

Patient Intake Management System

Functional Requirements Document

Document Version: 1.2
Project: HealthCare Portal - Patient Intake Module
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Compliance Framework: HIPAA, HITECH Act, ABDM (India)

1. Executive Summary

This document outlines the functional requirements for a digital patient intake system that captures patient demographics, medical history, insurance information, and consent forms prior to clinical consultation. The system must comply with HIPAA Privacy and Security Rules, support FHIR R4 interoperability standards, and integrate with existing Electronic Health Record (EHR) systems.

2. System Overview

2.1 Purpose

Enable patients to complete intake paperwork digitally via web portal or mobile app, reducing wait times and improving data accuracy while maintaining regulatory compliance.

2.2 Scope

- Patient demographic data collection
- Medical history questionnaire
- Insurance verification
- Consent form management
- HIPAA authorization
- Data validation and error handling
- Integration with EHR systems via HL7 FHIR

2.3 Users

- **Primary:** Patients (adults 18+)
- **Secondary:** Legal guardians (for minors)
- **Administrative:** Front desk staff, registration clerks
- **Clinical:** Nurses, physicians (read-only access to intake data)

3. Functional Requirements

FR-001: Patient Demographics Collection

Priority: CRITICAL
User Story: As a patient, I want to provide my basic demographic information so that the healthcare provider can identify me correctly and contact me.
Requirements:

1. System SHALL collect the following mandatory fields:
 - Legal first name (max 50 characters)
 - Legal last name (max 50 characters)
 - Date of birth (MM/DD/YYYY format, must validate age 0-120 years)
 - Biological sex (Male/Female/Intersex - for clinical care purposes)
 - Current residential address (street, city, state, ZIP)
 - Primary phone number (10 digits, US format)
 - Email address (RFC 5322 compliant)
2. System SHALL collect the following optional fields:
 - Preferred name (max 50 characters)
 - Middle name/initial
 - Preferred pronouns (He/Him, She/Her, They/Them, Other)
 - Secondary phone number
 - Emergency contact name and phone number
 - Preferred language for care (English, Spanish, Hindi, Mandarin, Other)
3. System SHALL validate:
 - Date of birth results in patient age between 0-120 years
 - Phone numbers contain exactly 10 digits
 - Email addresses contain @ symbol and valid domain
 - ZIP codes are valid 5-digit US postal codes
 - No special characters in name fields except hyphens and apostrophes
4. System SHALL prevent:
 - Duplicate patient records based on DOB + Last Name + First 3 letters of First Name match
 - Submission with missing mandatory fields
 - Future dates in date of birth field

Acceptance Criteria:

- All mandatory fields must be completed before proceeding
- Validation errors display clearly next to affected fields
- System suggests potential duplicate records for staff review
- Data auto-saves every 30 seconds to prevent loss

Compliance:

- HIPAA Privacy Rule: Minimum necessary standard for data collection
 - HIPAA Security Rule §164.312(a)(2)(i): Unique user identification
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FR-002: Medical History Questionnaire

Priority: HIGH

User Story: As a clinician, I need comprehensive medical history before the patient visit to provide appropriate care and avoid contraindications.

Requirements:

1. System SHALL present medical history questionnaire with sections:
 - Current medications (name, dosage, frequency, start date)
 - Known allergies (medication, food, environmental)
 - Past medical conditions (diabetes, hypertension, asthma, cancer, etc.)
 - Past surgical history (procedure name, approximate date)
 - Family history (immediate family chronic conditions)
 - Social history (smoking status, alcohol use, exercise habits)
 - Current symptoms or chief complaint
2. System SHALL provide:
 - Searchable medication database (RxNorm standard codes)
 - Allergy severity rating (Mild/Moderate/Severe/Life-threatening)
 - Pre-populated common conditions with checkboxes

- Free-text entry for conditions not listed
- "Review of Systems" standardized checklist (14 organ systems)
- 3. System SHALL implement drug interaction checking:
 - Cross-reference entered medications against known interaction database
 - Display warning if potential interaction detected
 - Flag high-risk combinations (e.g., warfarin + aspirin)
 - Provide option to proceed with physician consultation note
- 4. System SHALL support:
 - "Import from previous visit" functionality for returning patients
 - "None" or "Unknown" options for each section
 - Multilingual questionnaires (English, Spanish minimum)

Acceptance Criteria:

- Medical history questionnaire is comprehensive yet completable in under 10 minutes
- Drug interaction warnings appear in real-time as medications are added
- Previous medical history auto-populates for returning patients with option to update
- All allergy entries require severity selection and reaction description

Compliance:

- 21 CFR Part 11: Electronic signatures for medical records
 - FHIR R4: Medication, AllergyIntolerance, Condition resources
 - Meaningful Use Stage 2: Medication reconciliation
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FR-003: Insurance Information and Verification

Priority: HIGH

User Story: As a billing specialist, I need accurate insurance information to verify coverage and process claims correctly.

