



Exploring AI's Potential to Transform Specialty Pharmacy

NAVIGATING THE OPPORTUNITIES, CHALLENGES, AND POLICY LANDSCAPE

EXECUTIVE SUMMARY

The adoption and integration of artificial intelligence (AI) in specialty pharmacy presents a paradigm shift. In healthcare, AI has the potential to streamline processes, enhance efficiency, and improve patient outcomes. However, these opportunities come with unknowns, and healthcare organizations must carefully weigh the opportunities and risks of AI implementation.

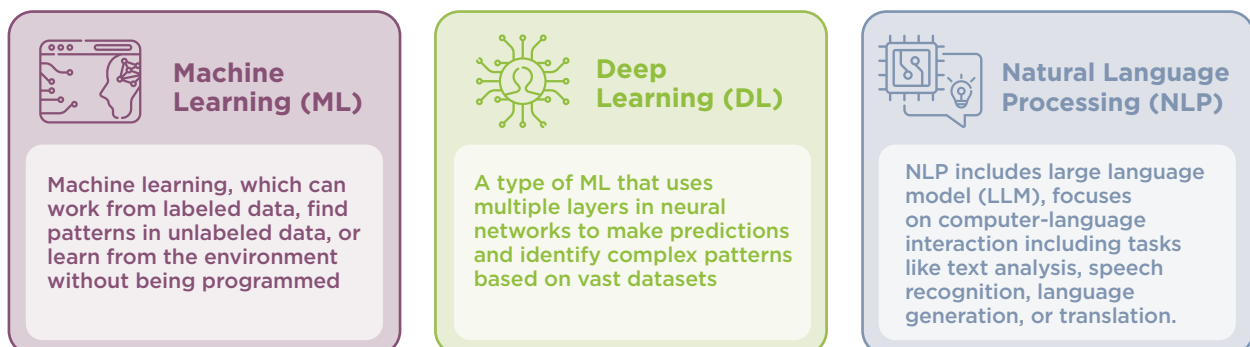
This white paper explores the potential of AI to transform aspects of specialty pharmacy and outlines the evolving regulatory and policy environment. As a patient-centric organization focused on specialty pharmacy, Shield Health Solutions views AI as a powerful tool capable of enhancing our mission of delivering industry-leading patient outcomes for health systems across the nation, while maintaining a high-touch approach to care. Drawing from Shields ongoing work and expertise, we ultimately advocate for innovative collaboration to overcome our challenges, promote responsible development, and encourage skillful deployment to unlock AI's full potential to improve patient outcomes and drive efficiency in healthcare.

KEY CONCEPTS

- AI has the potential to transform specialty pharmacy.
- AI tools in specialty pharmacy will be most prevalent in the areas of clinical support, operational efficiency, and patient engagement.
- Regulatory frameworks and guidelines for use of AI are critical.
- The integration of AI into specialty pharmacy services may offer the opportunity to enhance patient care, optimize operations, and drive innovation.

WHAT IS AI?

AI is a broad term encompassing computer-based systems that simulate human intelligence. Trained on vast amounts of data, AI can mimic cognitive processes, visual perception, generative capabilities, or other human-like functions. Key categories of AI are:^{1,2}



APPLICATIONS OF AI IN SPECIALTY PHARMACY

As AI tools evolve, they can improve, enhance, or streamline a spectrum of activities in specialty pharmacy, including clinical support, operational efficiency, and patient engagement, as outlined below. It is important to note that while some of these applications are already being explored, many are still in preliminary stages of development, and fully effective AI solutions have yet to be realized in all areas. While AI is not always the answer, its potential benefits make it worth considering as part of a comprehensive approach to pharmacy innovation and improvement.

Clinical Support

AI offers many opportunities for enhancing clinical support in specialty pharmacy, with the potential to transform various aspects of patient care, from patient records to personalized medicine.

Clinical Documentation

AI offers a variety of applications for automating and improving the quality of clinical documentation, as well as for streamlining transcription or summarization.

