but regulators have since pivoted from blanket waivers toward durable, risk-based rules that seek to preserve access while strengthening patient safety and oversight. For pharmacists, this means adapting to a patchwork that includes national statutes, professional standards, payer rules, and technology requirements.

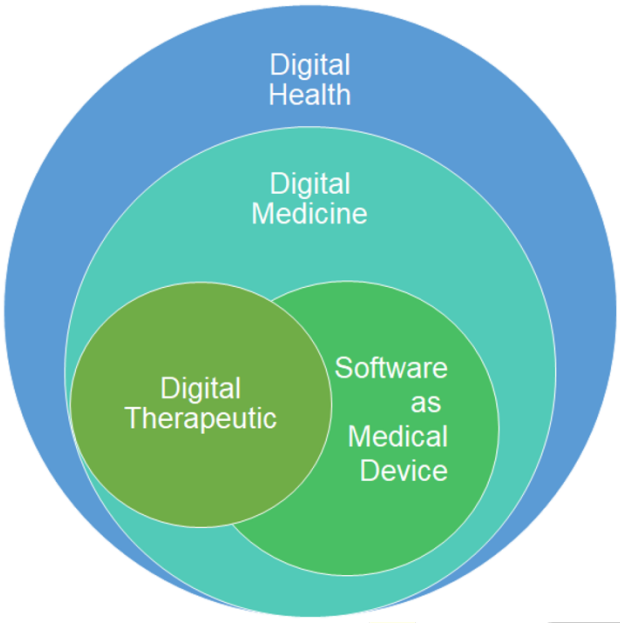

Fig.2 Regulatory Changes and Telehealth Pharmacy Practice,Source([2])

Three questions now dominate practice: (1) **What can be prescribed via telemedicine, and under what safeguards?** (2) **How should pharmacies verify identity, suitability, and clinical appropriateness when services are delivered online or across borders?** and (3) **What documentation, privacy, and reimbursement rules apply?** Recent actions by the US Drug Enforcement Administration (DEA), the UK General Pharmaceutical Council (GPhC), EU eHealth programs, India's Telemedicine Practice Guidelines, and Australian PBS arrangements illustrate the trajectory from emergency flexibility toward structured permanence. (DEA, telehealth.hhs.gov, assets.pharmacyregulation.org, Community Pharmacy England, Public Health, PMC, pbs.gov.au)

Literature Review

United States

During the PHE, federal agencies allowed broader telemedicine prescribing, including for controlled substances; these flexibilities have been extended through **December 31, 2025**, maintaining access while the DEA worked on longer-term rules. In January 2025, the DEA announced a triad of telemedicine rulemakings, including **proposed special registrations** to let eligible clinicians prescribe certain Schedule III–V medications without an initial in-person exam, subject to conditions. Complementary HHS guidance clarifies HIPAA compliance for telehealth, including audio-only scenarios, and CMS's **CY 2025 Physician Fee Schedule** sustains expanded telehealth categories and coding specifics through 2025 (with payment rate adjustments). Collectively, these changes steer practice toward persistent telehealth with tighter documentation and technology expectations. (Axios, DEA, jonesday.com, HHS.gov, cms.gov)

State boards meanwhile interpret and implement telepharmacy (remote verification, remote dispensing sites, and automated systems) unevenly. NABP has been updating its Model Act sections on shared services and telepharmacy to promote harmonization, but state variability remains a planning constraint for multi-state operators. (NABP)

United Kingdom

In **February 2025**, the GPhC issued updated guidance for **"pharmacy services at a distance (including on the internet)"**, strengthening safeguards for identity/suitability checks, prescriber collaboration, and particularly the supply of higher-risk medicines (e.g., weight-management injections). The GPhC also refreshed guidance for **pharmacist prescribers** in **April 2025**, adding online-specific safeguards. In parallel, the Nursing and Midwifery Council (NMC) required **face-to-face consultation** before remote prescribing of non-surgical cosmetic medicines from **June 1, 2025**, underscoring a trend toward higher scrutiny of elective indications in telehealth contexts. (assets.pharmacyregulation.org, Community Pharmacy England, nmc.org.uk)

