

Software Requirements Specification (SRS)

Medical Delegate Application with AI Scribe

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Project: Medical Delegate - Hospice Care Management System

Prepared by: Development Team

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1. Introduction

1.1 Purpose

This Software Requirements Specification (SRS) document describes the functional and non-functional requirements for the Medical Delegate Application, a comprehensive hospice care management system with integrated AI-powered clinical documentation assistance.

1.2 Scope

The Medical Delegate Application is designed to streamline hospice care operations by providing:

- Patient management and care coordination
- Visit scheduling and documentation
- AI-powered clinical note transcription and generation
- Task management and workflow optimization
- HIPAA-compliant data handling and storage
- Real-time communication between care team members

1.3 Definitions and Acronyms

- AI Scribe:** Artificial Intelligence-powered clinical documentation assistant
- HIPAA:** Health Insurance Portability and Accountability Act
- PHI:** Protected Health Information
- EHR:** Electronic Health Record
- API:** Application Programming Interface
- MCP:** Model Context Protocol
- SRS:** Software Requirements Specification

1.4 References

- HIPAA Privacy Rule (45 CFR Part 160 and Part 164)
- HIPAA Security Rule (45 CFR Part 164, Subparts A and C)

- FDA Guidelines for Software as Medical Device (SaMD)
 - HL7 FHIR R4 Implementation Guide
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2. Overall Description

2.1 Product Perspective

The Medical Delegate Application is a standalone mobile and web-based system designed specifically for hospice care providers. It integrates with existing healthcare infrastructure while maintaining independence for specialized hospice workflows.

2.2 Product Functions

Core Functions:

- **Patient Management:** Comprehensive patient profiles with medical history, care plans, and family information
- **Visit Management:** Scheduling, documentation, and assessment tracking
- **Task Management:** Assignment, tracking, and completion of care-related tasks
- **AI Clinical Documentation:** Real-time transcription and intelligent note generation
- **Communication Hub:** Secure messaging and care team coordination
- **Reporting and Analytics:** Care quality metrics and operational insights

2.3 User Classes and Characteristics

Primary Users:

1. Registered Nurses (RNs)

- Primary care providers
- Conduct patient visits and assessments
- Document care activities and patient status

2. Licensed Practical Nurses (LPNs)

- Assist with patient care
- Document basic assessments and interventions

3. Care Coordinators

- Manage patient care plans
- Coordinate between team members
- Oversee visit scheduling

4. Administrative Staff

- Manage user accounts and permissions
- Generate reports and analytics
- Maintain system configuration

Secondary Users:

- **Physicians:** Review patient status and care plans
- **Social Workers:** Access family support information
- **Chaplains:** View spiritual care needs and preferences

2.4 Operating Environment

- **Mobile Platforms:** iOS 14+ and Android 10+
- **Web Browsers:** Chrome 90+, Safari 14+, Firefox 88+, Edge 90+
- **Backend Infrastructure:** Cloud-based with 99.9% uptime SLA
- **Database:** Encrypted, HIPAA-compliant cloud storage
- **Network:** Secure HTTPS connections with end-to-end encryption

3. System Features

3.1 Patient Management System

3.1.1 Description

Comprehensive patient information management with secure access controls and audit trails.

3.1.2 Functional Requirements

- **FR-PM-001:** System shall maintain complete patient profiles including demographics, medical history, and care preferences
- **FR-PM-002:** System shall support family member information and contact details
- **FR-PM-003:** System shall track patient location and provide mapping integration
- **FR-PM-004:** System shall maintain care plan documentation with version control
- **FR-PM-005:** System shall support patient priority classification (urgent, high, medium, low)

3.1.3 Priority

High

3.2 Visit Management System

3.2.1 Description

Comprehensive visit scheduling, documentation, and assessment tracking system.

3.2.2 Functional Requirements

- **FR-VM-001:** System shall support visit scheduling with calendar integration
- **FR-VM-002:** System shall provide structured assessment forms for:
 - Vital signs monitoring
 - Pain assessment and management
 - Medication administration
 - Clinical interventions
 - Family support evaluation
 - Visit notes and documentation
- **FR-VM-003:** System shall track visit completion status and progress
- **FR-VM-004:** System shall generate visit summaries and care plan updates
- **FR-VM-005:** System shall support offline data entry with synchronization

3.2.3 Priority

High

3.3 AI Scribe System

3.3.1 Description

Intelligent clinical documentation assistant that transcribes speech to text and generates structured clinical notes.