Documentation Summarization and Streamlining:

Algorithms that summarize patient records and in-person or remote encounters into concise, relevant information for review

Clinical Documentation Improvement (CDI) Programs:

Tools that assist in identifying gaps or inaccuracies in documentation

Compliance Monitoring and Error Detection:

Tools that continuously monitor documentation practices to ensure completeness and adherence to regulatory standards

Voice-to-Text Transcription:

AI-powered voice recognition that transcribes spoken medical dictations into text

Clinical Decision Support

AI-powered clinical decision support tools can enhance patient care by assisting healthcare providers in making informed, evidence-based decisions while still relying on human expertise. Some tools may deliver comparable results to current methods but do it with greater efficiency and a streamlined process.³

Automated Patient Triage:

Tools that assess patient-reported symptoms and prioritize care based on urgency and severity, enabling prompt intervention

Medication Management:

AI that can analyze patient data to suggest optimal drug therapies, identify potential interactions, and recommend dosage adjustments

Treatment Protocol Adherence:

AI systems that monitor and ensure adherence to established treatment protocols, flagging deviations when necessary

Personalized Medicine and Pharmacogenomics

Pharmacogenomics explores the interplay between genes and medications affecting individual drug responses. The integration of AI with pharmacogenomic data offers promise for optimizing drug therapies and improving patient outcomes. While promising, real-time clinical implementation of these AI tools remains challenging due to the complexity of genomic and biomarker data interpretation.¹

Disease Prediction and Surveillance:

Algorithms to identify genetic patterns and biomarkers linked to disease diagnosis, susceptibility, or drug responses

Treatment Optimization:

AI profiling of genetic biomarkers to categorize disease subtypes, such as Alzheimer's disease and other dementias,⁴ impacting treatment decisions

Dose Optimization and Monitoring:

AI to tailor medication dosages and predict drug interactions based on genetic and biomarker data



Operational Efficiency

Operational efficiency presents an exciting area for AI tools in specialty pharmacy, with the potential to reduce time spent on routine tasks. This automation allows pharmacists, technicians, and other professionals to focus on higher-level clinical activities.

Data Management and Processing

With the capacity to intake and analyze vast quantities of data, AI tools are a natural fit for data management in specialty pharmacy. These applications may include data aggregation, data cleaning and preprocessing, data normalization, and real-time data processing.

Data Aggregation:

Systems that collect and unify data from various sources, such as EHRs, wearable devices, and laboratory systems

Data Cleaning and Preprocessing:

Algorithms that identify and correct errors, inconsistencies, and missing values in healthcare datasets

Data Normalization:

Tools that standardize data formats across different systems and sources

Real-time Data Processing:

AI systems that process and analyze healthcare data as it is generated

Process Optimization

Other administrative automation or optimization through AI includes automation to streamline clinical workflows and reduce the administrative burden on healthcare providers, allowing them to spend more time on patient care.

E-prescription Management & Claims Processing:

AI for enhancing prescription handling and accelerating claims adjudication

Prior Authorization (PA) & Financial Assistance (FA):

Tools for facilitating approvals and identifying eligible patients for assistance programs

Supply Chain and Workflow Automation:

Systems that optimize inventory management and routine tasks

Automated Medical Coding and Revenue Cycle Management (RCM):

Tools that can improve coding accuracy and enhance financial performance

340B Program Management:

Tools that can assist in compliance and optimizing savings for eligible organizations

Compliance and Quality Assurance

AI tools can play a role in enhancing compliance and quality assurance in specialty pharmacy. By using AI, specialty pharmacies can leverage technology to assist in navigating the complex regulatory landscape.

Regulatory Compliance:

Systems that can monitor adherence to regulatory requirements, reducing risk of non-compliance

Data Privacy and Security:

Algorithms that can enhance the protection of sensitive patient data

Quality Control Optimization & Auditing:

Automated processes that continuously monitor and improve the quality of healthcare services

Clinical Trial Management:

AI that can streamline patient identification, matching, enrollment, and remote monitoring

Patient Engagement

Patient engagement is a critical factor in the success of specialty pharmacy programs and can be enhanced by AI technologies.

Predictive Analytics

When provided with the appropriate historical data, AI-based analytics can predict trends and outcomes for a program or population.

Risk Stratification:

Algorithms that analyze patient data and identify individuals at high risk of non-adherence or adverse events, allowing for proactive interventions

Behavioral Patterns:

Models that can detect patterns in patient behavior, predicting when a patient might be likely to miss a dose or discontinue treatment

Outcome Forecasting:

AI that can forecast health outcomes, allowing pharmacies to allocate resources more effectively

Personalized Communication

On a more individualized level, AI tools, including virtual assistants and chatbots, can efficiently personalize patient communication, education, and support.

Tailored Content:

Tools that analyze patient data to deliver personalized educational content, addressing knowledge gaps

Adaptive Messaging:

Machine learning algorithms that optimize message timing, frequency, and content based on individual patient preferences and response patterns

Multilingual Support:

AI-powered translation services that can break down language barriers, ensuring effective communication with diverse patient populations

Monitoring and Follow-up

Automated AI systems can manage various aspects of patient care continuity, from routine appointment management tasks to adherence monitoring.

