Identomat

COMPLIANCE GUIDE

Healthcare Compliance in France

COUNTRY France

INDUSTRY Healthcare

LAST UPDATED 29 October 2026

KEY REGULATORS Ministère de la Santé · Agence du numérique en santé · Commission nationale de l'informatique et des libertés

Key takeaways

- Telehealth is lawful and mainstream in France: a doctor may consult, prescribe and follow up a patient remotely, provided every remote act authenticates the clinician and identifies the patient.
- A company that employs doctors to deliver teleconsultations needs ministerial approval, renewed every two years, before the public health insurer will pay for those consultations, and its software must hold a certificate of conformity from the national digital health agency.
- Online rules are stricter than in-person rules: since 27 June 2026 a remote doctor may issue only a first sick note of up to three days and no further renewals, and an online service may prescribe only after a live video or phone exchange, never on a questionnaire alone.
- Patient identity is anchored to the National Health Identity (Identité nationale de santé, INS), which may be used to file health data only after the identity has been checked against an original passport, identity card or residence permit, or an eIDAS "substantial" or "high" digital identity, and confirmed through the national INSi teleservice. Remotely, a patient may instead show the original document to the camera; an uploaded copy is not enough.
- Healthcare providers are not covered by France's anti-money laundering rules; identity duties come from the Public Health Code, data protection law and health-sector security standards. Anyone hosting patient data for others needs health data hosting certification, which since 16 May 2026 requires storage in the European Economic Area.

The French market is open to digital health services, but it is regulated by profession and by channel rather than by a single licence. Clinicians remain bound by their professional orders; telemedicine acts must meet the conditions of the Public Health Code; companies that bill the public health insurer for teleconsultations need ministerial approval; and anyone hosting patient data for others needs a health data hosting certificate.

The principal authorities are the Ministry of Health, which approves teleconsultation companies, the Agence du numérique en santé, which writes and certifies the binding interoperability and security frameworks, and the CNIL for health and biometric data. For a new entrant the biggest obstacle is the approval route: model validation by the ministry, a certified information system and a two-year renewal cycle.

CONTENTS

1 Who regulates this sector
2 Licensing and authorisation
3 Identity framework (AML rules do not apply)
4 Identity verification and onboarding
5 Digital channels: what's different
6 Data protection and biometrics
7 Sector-specific obligations
8 Risk indicators and red flags
9 Enforcement and penalties
10 Recent changes and what to watch
11 What this means for identity verification
- Sources

1 Who regulates this sector

Authority	Remit relevant to digital health	Level	Official site
Ministère de la Santé (with the minister for social security)	Approves teleconsultation companies (art. L4081-1 CSP) and validates their model before certification	National	sante.gouv.fr
Agence du numérique en santé (ANS)	INS doctrine, Pro Santé Connect, teleconsultation information-system framework and its certification desk	National	esante.gouv.fr
Haute Autorité de santé (HAS)	Good-practice guides on teleconsultation, tele-expertise and telecare	National	has-sante.fr
Commission nationale de l'informatique et des libertés (CNIL)	Health and biometric data, sector frameworks, fines	National	cnil.fr
Conseil national de l'Ordre des médecins (CNOM)	Medical ethics and discipline, including telemedicine platforms	National	conseil-national.medecin.fr

Ordre national des pharmaciens	Publishes the list of authorised online pharmacy websites (art. R5125-74 CSP)	National	ordre.pharmacien.fr
Agence nationale de sécurité du médicament (ANSM)	Medicines safety, public information on buying medicines online	National	ansm.sante.fr
European Union	GDPR; European Health Data Space Regulation (EU) 2025/327	Supranational	eur-lex.europa.eu

Regional health agencies receive the prior declaration of online pharmacy websites (art. L5125-36 CSP).

2 Licensing and authorisation

There is no general "telehealth licence". Registered health professionals practise remotely under the Code de la santé publique (CSP): article L6316-1 defines telemedicine, R6316-1 lists its five acts (teleconsultation, tele-expertise, remote monitoring, remote assistance and emergency regulation) and, under R6316-2, the clinician decides whether a remote act is appropriate.