3.3.2 Functional Requirements

- **FR-AI-001:** System shall provide real-time speech-to-text transcription during patient visits
- **FR-AI-002:** System shall generate structured clinical notes from unstructured voice input
- **FR-AI-003:** System shall support medical terminology recognition and auto-correction
- **FR-AI-004:** System shall provide note templates for common hospice care scenarios
- **FR-AI-005:** System shall allow manual editing and approval of AI-generated content
- **FR-AI-006:** System shall maintain audit trails for all AI-assisted documentation
- **FR-AI-007:** System shall support multiple languages for diverse patient populations
- **FR-AI-008:** System shall integrate with existing assessment forms and care plans

3.3.3 Priority

High

3.4 Task Management System

3.4.1 Description

Workflow management system for care team coordination and task tracking.

3.4.2 Functional Requirements

- **FR-TM-001:** System shall support task creation, assignment, and tracking
- **FR-TM-002:** System shall provide priority-based task organization
- **FR-TM-003:** System shall send notifications for overdue or urgent tasks
- **FR-TM-004:** System shall track task completion and time spent
- **FR-TM-005:** System shall generate task reports and analytics

3.4.3 Priority

Medium

3.5 Communication System

3.5.1 Description

Secure messaging and communication platform for care team coordination.

3.5.2 Functional Requirements

- **FR-CS-001:** System shall provide secure messaging between team members
- **FR-CS-002:** System shall support patient-specific communication threads
- **FR-CS-003:** System shall maintain message encryption and audit trails
- **FR-CS-004:** System shall provide notification management and preferences
- **FR-CS-005:** System shall support file sharing with security controls

3.5.3 Priority

Medium

4. External Interface Requirements

4.1 User Interfaces

- **Responsive Design:** Optimized for mobile devices and tablets
- **Accessibility:** WCAG 2.1 AA compliance for users with disabilities
- **Intuitive Navigation:** Role-based interface customization
- **Dark/Light Mode:** User preference support for various lighting conditions

4.2 Hardware Interfaces

- **Mobile Device Integration:** Camera, microphone, GPS, and biometric sensors
- **Bluetooth Support:** Integration with medical devices and peripherals
- **Barcode/QR Code Scanning:** Medication and patient identification

4.3 Software Interfaces

- **EHR Integration:** HL7 FHIR R4 compliant API for data exchange
- **Calendar Systems:** Integration with Google Calendar, Outlook, and Apple Calendar
- **Mapping Services:** Google Maps and Apple Maps integration
- **Cloud Storage:** Secure integration with HIPAA-compliant cloud providers

4.4 Communication Interfaces

- **HTTPS Protocol:** All data transmission encrypted with TLS 1.3
 - **RESTful APIs:** Standard HTTP methods for system integration
 - **WebSocket Support:** Real-time communication for messaging and notifications
 - **Push Notifications:** iOS and Android native notification support
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5. Non-Functional Requirements

5.1 Performance Requirements

- **Response Time:** 95% of user interactions complete within 2 seconds
- **Throughput:** Support 1000+ concurrent users
- **Scalability:** Horizontal scaling capability for growing user base
- **Offline Capability:** Core functions available without internet connectivity

5.2 Reliability Requirements

- **Uptime:** 99.9% system availability (8.76 hours downtime per year maximum)
- **Data Integrity:** Zero tolerance for data loss or corruption
- **Backup and Recovery:** Automated daily backups with 4-hour recovery time objective
- **Fault Tolerance:** Graceful degradation during partial system failures

5.3 Usability Requirements

- **Learning Curve:** New users productive within 2 hours of training
- **Error Prevention:** Intuitive interface design minimizing user errors
- **Help System:** Contextual help and documentation available
- **Accessibility:** Support for users with visual, auditory, and motor impairments

5.4 Compatibility Requirements

- **Cross-Platform:** Consistent functionality across iOS, Android, and web platforms
 - **Browser Support:** Compatible with major browsers (Chrome, Safari, Firefox, Edge)
 - **Legacy System Integration:** API compatibility with existing healthcare systems
 - **Version Control:** Backward compatibility for mobile app updates
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6. HIPAA Compliance Requirements

6.1 Administrative Safeguards

- **HC-AS-001:** System shall implement role-based access controls with minimum necessary access principles
- **HC-AS-002:** System shall maintain comprehensive audit logs for all PHI access and modifications
- **HC-AS-003:** System shall provide user authentication with multi-factor authentication (MFA)
- **HC-AS-004:** System shall support automatic session timeout after 15 minutes of inactivity
- **HC-AS-005:** System shall implement workforce training tracking and compliance monitoring