Requirements:

1. System SHALL collect:
 - Primary insurance carrier name
 - Policy/member ID number
 - Group number (if applicable)
 - Policy holder name (if different from patient)
 - Policy holder date of birth
 - Policy holder relationship to patient (Self/Spouse/Child/Other)
 - Insurance card front and back images (upload via camera or file)
2. System SHALL support:
 - Secondary insurance collection (same fields as primary)
 - Tertiary insurance (optional, same fields)
 - "Self-Pay" option if no insurance
 - Medicare/Medicaid identification numbers
 - Insurance card OCR scanning via mobile camera (extract member ID automatically)
3. System SHALL perform real-time eligibility verification:
 - Query clearinghouse API for active coverage status
 - Display coverage effective dates
 - Show copay/deductible information if available
 - Flag inactive or expired policies
 - Retry failed verifications up to 3 times before flagging for manual review
4. System SHALL validate:
 - Member ID format matches carrier requirements (alphanumeric, specific length)
 - Relationship field completed if policy holder ≠ patient
 - Insurance card images are legible (minimum resolution check)

Acceptance Criteria:

- Insurance verification completes within 10 seconds for 95% of requests
- System stores encrypted images of insurance cards
- Patients can update insurance information during intake if changes occurred
- Failed verifications generate alert for registration staff with patient contact info

Compliance:

- HIPAA Transaction Standards: X12 270/271 for eligibility inquiry
 - HIPAA Security Rule §164.312(e)(1): Transmission security during verification
 - PCI DSS: If payment information collected (credit card for copay)
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FR-004: Consent and Authorization Management

Priority: CRITICAL

User Story: As a compliance officer, I need documented patient consent and HIPAA authorizations before treatment to meet legal requirements.

Requirements:

1. System SHALL present the following consent forms:
 - **Consent to Treat** (required, cannot proceed without)
 - **HIPAA Notice of Privacy Practices** acknowledgment (required)
 - **Financial Responsibility Agreement** (required)
 - **Authorization for Release of Information** (optional)
 - **Research Participation** (optional, only if applicable)
 - **Marketing Communications Opt-in** (optional)
2. System SHALL require electronic signature:
 - Full legal name typed by patient
 - Date and time automatically stamped
 - IP address and device information logged (audit trail)
 - "I agree to the terms" checkbox for each form
 - Option to download PDF copy of signed forms
3. System SHALL provide:
 - Consent form content in patient's preferred language
 - Text-to-speech audio version for accessibility
 - Print-friendly version for patients who prefer paper
 - Version control tracking (if forms updated, patient must re-sign)
4. System SHALL enforce:
 - Minimum age of consent (18 years, or state-specific minor consent laws)
 - Legal guardian signature requirement for patients under 18
 - Expiration tracking (HIPAA authorizations expire after 1 year or as specified)
 - Re-consent prompts for expired authorizations
5. System SHALL prevent:
 - Proceeding to appointment booking without required consents
 - Editing of signed consent forms (immutable once signed)
 - Sharing of consent forms via unsecured methods

Acceptance Criteria:

- All consent forms clearly display in patient's preferred language
- Electronic signatures meet 21 CFR Part 11 requirements
- Consent status visible to clinical staff before patient visit
- Expired consents trigger automatic patient notification 30 days before expiration

Compliance:

- HIPAA Privacy Rule §164.508: Authorization requirements
- HIPAA Privacy Rule §164.520: Notice of Privacy Practices
- 21 CFR Part 11: Electronic signatures and records



- State-specific informed consent laws (vary by jurisdiction)
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FR-005: Data Validation and Error Handling

Priority: HIGH

User Story: As a patient, I want clear guidance when I make mistakes so I can correct them quickly and complete my intake.