European Union

The EU's **MyHealth@EU** infrastructure is scaling **cross-border ePrescription** exchange and patient summaries—allowing EU citizens to obtain medicines in another member-state pharmacy using an electronic prescription. The European Court of Auditors and Commission updates

highlight ongoing roll-out and the ambition to broaden the shared data set to lab results and images. Telepharmacies operating near borders or serving mobile populations must therefore align with eID, data protection (GDPR), and dispensing validation requirements across jurisdictions. (Public Health, European Court of Auditors)

India

India's **Telemedicine Practice Guidelines (2020)** provide the legal backbone for teleconsultation by registered medical practitioners and indirectly structure pharmacist-supported telehealth pathways (e.g., e-prescriptions following teleconsultation). Recent legal analyses note the government's integration of telemedicine into public health via platforms like **eSanjeevani**, reinforcing remote access without dismantling core prescribing/dispensing controls. (PMC, Nishith Desai Associates)

Australia

Australia has iteratively refined **electronic prescribing** and **continued dispensing** arrangements (supply without a prescription in defined circumstances), with 2025 updates emphasizing disaster-response flexibility and emergency measures for affected regions. National resources explain "owing prescriptions" and pharmacist obligations to secure prescriber follow-up and maintain compliance with state/territory poisons laws. (digitalhealth.gov.au, pbs.gov.au)

Canada

Canada relies on national **model standards** (NAPRA) that provincial/territorial authorities adopt or adapt, providing a harmonized foundation for pharmacist practice—including telepharmacy-relevant domains such as documentation, professional judgment, quality assurance, and delegation/supervision. Telepharmacy specifics remain provincial in detail, but the NAPRA standards act as the baseline reference for safe practice. (NAPRA)

Cross-cutting Themes

Across these jurisdictions, the literature and regulatory outputs converge on: (1) **risk stratification** of medicines (tightened oversight of high-risk categories), (2) **identity and suitability checks** that go beyond forms to include video or verified records where appropriate, (3) **data protection and secure technologies** compatible with HIPAA/GDPR, (4) **documentation and auditability** as routine, and (5) **payment policy normalization** that cements telehealth as a standard modality rather than an exception. (assets.pharmacyregulation.org, HHS.gov, cms.gov)

METHODOLOGY

We conducted a comparative policy analysis using a structured scoping approach:

1. **Sources and timeframe.** Primary regulatory texts, professional standards, and official policy summaries published **2019–2025** by US DEA/HHS/CMS, UK GPhC/NMC, EU Commission/eHealth, India's national guidance, Australia's Department of Health/PBS, and Canada's NAPRA. Where appropriate, reputable news analyses were incorporated to contextualize imminent or proposed changes (e.g., DEA and UK updates). (DEA, telehealth.hhs.gov, cms.gov, assets.pharmacyregulation.org, Public Health, PMC, pbs.gov.au, NAPRA)

2. **Inclusion criteria.** Documents had to (a) materially affect telehealth pharmacy practice (prescribing, supervision, supply, documentation, privacy, or reimbursement); (b) be nationally authoritative or issued by a statutory professional regulator; and (c) be current as of **August 18, 2025**.

3. **Extraction and coding.** Two passes of manual coding captured: **authorization** (what's allowed), **conditions/safeguards**, **technology requirements**, **professional accountability**, **cross-border issues**, and **payer rules**. A third pass identified **practice implications** for community, hospital, mail-order/online, and hybrid models.

4. **Limitations.** The analysis focuses on national/UK-GB-level frameworks and selected state-level signals (e.g., NABP Model Act updates). It does not catalogue every state or provincial rule, and it relies on official summaries where the primary legal text is lengthy. Payment policies were reviewed at a high level; private payer variation is outside scope.

RESULTS

1) Prescribing and Controlled Substances (US)

Access maintained, structure emerging. The United States preserved pandemic-era flexibilities through **December 31, 2025**, allowing certain controlled substances to be prescribed via telemedicine without a prior in-person exam when conditions are met. In **January 2025**, the DEA outlined **three new telemedicine rules**, including a **special registration** pathway that—once finalized—would provide a lasting mechanism for telemedicine-only relationships to support Schedule III–V prescribing (e.g., for behavioral health), paired with monitoring and verification duties. Pharmacies receiving such e-prescriptions must be prepared for stronger audit trails, prescriber registration checks, and coordination on PDMP use and red-flag resolution. (Axios, DEA, jonesday.com)

Practice takeaways.