Teleconsultation companies

A company that employs doctors may claim public health insurance coverage for their teleconsultations only with approval from the ministers for health and social security (art. L4081-1 CSP). It must be a commercial company not controlled by a supplier of medicines or medical devices, and its tools must meet the GDPR and the frameworks in L1470-5 (L4081-2); several doctors require a medical committee with patient representatives (L4081-3).

Under D4081-1 (décret 2026-626, in force since 13 July 2026) the application is electronic and includes the SIRET number, the planned medical organisation, the legal representative's commitments and the ANS certificate for the teleconsultation information system. Ministers decide within four months; approval lasts two years, substantial changes must be notified within one month, and renewal also depends on the quality framework in L161-37 22° CSS (L4081-4 CSP).

Health data hosting and online pharmacy

Anyone hosting personal health data for others needs a certificate from an accredited body (art. L1111-8 II CSP); taking data briefly to enter or digitise them is not hosting (R1111-8-8). Version 2.0 of the health data hosting (HDS) framework, published on 16 May 2024, requires storage exclusively in the European Economic Area and disclosure of any remote access from outside the EU; existing hosts had until 16 May 2026 to recertify. Selling identifiable health data is prohibited (L1111-8 VII). Online sale of medicines is reserved to a community pharmacy's own website (L5125-33), limited to non-prescription medicines (L5125-34) and declared in advance to the regional health agency (L5125-36); the Ordre national des pharmaciens listed 869 authorised sites on 28 October 2026.

3 Identity framework (AML rules do not apply)

Healthcare providers, telehealth platforms and doctors are not obliged entities under France's anti-money laundering regime: article L561-2 of the Code monétaire et financier (version in force since 5 August 2026) lists credit, payment and insurance institutions and certain professions, but no health professions or care providers. Customer due diligence, beneficial ownership checks and reporting to Tracfin therefore do not apply to care activity.

Identity obligations come instead from three health-sector layers:

Telemedicine conditions

Every telemedicine act or telecare activity must guarantee authentication of the professionals, identification of the patient and access to the health data needed (art. R6316-3 CSP).

National Health Identity

The NIR (social security number) is the health identifier for care (art. L1111-8-1 CSP). ANS doctrine requires all health data to be referenced with the INS since 1 January 2021, once the INS is qualified.

Professional identity

Clinicians authenticate to national digital health services through Pro Santé Connect with a CPS smart card or the e-CPS mobile app; connection has been mandatory for national services since 1 January 2023.

4 Identity verification and onboarding

The INS combines the INS number (the person's NIR, or a temporary NIA) with five identity traits: birth surname, birth first names, date of birth, sex and place of birth. Under the ANS INS doctrine, an INS may reference health data only once "qualified": identity validated with a high-confidence means under the national identity-vigilance framework (RNIV 1), and the INS retrieved or checked through the INSi teleservice. The INS framework in force is version 2.0 (arrêté of 13 December 2024).

RNIV 1 (version 2.0, December 2024) accepts: for French nationals, an identity card or passport; for nationals of the EU and certain other countries, a passport, identity card or residence permit; for others, a passport or residence permit; and eIDAS "substantial" or "high" electronic identification, such as the electronic identity card, La Poste's digital identity or the Carte Vitale app. A paper or digital copy without the original cannot validate an identity. Only a "qualified" identity (INS retrieved through INSi and identity validated) may be used in data exchanges.

For a patient who is not physically present, RNIV 1 (section 4.9.4) names telehealth acts and online booking or pre-admission portals as uses for an eIDAS "substantial" or "high" identification means, which can create or upgrade an identity to "validated". Where such a means cannot be used remotely, the patient may be asked to show the identity document to the camera so that the professional can check it and carry out the coherence check. Identity checks still apply when the patient is later seen in person.

The HAS teleconsultation guide (May 2019) applies R6316-3: the identity check is traced, the patient must be able to show photo ID on request, the clinician knows the patient's exact location and phone number and uses two-factor authentication, and consent to the remote format is recorded.