6.2 Physical Safeguards

- **HC-PS-001:** System shall encrypt all data at rest using AES-256 encryption
- **HC-PS-002:** System shall implement secure data center hosting with 24/7 monitoring
- **HC-PS-003:** System shall provide device management and remote wipe capabilities
- **HC-PS-004:** System shall maintain physical access controls for server infrastructure

6.3 Technical Safeguards

- **HC-TS-001:** System shall encrypt all data in transit using TLS 1.3 or higher
- **HC-TS-002:** System shall implement end-to-end encryption for sensitive communications
- **HC-TS-003:** System shall provide data backup and recovery with encryption
- **HC-TS-004:** System shall implement intrusion detection and prevention systems
- **HC-TS-005:** System shall support secure API authentication using OAuth 2.0 with PKCE

6.4 Business Associate Agreements

- **HC-BA-001:** All third-party integrations must have signed Business Associate Agreements
 - **HC-BA-002:** AI processing services must comply with HIPAA requirements
 - **HC-BA-003:** Cloud hosting providers must maintain HIPAA compliance certifications
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7. AI Scribe Specifications

7.1 Speech Recognition Engine

- **AI-SR-001:** System shall support real-time speech-to-text with 95%+ accuracy
- **AI-SR-002:** System shall recognize medical terminology and abbreviations
- **AI-SR-003:** System shall support noise cancellation and audio enhancement
- **AI-SR-004:** System shall process multiple speakers and conversation flows
- **AI-SR-005:** System shall support offline speech recognition for sensitive environments

7.2 Natural Language Processing

- **AI-NLP-001:** System shall extract clinical entities (symptoms, medications, procedures)
- **AI-NLP-002:** System shall generate structured SOAP notes from unstructured input
- **AI-NLP-003:** System shall maintain context awareness throughout documentation sessions
- **AI-NLP-004:** System shall support clinical decision support and alerts
- **AI-NLP-005:** System shall provide confidence scores for AI-generated content

7.3 Clinical Documentation

- **AI-CD-001:** System shall generate hospice-specific documentation templates
- **AI-CD-002:** System shall support care plan updates based on visit notes
- **AI-CD-003:** System shall maintain version control for AI-assisted documentation
- **AI-CD-004:** System shall provide human review and approval workflows
- **AI-CD-005:** System shall integrate with existing assessment forms and protocols

7.4 Privacy and Security for AI

- **AI-PS-001:** All AI processing shall occur in HIPAA-compliant environments
 - **AI-PS-002:** Patient data shall not be used for AI model training without explicit consent
 - **AI-PS-003:** AI models shall be regularly audited for bias and accuracy
 - **AI-PS-004:** System shall provide opt-out mechanisms for AI assistance
 - **AI-PS-005:** AI-generated content shall be clearly marked and attributed
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8. Data Requirements

8.1 Data Types

Patient Data:

- Demographics and contact information
- Medical history and diagnoses
- Medication lists and allergies
- Care preferences and advance directives
- Family and emergency contacts

Clinical Data:

- Vital signs and assessments
- Pain scores and symptom tracking
- Medication administration records
- Nursing interventions and outcomes
- Visit notes and care plan updates

Operational Data:

- User accounts and permissions
- Audit logs and system events
- Task assignments and completion
- Communication records
- System configuration settings

8.2 Data Storage

- **Encryption:** AES-256 encryption for data at rest
- **Backup:** Automated daily backups with geographic redundancy
- **Retention:** 7-year retention policy for clinical data
- **Archival:** Secure long-term storage for compliance requirements

8.3 Data Integration

- **Import/Export:** Support for standard healthcare data formats (HL7, FHIR)
 - **API Access:** RESTful APIs for third-party integrations
 - **Data Validation:** Real-time validation and error checking
 - **Synchronization:** Conflict resolution for offline/online data sync
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9. Security Requirements

9.1 Authentication and Authorization

- **SEC-AA-001:** Multi-factor authentication required for all users
- **SEC-AA-002:** Role-based access control with principle of least privilege
- **SEC-AA-003:** Password complexity requirements and regular rotation
- **SEC-AA-004:** Account lockout after failed authentication attempts
- **SEC-AA-005:** Single sign-on (SSO) integration support

9.2 Data Protection

- **SEC-DP-001:** End-to-end encryption for all sensitive data transmission
- **SEC-DP-002:** Data loss prevention (DLP) monitoring and alerts
- **SEC-DP-003:** Secure key management and rotation
- **SEC-DP-004:** Data anonymization for analytics and reporting
- **SEC-DP-005:** Secure data disposal and deletion procedures

