# Software Requirements Specification (SRS)

## Medical Delegate Application with AI Scribe

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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

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## 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

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## 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 |

| Risk Category | Probability | Impact | Mitigation Strategy |
|---|---|---|---|
| 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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