- Build workflows to **capture prescriber eligibility** (including any special registration) and **document due diligence** (identity, clinical indication, red-flag review).
- Ensure **EPCS** systems are configured for telemedicine-initiated scripts and that staff can reconcile temporary-flex prescriptions vs. post-2025 frameworks.

2) Distance-Selling & High-Risk Medicines (UK)

The **GPhC's February 2025 guidance** strengthens expectations for pharmacies providing services at a distance (including online): rigorous **identity/suitability checks**, clear arrangements with prescribers, and **additional safeguards** for high-risk medicines. Public statements contextualize these updates with concerns around inappropriate supplies (notably **weight-loss injections**), pushing pharmacies to move beyond passive questionnaires to proactive verification (video, validated clinical records). The **April 2025** update for **pharmacist prescribers** complements this with online-specific requirements. (assets.pharmacyregulation.org, Pharmacy Regulation Authority, Community Pharmacy England)

Practice takeaways.

- Implement **tiered checks**: passive forms for low-risk items; **live/video** or record-verified assessments for higher-risk requests.
- Maintain **documented clinical reasoning** and communication with the patient's regular prescriber, with consent.

3) Cosmetic Medicines and Remote Prescribing (UK NMC)

From **June 1, 2025**, the **NMC** requires a **face-to-face consultation** before prescribing non-surgical cosmetic medicines remotely, signaling a stricter posture for elective indications while not directly restricting medically necessary teleprescribing. Pharmacies partnering with aesthetic providers must hard-stop online orders without verified in-person assessment. (nmc.org.uk)

4) Cross-Border ePrescriptions (EU)

Through **MyHealth@EU**, more member states are exchanging **ePrescriptions** and **patient summaries**, enabling EU citizens to fill medications in pharmacies abroad. Telepharmacies near borders should align stock management and dispensing systems with **eID/eSignature** verification and **GDPR-compatible** data flows. Expansion plans include labs and imaging over time, which will further integrate pharmacists into cross-border care pathways. (Public Health, European Court of Auditors)

5) Telemedicine Governance (India)

India's **2020 Telemedicine Practice Guidelines** legitimize remote consultations by registered medical practitioners and clarify modes (text, audio, video), forming the upstream precondition for lawful e-prescriptions that pharmacies dispense. Expansion via **eSanjeevani** means more prescriptions originate in teleconsults; pharmacies must retain prescription authenticity checks and counsel patients on the same duty-of-care standards as in-person care. (PMC, Nishith Desai Associates)

6) Emergency Supply & Electronic Prescribing (Australia)

Australia maintains and updates **electronic prescribing** resources and **continued dispensing** policies, including **2025 emergency measures** for disaster-affected regions. Pharmacists can supply certain medicines without an immediate prescription under defined conditions and must secure an **owing prescription** within timelines per state law. Telehealth providers and pharmacies need clear SOPs to toggle between normal and emergency regimes. (digitalhealth.gov.au, pbs.gov.au)

7) Model Standards and Provincial Adoption (Canada)

NAPRA's Model Standards of Practice (2022) remain the national reference adopted/adapted by provincial regulators. While not a telepharmacy rulebook per se, the standards mandate patient-centred care, documentation, and quality systems that underpin remote practice. Operators spanning multiple provinces should map telepharmacy-specific bulletins and bylaws to these shared foundations. (NAPRA)

8) Privacy, Security, and Technology (US focus; EU parallels)

US OCR guidance clarifies how **HIPAA** rules apply to **audio-only telehealth** and other remote modalities when PHE enforcement discretions have expired, emphasizing secure technology selection, identity verification, and minimum necessary disclosures. EU pharmacies must maintain **GDPR** compliance, especially when processing cross-border ePrescription data or offering online counseling across jurisdictions. (HHS.gov)

9) Reimbursement Signals (US Medicare)

CMS's **CY 2025 PFS** continues key telehealth flexibilities and coding guidance for this year, though with conversion-factor reductions that affect revenue planning. Educational materials emphasize correct coding of audio-only vs. audio-video and patient-home services—details that shape telepharmacy-adjacent pharmacist services (e.g., MTM via telehealth). (cms.gov)