9.3 Network Security

- **SEC-NS-001:** Web Application Firewall (WAF) protection
- **SEC-NS-002:** Intrusion detection and prevention systems
- **SEC-NS-003:** DDoS protection and mitigation
- **SEC-NS-004:** Network segmentation and access controls
- **SEC-NS-005:** Regular security scanning and vulnerability assessments

9.4 Incident Response

- **SEC-IR-001:** 24/7 security monitoring and alerting
 - **SEC-IR-002:** Incident response plan with defined procedures
 - **SEC-IR-003:** Breach notification within 72 hours of discovery
 - **SEC-IR-004:** Forensic capabilities for security investigations
 - **SEC-IR-005:** Regular security training and awareness programs
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10. Performance Requirements

10.1 Response Time Requirements

- **Page Load Time:** < 3 seconds for 95% of page loads
- **API Response Time:** < 500ms for 95% of API calls
- **Search Functionality:** < 2 seconds for patient and data searches
- **AI Transcription:** Real-time processing with < 1 second delay
- **Offline Sync:** < 30 seconds for data synchronization

10.2 Throughput Requirements

- **Concurrent Users:** Support 1000+ simultaneous active users
- **Data Processing:** Handle 10,000+ transactions per hour
- **File Uploads:** Support multiple concurrent file uploads
- **Message Delivery:** Process 1000+ messages per minute
- **Report Generation:** Generate complex reports within 60 seconds

10.3 Scalability Requirements

- **Horizontal Scaling:** Auto-scaling based on demand
 - **Database Performance:** Optimized queries and indexing
 - **CDN Integration:** Global content delivery for improved performance
 - **Load Balancing:** Distributed traffic management
 - **Resource Optimization:** Efficient memory and CPU utilization
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11. Quality Assurance

11.1 Testing Requirements

- **Unit Testing:** 90%+ code coverage for all modules
- **Integration Testing:** End-to-end workflow validation
- **Performance Testing:** Load testing under peak conditions
- **Security Testing:** Penetration testing and vulnerability scanning
- **Usability Testing:** User acceptance testing with healthcare professionals

11.2 Validation and Verification

- **Clinical Validation:** Healthcare professional review of AI-generated content
- **Regulatory Compliance:** Validation against HIPAA and healthcare standards
- **Data Accuracy:** Verification of data integrity and consistency
- **Workflow Validation:** Confirmation of clinical workflow support
- **Accessibility Testing:** Compliance with WCAG 2.1 AA standards

11.3 Continuous Monitoring

- **System Health:** Real-time monitoring of system performance
 - **User Experience:** Analytics and feedback collection
 - **Security Monitoring:** Continuous threat detection and response
 - **Compliance Auditing:** Regular compliance assessments and reporting
 - **AI Model Performance:** Ongoing evaluation of AI accuracy and bias
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12. Appendices

Appendix A: Glossary of Terms

- **Care Plan:** Comprehensive document outlining patient care goals and interventions
- **SOAP Notes:** Subjective, Objective, Assessment, Plan documentation format
- **Hospice Care:** Specialized medical care focused on comfort and quality of life
- **Protected Health Information (PHI):** Individually identifiable health information
- **Business Associate:** Third-party entity that handles PHI on behalf of covered entities

Appendix B: Regulatory References

- 45 CFR Part 160 - General Administrative Requirements (HIPAA)
- 45 CFR Part 164 - Security and Privacy (HIPAA)
- 21 CFR Part 820 - Quality System Regulation (FDA)
- ISO 27001 - Information Security Management
- SOC 2 Type II - Security, Availability, and Confidentiality

Appendix C: Technical Standards

- HL7 FHIR R4 - Healthcare data exchange standard
- OAuth 2.0 with PKCE - Secure API authentication
- TLS 1.3 - Transport layer security protocol
- AES-256 - Advanced encryption standard
- WCAG 2.1 AA - Web content accessibility guidelines

Appendix D: Risk Assessment Matrix

Risk Category	Probability	Impact	Mitigation Strategy
Data Breach	Low	High	Multi-layered security, encryption, monitoring
System Downtime	Medium	High	Redundancy, backup systems, SLA monitoring
AI Accuracy	Medium	Medium	Human oversight, continuous training, validation
Regulatory Non-compliance	Low	High	Regular audits, compliance monitoring, training
User Adoption	Medium	Medium	Training programs, user feedback, iterative design

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