The Carte Vitale app as a remote identity route

Issuing the Carte Vitale app requires remote identity verification (art. R161-33-13 Code de la sécurité sociale): an electronic identity card used with the State's digital identity guarantee service (SGIN, created by décret 2022-676, the route used through France Identité) or, failing that, a face match between the person's image and the ID photograph, run by the health insurance funds, with templates destroyed within 96 hours of activation (R161-33-18). RNIV 1 describes the second route as a certified remote identity verification provider (PVID) "or equivalent". In 2022 the CNIL asked for the SGIN route to be favoured and video enrolment progressively abandoned, and noted that in-person enrolment remains available. RNIV 1 treats the INS read from a holder's own app as qualified.

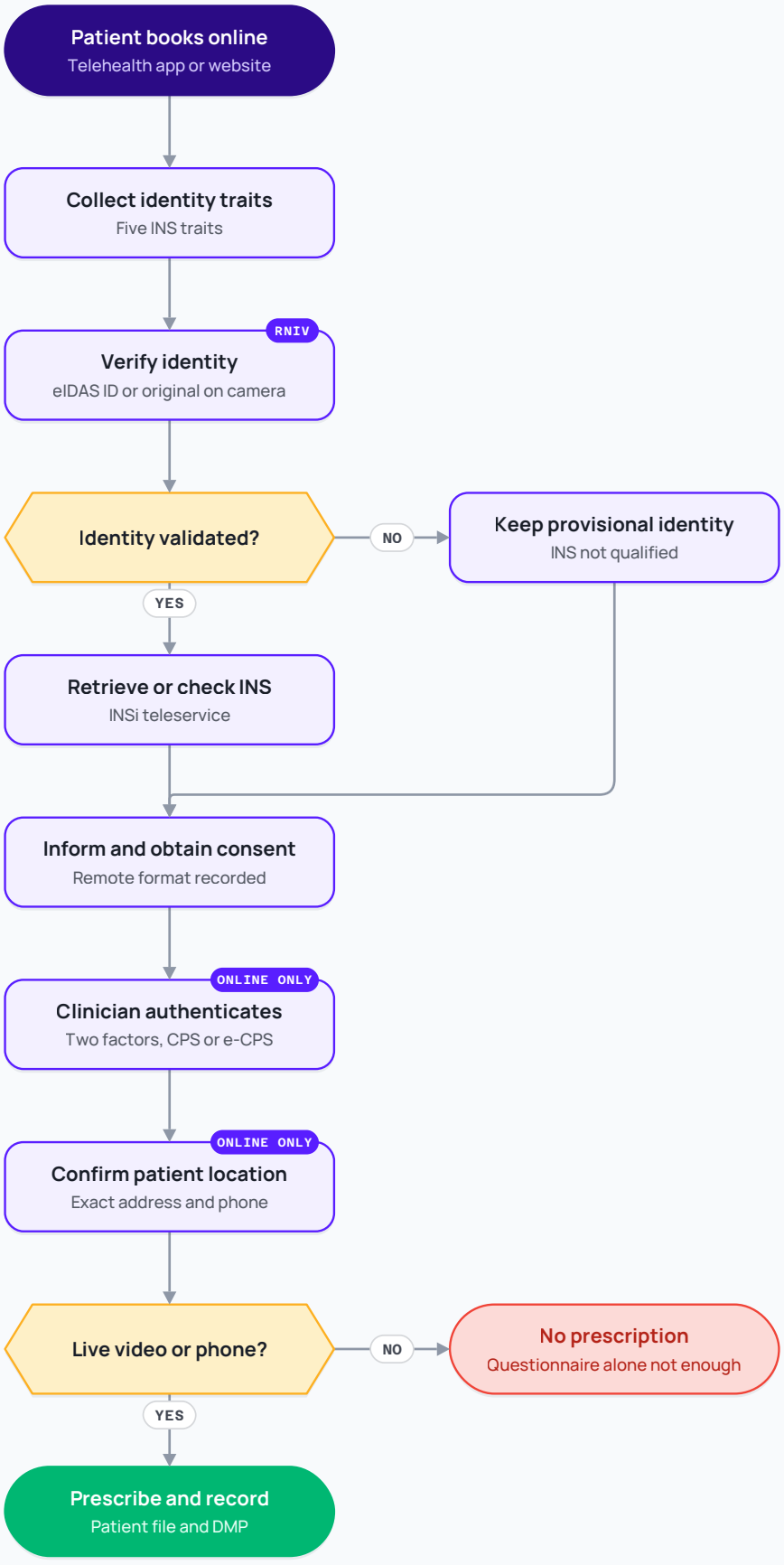


Figure 1. Remote patient onboarding and teleconsultation on a French telehealth platform.