Requirements:

1. System SHALL implement real-time validation:
 - Field-level validation on blur (when user leaves field)
 - Form-level validation on submit
 - Inline error messages next to affected fields (red text, icon)
 - Summary of all errors at top of form before submission
2. System SHALL validate data types:
 - Numeric fields (age, phone, ZIP) only accept numbers
 - Date fields use calendar picker with manual entry fallback
 - Email fields check for @ and domain structure
 - Name fields reject numbers and most special characters
3. System SHALL provide helpful error messages:
 -  Bad: "Invalid input"
 -  Good: "Phone number must be exactly 10 digits. You entered 9 digits."
 - Include suggestion for how to fix (e.g., "Did you mean MM/DD/YYYY?")
4. System SHALL handle edge cases:
 - Patient without permanent address: Allow "Homeless" selection with alternate contact
 - Patient without SSN: Optional field, accept alternatives (passport, state ID)
 - Patient without insurance: Clear "Self-Pay" path without friction
 - Non-binary patients: Gender identity separate from biological sex
5. System SHALL implement progressive disclosure:
 - Show only relevant follow-up questions (e.g., "If yes, please specify...")
 - Hide optional sections initially, reveal with "Add optional information" button
 - Multi-step form with progress indicator (Step 1 of 5)

Acceptance Criteria:

- 95% of patients complete intake without staff assistance
- Average completion time under 8 minutes for new patients, 3 minutes for returning
- Error rate for submission failures due to validation under 5%
- Accessibility compliance: WCAG 2.1 Level AA for error identification and recovery

Compliance:

- WCAG 2.1 Level AA: Error identification, labels, and instructions
 - Section 508: Accessible error handling for users with disabilities
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FR-006: Data Security and Privacy

Priority: CRITICAL

User Story: As a patient, I need assurance that my sensitive health information is protected from unauthorized access.

Requirements:

1. System SHALL encrypt data:
 - At rest: AES-256 encryption for database storage
 - In transit: TLS 1.3 for all data transmission
 - Backups: Encrypted backups with separate key management

2. System SHALL implement access controls:
 - Role-based access control (RBAC)
 - Multi-factor authentication for staff access
 - Automatic session timeout after 15 minutes of inactivity
 - Patient-only access to own data (no cross-patient viewing)
3. System SHALL maintain audit logs:
 - Log all data access (who, what, when)
 - Log all data modifications (create, update, delete)
 - Immutable audit trail (cannot be altered or deleted)
 - Minimum 6-year retention for HIPAA compliance
4. System SHALL prevent:
 - SQL injection attacks (parameterized queries)
 - Cross-site scripting (XSS) attacks (input sanitization)
 - Brute force attacks (account lockout after 5 failed attempts)
 - Data export without explicit authorization
5. System SHALL support:
 - Patient rights to access their data (download within 30 days of request)
 - Patient rights to amend their data (with clinical approval)
 - Patient rights to restrict disclosure (mark records as highly sensitive)
 - Data breach notification (automated alerts to compliance team)

Acceptance Criteria:

- Penetration testing passes with no critical vulnerabilities
- Annual HIPAA Security Rule risk assessment completed
- Business Associate Agreements (BAAs) signed with all third-party vendors
- Incident response plan documented and tested annually

Compliance:

- HIPAA Security Rule: Administrative, Physical, and Technical Safeguards (§164.308, §164.310, §164.312)
 - HITECH Act: Breach notification requirements
 - GDPR (if applicable): Right to access, right to erasure, data portability
 - NIST Cybersecurity Framework: Protect, Detect, Respond, Recover
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FR-007: EHR Integration and Interoperability

Priority: MEDIUM

User Story: As a physician, I need patient intake information automatically available in the EHR so I don't have to re-enter data.

Requirements:

1. System SHALL integrate with EHR via HL7 FHIR R4:
 - Patient resource (demographics)
 - Observation resource (vital signs if collected)
 - MedicationStatement resource (current medications)
 - AllergyIntolerance resource (allergies)
 - Condition resource (active medical conditions)
 - Consent resource (signed authorizations)
2. System SHALL support:
 - Bidirectional data sync (pull existing patient data, push new intake data)
 - Real-time updates (intake data available in EHR within 60 seconds)
 - Conflict resolution (if EHR data differs from intake, flag for review)
 - Multiple EHR system compatibility (Epic, Cerner, Allscripts, athenahealth)
3. System SHALL provide:
 - API endpoints for RESTful integration
 - OAuth 2.0 authentication for secure API access

- Webhook notifications for data updates
 - SMART on FHIR app launch capability
4. System SHALL handle integration failures:
- Retry logic with exponential backoff (3 attempts)
 - Queue failed transactions for manual review
 - Alert IT team if integration down for more than 15 minutes
 - Allow intake to proceed even if EHR unavailable (sync later)

