



## ChatRx & ChatMD Regulatory Compliance Summary

ChatRx is committed to meeting or exceeding all federal and state regulatory requirements governing telemedicine, medical devices, consumer protection, health data privacy, and AI-enabled clinical tools. This page provides transparent information about how ChatRx and the ChatMD SaMD comply with U.S. healthcare laws, ensure patient safety, and uphold best-practice standards across all states where services are provided.

This updated summary replaces the prior version.

### 1. FDA Compliance

#### ChatMD as an FDA-Registered Class I Medical Device

ChatMD is registered with the U.S. Food and Drug Administration (FDA) as a **Class I, 510(k)-exempt Software as a Medical Device (SaMD)**. ChatMD is subject to FDA's General Controls, including:

- Device registration and listing
- Truthful labeling and intended-use requirements
- Quality system expectations appropriate for Class I SaMD
- Software safety, reliability, and cybersecurity monitoring
- Complaint investigation and adverse event reporting (as applicable)
- Post-market controls and modification reviews

## Intended Use

**ChatMD collects structured symptom information for licensed clinicians who diagnose and treat eligible low-acuity infectious conditions through ChatRx asynchronous telemedicine. ChatMD does not independently diagnose, recommend treatment, or replace in-person clinical evaluation.**

## Device Listing and Ownership

**Device ID:** ChatMD v0.5.2 build 251204\*\* version number ID changes dynamically in the Engine

**Manufacturer:**

ChatMD

328 S. Michigan Street

Plymouth, IN 46563

[clinical@chatrx.md](mailto:clinical@chatrx.md)

**Development Partner:**

Smart Data Enterprises Inc.

151 E 85th Street #9D

New York, NY

[info@smartdatainc.net](mailto:info@smartdatainc.net)

## 2. FTC Compliance & Truth-in-Advertising Standards

ChatRx adheres to the Federal Trade Commission Act and all FTC healthcare advertising rules, including new digital health and AI-specific guidance.

### Advertising and Marketing Requirements

- All statements must be truthful, non-misleading, and substantiated.
- ChatRx does not claim to cure disease, guarantee outcomes, or replace in-person medical care.
- ChatMD's AI functionality is accurately described—AI does not diagnose or treat.
- Any educational content is general and not a substitute for medical advice.
- Testimonials are real, non-fabricated, and include required disclosures.
- Any paid endorsements or partnerships are clearly disclosed.

## Prohibited Claims

ChatRx does not:

- Represent ChatMD as “FDA-approved”
- Guarantee accuracy of AI findings
- Imply superiority over in-person care
- Make unverifiable or anecdotal medical claims

## 3. HIPAA, HITECH & Data Security Compliance

ChatRx complies with all federal and state privacy and security requirements, including HIPAA, HITECH, and the FTC Health Breach Notification Rule (for non-HIPAA consumer data).

### HIPAA Compliance

- All Protected Health Information (PHI) is encrypted in transit and at rest using AES-256 encryption.
- Strict role-based access controls govern who may access patient information.
- Comprehensive audit logs record all system access and modification events.
- Business Associate Agreements (BAAs) are in place with all required vendors.

### Consumer Privacy Laws

ChatRx complies with U.S. consumer privacy laws including:

- CCPA/CPRA (California)
- CPA (Colorado)
- CTDPA (Connecticut)
- VCDPA (Virginia)
- UCPA (Utah)

Non-PHI personal data is managed under the **ChatRx & ChatMD Privacy Policy & Consumer Data Consent Notice**.

### Breach Notification

ChatRx complies with HIPAA and FTC HBNR requirements for identification, mitigation, and notification of data breaches.

#### 4. Telemedicine & Multi-State Licensing Compliance

ChatRx complies with all state-specific telehealth regulations and professional licensure rules governing asynchronous telemedicine, including:

##### Current Service States

- Indiana
- Michigan
- Illinois

As ChatRx expands nationally, licensing verification and compliance will be maintained for every state.

##### Required Compliance Elements

- Clinicians are licensed in the state where the patient is physically located.
- Patient identity and geographic location are verified prior to treatment.
- Asynchronous telemedicine workflows comply with each state's statutes.
- Prescriptions are issued only after appropriate clinician review.
- Controlled substances are not prescribed via asynchronous care unless expressly permitted by law (currently not permitted in service states).
- Minor consent requirements follow jurisdiction-specific statutes.

#### 5. Medical Safety & Emergency Disclaimers

ChatRx provides care for **non-emergency low-acuity infectious conditions only**.

ChatRx is **not** appropriate for life-threatening or rapidly worsening symptoms. Patients experiencing emergency conditions—including chest pain, difficulty breathing, severe pain, neurological symptoms, or loss of consciousness—should call **911** or seek immediate in-person care.

ChatRx does not replace in-person evaluation when physical examination or diagnostic testing is necessary.

## 6. AI Transparency & Clinical Oversight Requirements

ChatRx complies with FTC and FDA transparency rules for AI in healthcare.

### Required Disclosures

- ChatMD uses AI only for structured symptom collection.
- AI outputs may have limitations and may not capture every clinical nuance.
- All diagnoses, treatment decisions, and prescriptions are made solely by licensed clinicians.
- Providers retain full responsibility for medical decision-making.

No autonomous diagnostic or prescribing actions occur within ChatRx.

## 7. Complaint Handling, Incident Reporting & Regulatory Inquiries

ChatRx maintains federally compliant procedures for reporting, investigating, and resolving:

- Patient complaints
- Device malfunctions
- Adverse events
- Data privacy concerns
- Regulatory inquiries

### Contact Information

**Compliance & Data Privacy:** [trust@chatrx.md](mailto:trust@chatrx.md)

**Clinical Questions:** [clinical@chatrx.md](mailto:clinical@chatrx.md)

**Support:** [support@chatrx.md](mailto:support@chatrx.md)

### Regulatory Mail:

328 S. Michigan Street  
Plymouth, IN 46563

ChatRx adheres to FDA complaint-handling requirements, HIPAA breach notification timelines, and applicable state reporting obligations.

## 8. Ongoing Regulatory Review & Updates

Healthcare, AI, privacy, and telemedicine regulations evolve rapidly. ChatRx performs ongoing evaluations of:

- FDA SaMD regulatory updates
- FTC advertising and data privacy enforcement trends
- State telemedicine law changes
- HIPAA and cybersecurity updates
- AI governance standards
- Digital health best practices

This page will be updated as new regulations take effect or ChatRx expands service availability.

## 9. Trust Center Policies

For more detailed information, users may review the policies listed below at:

- [The ChatRx Trust Center](#)
- [The ChatMD Device Trust Center](#)
- ChatRx Terms of Use
- ChatMD Device Terms of Use
- ChatRx HIPAA Notice of Privacy Practices
- ChatRx & ChatMD Privacy Policy & Consumer Data Consent Notice
- ChatRx Cookie Policy
- ChatRx Data Security Policy
- ChatRx Medical Services Agreement
- ChatRx Consent to Treat Form
- ChatRx Telemedicine Consent Form