



ChatRx & ChatMD FTC Compliance Policy

This FTC Compliance Policy describes the standards and obligations that govern how ChatRx and the ChatMD FDA-registered medical device communicate with consumers. This policy ensures full compliance with the Federal Trade Commission (FTC) Act, FDA regulations for medical devices, HIPAA and HITECH privacy requirements, state consumer protection laws, and emerging expectations for AI-enabled healthcare products.

1. Clear Identification of ChatMD as an FDA-Registered Medical Device

ChatRx is powered by **ChatMD**, an FDA-registered Class I Software as a Medical Device (SaMD). All public-facing descriptions must include:

a. Device Identification

- ChatMD is a Software as a Medical Device used to collect structured symptom information for remote evaluation of low-acuity infectious conditions.
- ChatMD is registered with the FDA as a **Class I, 510(k)-exempt medical device**.

b. FDA Status and Compliance

All communications must truthfully state:

- ChatMD complies with FDA “General Controls” for Class I devices.
- ChatMD does **not** diagnose, treat, or replace the judgment of a licensed clinician.
- The device is exempt from premarket notification (510(k)) but not exempt from FDA regulatory oversight.

c. Intended Use Statement

All consumer-facing descriptions must use a standardized intended-use statement:

“ChatMD is intended to collect and structure 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 medical evaluation.”

2. FTC-Compliant Medical and Advertising Disclaimers

The website, ads, and promotional materials must include:

a. Medical Advice Disclaimer

- ChatRx does not replace in-person medical care, especially for emergencies.
- ChatMD does not provide medical advice and is not a substitute for a clinician’s evaluation.

b. No Unsubstantiated Claims

Under FTC rules, ChatRx may not:

- Overstate the effectiveness of digital triage or treatment
- Guarantee outcomes (e.g., “cure,” “faster recovery,” “works every time”)
- Make comparative claims without substantiation

c. AI-Specific Transparency

FTC guidance requires explicit AI transparency:

- ChatMD uses AI only for structured symptom collection
- All diagnoses and prescriptions are made solely by licensed clinicians
- AI limitations must be clearly disclosed

3. Privacy and Data Use Transparency

To comply with FTC, HIPAA, HITECH, and the Health Breach Notification Rule (HBNR), the website must:

a. State HIPAA Applicability

- ChatRx clinical data is HIPAA-protected.
- ChatMD's health-related data processing follows HIPAA standards when used within treatment workflows.

b. Clearly Distinguish PHI vs. Consumer Data

- PHI = governed by the ChatRx HIPAA Notice of Privacy Practices
- Non-PHI consumer data = governed by the ChatRx & ChatMD Privacy Policy & Consumer Data Consent

c. Data Collection Disclosure

All communications must specify:

- What data is collected
- Why it is collected
- How it is used
- The categories of entities with whom it may be shared

d. Cookie & Tracking Disclosures

A compliant cookie banner must:

- Appear on first website visit
- Provide opt-out options where required by state law (CT, CO, CA, VA)
- Link to the full Cookie Policy

4. FDA Class I Device Information Requirements

FTC and FDA require truthful, non-misleading disclosures:

a. Mandatory Labeling Elements

Your website must reference:

- Device status (FDA Class I)
- Registration number (optional but permitted)
- Compliance with General Controls
- Exemption from 510(k) notification

b. Prohibited Statements

ChatRx must *not* claim:

- FDA approval
- FDA endorsement
- FDA certification

Correct language:

“ChatMD is an FDA-registered Class I medical device.”

5. User Instructions and Consumer Warnings

FTC requires accessible, understandable instructions and warnings:

a. Directions for Use

Website and product descriptions must outline:

- Steps to initiate a telemedicine encounter
- How symptom intake works
- When a clinician becomes involved
- Any limitations on use

b. Required Warnings

Disclose:

- Conditions not treatable through ChatRx
- That the service does not replace physical examination

- That inaccurate user-provided information may affect diagnosis
- That emergencies require 911 or in-person care

6. Terms of Service and Privacy Policy Integration

FTC requires that:

- Links to Terms of Use, Privacy Policy, Cookie Policy, HIPAA Notice, Device Terms, and Consent Forms must be prominent, accessible, and written in consumer-friendly language.
- No unfair or deceptive contract terms may be used.

7. Marketing and Advertising Standards

All marketing materials must:

a. Comply with FTC Truth-in-Advertising Rules

- Claims must be truthful, non-misleading, and evidence-based
- Substantiation must exist before claims are made
- Disclosures must be clear, conspicuous, and unavoidable

b. Testimonials and Endorsements

FTC requires:

- Real testimonials only
- Typicality disclosures when necessary (“Results may vary”)
- No compensation without disclosure
- No fabricated or unverified claims

c. Prohibited Conduct

Marketing may not:

- Exaggerate diagnostic accuracy
- Suggest ChatMD “replaces a doctor”

- Claim guaranteed treatment outcomes
- Use dark patterns to force user consent

8. AI Marketing and Disclosure Requirements

New FTC guidance requires:

- Clear explanation that AI assists only with structured intake
- Disclosure of AI limitations
- No anthropomorphizing claims (“Our AI thinks...”)
- No overstated performance metrics without clinical validation

9. Contact Information for Compliance and Consumer Support

To comply with FTC and FDA accessibility requirements:

ChatRx Compliance Department

trust@chatrx.md

328 S. Michigan Street
Plymouth, IN 46563

Technical Support

support@chatrx.md

Regulatory Inquiries

FDA
Center for Devices and Radiological Health (CDRH)
10903 New Hampshire Avenue
Silver Spring, MD 20993

10. Accessibility Compliance (WCAG)

FTC and ADA guidelines require:

- WCAG 2.1 AA compliance
- Screen-reader compatibility
- Alternative text for images
- Captions for videos
- Accessible font sizes and navigation

11. Device Labeling Requirements

FTC and FDA require:

- Clear access to device labeling and Instructions for Use (IFU)
- A link to the ChatMD Device Terms of Use
- A visible section explaining device limitations, warnings, and intended uses

Compliance Affirmation

ChatRx and ChatMD commit to maintaining truthful, transparent, and regulatory-compliant communication across all consumer interactions, marketing materials, digital content, clinical workflows, and device-related disclosures.