Article R6316-4 requires the report of the act, prescriptions, the professionals' identities, date and time and any technical incidents to be recorded in the patient's file and, where applicable, the shared medical record (DMP).

5 Digital channels: what's different

Bottom line: the duty to identify the patient is the same in the surgery and on screen, but remote care adds clinician authentication, patient location, limits on sick notes and a ban on prescribing without a live exchange.

Requirement	In person	Online / remote	Difference
Duty to identify the patient	Identity checked on reception (ANS INS doctrine)	Required for every act (R6316-3); same INS rules	Same
How identity is validated	Original ID document shown (RNIV 1)	eIDAS substantial or high means, or the original shown on camera; an uploaded copy cannot validate	Differs
Clinician authentication	Physical presence	Authentication required (R6316-3); two factors (HAS)	Differs
Patient location	Known by definition	Exact location and phone number known to the clinician (HAS)	Differs
Sick notes	No channel-specific cap	First note or first renewal up to 3 days; no later renewal, with narrow exceptions	Differs
Prescriptions by online services	Issued during the consultation	Only after a synchronous video or phone exchange (L6316-1)	Differs
Prescriber based abroad	Not applicable	Cannot prescribe or renew a sick note by telemedicine	Differs

Reimbursement conditions	Coordinated care pathway	Same pathway, plus video link, local clinician and a 20% cap on each doctor's remote activity; companies need approval	`Differs`
Medicines sales	Pharmacy dispenses prescription and non-prescription medicines	Non-prescription medicines only, from an authorised pharmacy website	`Differs`

Sick notes and prescriptions online `In force since 27 Jun 2026`

Article L6316-1 CSP, as amended by loi 2026-534 of 25 June 2026 (found constitutional before promulgation, decision 2026-904 DC), caps a telemedicine sick note or its first renewal at three days and bars later remote renewals, unless the regular doctor or referring midwife prescribes it or the patient justifies being unable to see a clinician in person. Online services whose main activity is issuing prescriptions may prescribe only after a synchronous video or telephone exchange. A clinician practising mainly abroad cannot issue any sick note by telemedicine.

Reimbursed teleconsultations

The Assurance Maladie (21 January 2026) reimburses teleconsultations within the coordinated care pathway, with exceptions such as patients under 16 or without an available regular doctor. The consultation must be by video, the doctor must be near the patient's home (with exceptions), and no doctor may do more than 20% of annual activity remotely (40% for psychiatrists), a cap that applies individually to platform-employed doctors.

Certified teleconsultation systems

The ANS teleconsultation framework version 1.5.1, binding since the arrêté of 18 October 2024, covers among other domains GDPR, the INS, Pro Santé Connect, health information-system security, ethics and territoriality, billing and digital prescriptions. Since 31 December 2025 a definitive certificate is required for any approval application.

What is changing

The ANS states that the certification obligation will later extend to teleconsultation software used in health centres and private practice `Announced, date not set`. The 2027 social security financing bill (n° 3211) would let ministers restrict antibiotic prescribing by telemedicine and open reimbursement of assisted teleconsultations by nurses employed

by teleconsultation companies `Bill, not enacted`; the National Assembly rejected it at first reading on 23 October 2026.

6 Data protection and biometrics

Article 6 of loi 78-17 (Informatique et Libertés) prohibits processing health data and biometric data used to identify a person uniquely unless an exception in article 9(2) GDPR applies. Care processing by health professionals needs no CNIL formality but must appear in the record of processing (CNIL, May 2024). Since 28 May 2026, other health processing, such as data warehouses, must conform to a CNIL framework and be declared, or be authorised (art. 66). The CNIL's non-binding framework for medical practices (2020) indicates legitimate interest as the basis for telemedicine, expects an impact assessment and a data protection officer for shared systems above 10,000 patients a year, and recommends two-factor authentication with the CPS card. The CNIL's impact assessment list covers telemedicine in health establishments and biometric identity checks of patients.