DISCUSSION

Practice Implications

From flexibility to fidelity. Regulators are converging on a **safety-first** approach that preserves access while increasing expectations for **identity, suitability, and longitudinal care coordination**. UK changes exemplify graduated safeguards for higher-risk medicines, while US proposals seek durable frameworks for telemedicine prescribing of controlled substances with identifiable, auditable prescribers. EU initiatives normalize cross-border dispensing with electronic validation, and India/Australia/Canada demonstrate that national frameworks can scale remote access without diluting accountability. (assets.pharmacyregulation.org, DEA, Public Health)

Operational priorities for telehealth pharmacies:

1. **Credentialing & Prescriber Assurance.** Verify prescriber authority for telemedicine scripts (e.g., US special registration status when finalized), retain proof in the dispensing record, and embed **PDMP**/red-flag workflows for controlleds. (DEA)
2. **Tiered Patient Verification.** Adopt **risk-based identity checks**: low-risk repeats may rely on verified demographics; high-risk initiations should require **video consultation** or validated clinical records, mirroring UK expectations. (assets.pharmacyregulation.org)

3. **Cross-Border Readiness.** Where applicable, implement **eIDAS-compatible** signature verification and multilingual counseling scripts for EU ePrescription flows; maintain **GDPR** records of processing. (Public Health)

4. **Privacy-by-Design.** Align technology stacks with HIPAA/GDPR guidance, especially for audio-only or mobile-first consults, and document security risk assessments. (HHS.gov)

5. **Billing Accuracy.** Update telehealth coding and place-of-service logic (US) to reflect current CMS rules through 2025; monitor payer bulletins for changes beyond Medicare. (cms.gov)

6. **Emergency SOPs.** Maintain playbooks for disasters (e.g., **continued dispensing**, **owing prescriptions**), including communication pathways with prescribers and inventory controls. (pbs.gov.au)

7. **Quality & Audit.** Map local SOPs to national model standards (e.g., **NAPRA** in Canada; **NABP** Model Act elements in the US) and regulator guidance (e.g., **GPhC**), with routine audit cycles. (NAPRA, NABP)

Conclusion

Telehealth pharmacy has transitioned from emergency improvisation to **regulated normalization**. The broad arc is clear: continued access to remote care, tempered by **stronger safeguards** where risk is higher, and reinforced by **interoperable data infrastructures** (e.g., EU cross-border eRx). The **United States** preserves access through 2025 while crafting durable rules (including special registrations) for controlled substances in telemedicine. The **United Kingdom** has added targeted protections for high-risk medicines and clarified expectations for pharmacist prescribers online, while **India**'s national guidelines and **Australia**'s prescribing/continued-dispensing arrangements embed telehealth in routine systems. **Canada**'s model standards buttress provincial regulation with consistent expectations for professional judgment and quality.

For practitioners, the path forward is pragmatic:

- **Compliance-by-design:** Bake regulator expectations into the software and workflow—ID/suitability controls, eligibility checks for prescribers, dynamic consent, and automated audit trails.
- **Risk-tiered clinical governance:** Escalate verification and counseling intensity with medicine risk and clinical complexity; formalize collaboration with the patient's usual prescriber.
- **Interoperability:** Prepare dispensing and record systems for cross-border eRx verification and shared summaries where relevant, and maintain privacy compliance (HIPAA/GDPR).
- **Education & reimbursement alignment:** Train teams on the latest coding/coverage and on jurisdiction-specific nuances; forecast revenue impacts of PFS changes and private payer policies.
- **Resilience:** Keep emergency SOPs current for disasters and supply chain disruptions, including clear "owing prescription" and continued-dispensing protocols.

Telehealth pharmacy's next phase is **not** a return to pre-pandemic limits but a maturation into **safer, more auditable, and more equitable** remote care. Pharmacies that invest in documentation rigor, identity assurance, prescriber collaboration, and secure technology will be best placed to deliver on telehealth's promise while staying comfortably inside the regulatory guardrails. (DEA, assets.pharmacyregulation.org, Public Health)

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