Acceptance Criteria:

- 99% of intake submissions successfully sync to EHR within 60 seconds
- Zero data loss during integration failures (queuing system works)
- EHR integration passes FHIR Connectathon validation tests
- Support for ONC Cures Act interoperability requirements

Compliance:

- ONC 21st Century Cures Act: Patient access and interoperability
 - HL7 FHIR R4: US Core Implementation Guide
 - TEFCA (Trusted Exchange Framework and Common Agreement): Interoperability standards
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4. Non-Functional Requirements

NFR-001: Performance

- Page load time: < 2 seconds for 95th percentile
- Form submission processing: < 5 seconds
- Insurance verification: < 10 seconds for 95% of requests
- Support 500 concurrent users without degradation

NFR-002: Availability

- System uptime: 99.9% (excluding planned maintenance)
- Planned maintenance windows: 2 AM - 4 AM on Sundays
- Maximum unplanned downtime: 4 hours per month

NFR-003: Scalability

- Support 10,000 patient intake submissions per day
- Auto-scaling to handle 3x traffic during peak registration periods
- Database capacity for 1 million patient records

NFR-004: Usability

- Mobile-responsive design (iOS Safari, Android Chrome)
- Completion rate > 90% for patients who start intake
- Average completion time: 8 minutes for new patients, 3 minutes for returning patients
- Accessibility: WCAG 2.1 Level AA compliance

NFR-005: Maintainability

- Modular architecture for easy updates to individual forms
 - Comprehensive API documentation
 - Automated testing coverage > 80%
 - Deployment via CI/CD pipeline with zero-downtime releases
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5. Acceptance Criteria Summary

Must Have (MVP):

- ✓ FR-001: Patient demographics collection
- ✓ FR-004: Consent management (Consent to Treat + HIPAA Notice)
- ✓ FR-006: Data security (encryption, access control)
- ✓ FR-005: Basic validation and error handling

Should Have (Phase 1):

- ✓ FR-002: Medical history questionnaire
- ✓ FR-003: Insurance verification
- ✓ FR-005: Advanced validation and progressive disclosure

Could Have (Phase 2):

- ✓ FR-007: EHR integration via FHIR
- ✓ Multilingual support (Spanish)
- ✓ OCR for insurance cards

Won't Have (Future):

- Patient portal login (out of scope, separate project)
- Telemedicine scheduling (separate module)
- Payment processing (handled by billing system)

6. Testing Requirements

Test Scenarios:

1. **Happy Path:** New patient completes entire intake successfully in under 8 minutes
2. **Returning Patient:** Existing patient updates demographics and medical history in under 3 minutes
3. **Validation Errors:** Patient makes multiple errors; system provides clear guidance and allows correction
4. **Insurance Verification Failure:** Insurance API is down; system proceeds with manual verification flag
5. **Minor Patient:** Legal guardian completes intake for patient under 18
6. **No Insurance:** Self-pay patient completes intake without insurance information
7. **Duplicate Detection:** System suggests potential duplicate when similar demographics entered
8. **Session Timeout:** Patient leaves intake incomplete; returns later and finds auto-saved data
9. **Accessibility:** Screen reader user completes intake using keyboard navigation only
10. **Security:** Unauthorized user attempts to access another patient's data and is denied

Edge Cases:

- Patient age 0 (newborn)
- Patient age 120 (maximum age)
- Patient with 20+ medications
- Patient with 10+ known allergies
- Patient with no permanent address (homeless)
- Patient without SSN (undocumented)
- Non-English speaking patient (Spanish interface)
- Patient with visual impairment (screen reader, high contrast)
- Patient on mobile device with poor internet connection

- Simultaneous updates from patient and staff (conflict resolution)
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7. Glossary

EHR: Electronic Health Record

FHIR: Fast Healthcare Interoperability Resources

HIPAA: Health Insurance Portability and Accountability Act

PHI: Protected Health Information

ePHI: Electronic Protected Health Information

BAA: Business Associate Agreement

RxNorm: Standardized nomenclature for medications

OCR: Optical Character Recognition

TLS: Transport Layer Security

RBAC: Role-Based Access Control

WCAG: Web Content Accessibility Guidelines

MVP: Minimum Viable Product

8. Approval

Document Owner: Clinical Informatics Director

Technical Lead: Software Engineering Manager

Compliance Officer: HIPAA Privacy Officer

Clinical Stakeholder: Chief Medical Information Officer

Approval Date: _____

Next Review Date: _____

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