The CNIL's multi-factor authentication recommendation (20 March 2025) accepts biometrics only on explicit consent unless a legal text requires or explicitly authorises them, says they cannot be imposed without an alternative, and prefers templates on a device under the user's exclusive control. For the decree-based Carte Vitale app, the CNIL noted in 2022 that face matching only checks that the person holds the identity document; in May 2023 it opposed a biometric Carte Vitale. Breaches must be notified to the CNIL within 72 hours.

7 Sector-specific obligations

Digital prescriptions

Since 22 December 2023, prescribers must issue prescriptions for care, products or services electronically and transmit them through the teleservices provided by the national health insurance fund (art. L4071-1 and L4071-3 CSP); dispensing professionals transmit execution data the same way (L4071-2). Prescriptions both issued and filled inside hospitals are excluded (L4071-4), and paper remains allowed where the patient cannot be identified through the dedicated digital health services (R4073-2 5°).

Professional ethics on platforms

In March 2023 the CNOM warned doctors using the FEELI platform of disciplinary risk: the "teleconsultation" was a message exchange, patients did not know in advance which doctor would respond, and reimbursement and fee information breached the rules.

8 Risk indicators and red flags

TELEHEALTH FRAUD AND IDENTITY-ABUSE INDICATORS

- **Questionnaire-only prescribing**: prescriptions or sick notes issued without a live video or phone exchange.
- **Serial remote sick notes**: renewals by telemedicine, or notes longer than three days, outside the regular-doctor exception.
- **Offshore prescribers**: sick notes issued by a clinician practising mainly abroad.
- **Anonymous clinician**: the patient cannot see who will treat them before the consultation.
- **Unqualified identities**: health data filed under an INS not checked against a high-confidence means or INSi, or "validated" from an uploaded copy.
- **Shared or single-factor logins**: clinicians using shared accounts or passwords alone.
- **Unlisted pharmacy sites**: prescription medicines offered online, or sites absent from the Ordre list.
- **Silent data harvesting**: software that copies insurer data into patient files without a choice to consult only.

9 Enforcement and penalties

The CNIL may fine up to €10 million or 2% of worldwide turnover, whichever is higher, or €20 million or 4% for the breaches in article 83(5) and (6) GDPR, and order processing limited or stopped (art. 20 loi 78-17). It fined HÔPITAL PRIVÉ DE LA LOIRE €500,000 on 21 July 2026 after an attacker used remote access without VPN or multi-factor authentication to reach 524,867 patients' records; IQVIA OPERATIONS FRANCE €5 million on 26 May 2026 over health data warehouses, including missing multi-factor authentication; and CEGEDIM SANTÉ €800,000 on 5 September 2024 for an unauthorised warehouse, upheld by the

Conseil d'État on 13 February 2026. In the warehouse cases pseudonymised data were treated as personal data. Hosting health data without HDS certification is punishable by three years' imprisonment and a €45,000 fine (art. L1115-1 CSP).

For teleconsultation companies, article L162-1-15 I bis of the Code de la sécurité sociale (as amended by loi 2026-534) lets a local health insurance fund director, after hearing the company and where the medical control service finds the listed situations, make coverage of its acts, prescriptions or sick-leave payments subject to prior medical approval for up to six months. Clinicians remain answerable to their professional order.

10 Recent changes and what to watch

- **23 October 2026** `Bill, not enacted` The National Assembly rejected the 2027 social security financing bill at first reading; its telehealth articles (antibiotic prescribing, nurse-assisted teleconsultation) remain proposals.
- **13 July 2026** `In force` Décret 2026-626 rewrites D4081-1: electronic application, ANS certificate, four-month decision, two-year approval. Prepare renewal files early.
- **27 June 2026** `In force` Loi 2026-534 tightens L6316-1: three-day cap on remote sick notes, no remote renewals, live exchange before online prescriptions. The same law lets health insurance funds put a teleconsultation company's billing under prior medical approval for up to six months.
- **16 May 2026** `In force` End of the HDS transition: all certified hosts must meet framework version 2.0, including storage in the European Economic Area.
- **31 December 2025** `In force` End of the ANS transitional milestones: a definitive certificate under framework v1.5.1 is now needed for approval.
- **26 March 2027** `Adopted, applies 26 Mar 2027` European Health Data Space Regulation (EU) 2025/327; patient-access and electronic health record rules apply from 26 March 2029 for patient summaries, e-prescriptions and e-dispensations, and from 26 March 2031 for imaging, test results and discharge reports.
- **Date not set** `Announced, date not set` ANS certification to extend to teleconsultation software in health centres and private practice.

11 What this means for identity verification

- **Capture the five INS traits** (birth surname, birth first names, date of birth, sex, place of birth) from the identity document.

- **Remote validation needs a strong means**: under RNIV 1 an eIDAS substantial or high digital identity, such as the Carte Vitale app, validates an identity; the fallback is the original document shown on camera to a professional; an uploaded copy or scan does not.
- **Validate identity with a high-confidence means** before filing data under the INS, and call INSi; keep a provisional status until both are done.
- **Treat clinician authentication as part of onboarding**: two factors, with Pro Santé Connect (CPS or e-CPS) where the service connects to national systems.
- **Record the evidence**: who checked identity, how and when, alongside the R6316-4 record of the act.
- **Face matching needs explicit consent and an alternative** unless a legal text authorises it (CNIL, March 2025); keep templates briefly, as the Carte Vitale app does with 96-hour deletion.
- **Re-identify at each act**: R6316-3 applies to every remote act, and the ANS still requires an identity check when the patient is received.

IDENTOMAT

How Identomat helps

Identomat runs identity verification, screening and monitoring for regulated businesses on one platform, with workflows you configure for each market. For the requirements in this guide, that means:

- Remote patient identity verification with ID document capture and verification (including NFC), face match and biometric liveness before health data are filed.
- Configurable no-code workflows that capture the identity traits a telehealth service needs and keep an audit trail of each check.
- Phone and email verification to support patient contact details and account recovery.
- KYB checks on partner clinics and suppliers, with cloud, on-premises or hybrid deployment to fit health data hosting choices.

Request a meeting

DISCLAIMER

This article is intended for informational purposes only and does not constitute legal advice. It is a compilation of information from various sources and reflects the information available as of the last updated date indicated above. Laws, regulations, and regulatory guidance may change, so readers should consult qualified legal professionals for advice specific to their circumstances.

Sources

- **Code de la santé publique, art. L6316-1** [Telemedicine], version in force since 27 June 2026, Légifrance, legifrance.gouv.fr
- **Code de la santé publique, art. R6316-1 to R6316-5** [Telehealth], versions in force since 5 June 2021 (décret 2021-707), Légifrance, legifrance.gouv.fr
- **Loi n° 2026-534 du 25 juin 2026 relative à la lutte contre les fraudes sociales et fiscales** [Social and tax fraud act], art. 49 and 75, Légifrance, legifrance.gouv.fr
- **Code de la santé publique, art. L4081-1 to L4081-4** [Teleconsultation companies], in force since 31 December 2023, and **art. D4081-1**, in force since 13 July 2026 (décret 2026-626 of 8 July 2026), Légifrance, L4081 and D4081-1
- **Code de la santé publique, art. L1111-8** [Health data hosting], in force since 1 July 2025, and **art. L1111-8-1** [Health identifier], in force since 9 December 2020, Légifrance, legifrance.gouv.fr
- **Code de la santé publique, art. L4071-1 to L4071-6** [Electronic prescriptions], in force since 22 December 2023, Légifrance, legifrance.gouv.fr
- **Code de la santé publique, art. L5125-33 to L5125-36** [Online sale of medicines], Légifrance, legifrance.gouv.fr
- **Code de la sécurité sociale, art. R161-33-11 to R161-33-18** [Carte Vitale mobile app], in force since 1 January 2023, Légifrance, legifrance.gouv.fr
- **Code monétaire et financier, art. L561-2** [AML obliged persons], version in force since 5 August 2026, Légifrance, legifrance.gouv.fr
- **Loi n° 78-17 du 6 janvier 1978 (Informatique et Libertés)**, art. 6, 20, 65 and 66, Légifrance, legifrance.gouv.fr
- **Agence du numérique en santé, "INS: Identité Nationale de Santé"**, Doctrine du numérique en santé 2025, esante.gouv.fr
- **Agence du numérique en santé, "Téléconsultation : réglementation et référentiel"** (framework v1.5.1, arrêté of 18 October 2024), esante.gouv.fr
- **Agence du numérique en santé, "Pro Santé Connect"**, esante.gouv.fr
- **HAS, "Qualité et sécurité des actes de téléconsultation et de téléexpertise : guide de bonnes pratiques"**, May 2019, pp. 15 to 16, has-sante.fr
- **HAS, "Téléconsultation et téléexpertise : guide de bonnes pratiques"**, published 20 June 2019, updated 7 June 2021, has-sante.fr
- **CNIL, "Quelles formalités pour les traitements de données de santé ?"**, 22 May 2024, cnil.fr

- **CNIL, référentiel for medical and paramedical practices** (published 28 July 2020, non-binding), cnil.fr
- **CNIL, list of processing operations requiring an impact assessment**, cnil.fr
- **CNIL, "Recommandation relative à l'authentification multifacteur"**, adopted 20 March 2025, s. 3.3 and 3.4, cnil.fr
- **CNIL, délibération n° 2022-097 du 8 septembre 2022** [Opinion on electronic identification means including the e-Carte Vitale], Légifrance, legifrance.gouv.fr
- **CNIL, "Fusion de la carte Vitale et de la carte d'identité : les points d'attention de la CNIL"**, 30 May 2023, cnil.fr
- **CNIL, "Violations de données personnelles : les règles à suivre"**, cnil.fr
- **CNIL, sanction of €5 million against IQVIA** (SAN-2026-008, 26 May 2026), cnil.fr
- **CNIL, sanction of €500,000 against HÔPITAL PRIVÉ DE LA LOIRE** (SAN-2026-009, 21 July 2026), cnil.fr
- **Conseil d'État, 13 February 2026, n° 498628** [GERS and Cegedim Santé v. CNIL], Légifrance, legifrance.gouv.fr
- **CNIL, "Données de santé : sanction de 800 000 euros à l'encontre de la société CEGEDIM SANTÉ"**, 5 September 2024, cnil.fr
- **CNOM, notice on the FEELI teleconsultation platform**, 9 March 2023, conseil-national.medecin.fr
- **Assurance Maladie, "La téléconsultation"**, 21 January 2026, ameli.fr
- **Agence du numérique en santé, RNIV 1 "Principes communs"**, version 2.0, December 2024, esante.gouv.fr
- **Agence du numérique en santé, HDS framework press release**, 16 May 2024, and FAQ on the transition, updated 22 September 2026, esante.gouv.fr, esante.gouv.fr
- **Assemblée nationale, projet de loi de financement de la sécurité sociale pour 2027, n° 3211**, art. 23, 28 and 32, and legislative file, assemblee-nationale.fr
- **Code de la santé publique, art. R1111-8-8** [Scope of hosting], legifrance.gouv.fr; **art. L1115-1** [Penalties], legifrance.gouv.fr; **art. R4073-2** [E-prescription exceptions], legifrance.gouv.fr
- **Code de la sécurité sociale, art. L162-1-15**, version in force since 27 June 2026, legifrance.gouv.fr
- **Conseil constitutionnel, décision n° 2026-904 DC du 18 juin 2026**, paras 77 to 86, legifrance.gouv.fr
- **Ordre national des pharmaciens, list of authorised online pharmacy sites** (art. R5125-74 CSP), updated 28 October 2026, apiop.ordre.pharmacien.fr
- **ANSM, "Où peut-on acheter des médicaments en ligne en toute sécurité ?"**, ansm.sante.fr
- **Regulation (EU) 2025/327 on the European Health Data Space**, art. 105, EUR-Lex, eur-lex.europa.eu