Appointment Management:

AI that assists in booking, rescheduling, and cancellations

Smart Reminders:

AI that sends context-aware reminders for appointments, medication refills, and follow-up visits, adjusting timing and frequency based on patient response patterns

Adherence Tracking:

Devices and algorithms that can monitor medication usage in realtime, triggering interventions when non-adherence is detected

THE CHALLENGES OF IMPLEMENTING AI IN SPECIALTY PHARMACY

Implementing AI in specialty pharmacy presents a complex set of challenges, not the least of which is that the technology is developing extremely rapidly and with minimal oversight. Generative AI, which produces content, is developing particularly rapidly⁵ and poses both great risks and opportunities. Other key concerns include:

Ethical and Regulatory:

- » Ensuring equity and bias in AI algorithms and outcomes
- » Navigating regulatory, ethical, and privacy considerations
- » Managing liability and risk management

Technical:

- » Addressing data quality, availability, and appropriateness for AI model training
- » Achieving scalability and integration with existing pharmacy systems and infrastructure

Implementation and Trust

- » Enhancing interpretability and transparency of AI decision-making processes
- » Establishing governance frameworks for AI deployment

Proving the benefit of AI presents another significant challenge to specialty pharmacies, who must evaluate the efficacy and cost effectiveness of AI tools and applications in practice. This aligns with the American Society of Health-System Pharmacists (ASHP) recommendation that “full automation using AI should be reserved for algorithmic tasks for which it is demonstrated that AI performs as well or better than pharmacists.”⁶ Similarly, the American Medical Association (AMA) emphasizes AI’s supportive role, preferring the term “augmented intelligence” to highlight its function in enhancing human capabilities rather than replacing them.⁷

Considerations for implementing AI tools in practice directly relate to the challenges of implementation and trust. Providers often mistrust or lack understanding of AI-based clinical decision support systems due to unclear risks, which hinders adoption.⁸ These issues highlight the importance of addressing technical challenges of data quality and the ethical concerns of liability, while also highlighting the need for robust governance structures to ensure responsible AI deployment in specialty pharmacy settings.

POLICY CONSIDERATIONS AND CONTINUING ENGAGEMENT

Regulatory frameworks and guidelines for AI are critical for healthcare, and agencies in the United States and internationally have been engaged in the complex work of creating them for several years. For example, final FDA guidance on AI/ML-based software as a medical device is pending.⁹ Additionally, in 2024, the U.S. Department of Health and Human Services (HHS) published its final rule regarding Section 1557 of the Affordable Care Act, which governs “non-discrimination in health programs and activities,” including a sub-section on “Non-Discrimination in the Use of Patient Care Decision Support Tools.”¹⁰ Equity is at the forefront of healthcare policy considerations, and the potential of AI models to not only reflect but exacerbate bias by amplifying existing disparities in healthcare data and decision making processes has been widely discussed.¹¹ AI models must be built with high-quality, appropriate, relevant data to equitably deliver on the potential benefits.

Other industry stakeholders are also engaged in developing best practices. In addition to agencies within HHS, which recently reorganized certain strategy and policy functions to be better positioned to address healthcare AI concerns,¹² organizations like the Alliance for Health Policy and the Coalition for Health AI (CHAI) are doing important work in building frameworks for standards and



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regulations. In December 2023, 28 healthcare entities, primarily health systems, in conjunction with the federal government, committed to the “FAVES” principles of outcomes for healthcare AI, meaning Fair, Appropriate, Valid, Effective, and Safe.¹³ Additional policy is likely to be developed by federal and state governments, including the U.S. Congress. The Senate released a road map in May 2024 for further work on AI legislation, including healthcare AI.¹⁴

The ethical considerations of AI transcend industries, but the quality-of-life impact of healthcare decisions makes ethics and bias mitigation extraordinarily important in this context. These considerations include algorithmic fairness and non-discrimination, transparency, and explicability of AI models, which may hallucinate and create false information or may “drift” and become less applicable, and human oversight and accountability to investigate and mitigate problems and affirm correct results.

CONCLUSION

As a people-centric healthcare company with a primary focus on patient care, Shields Health Solutions views AI as an enabler, not a replacement for comprehensive and bespoke services. Our strength lies in our dedicated professionals who deliver high-touch care to support our mission of improving the lives and outcomes of patients. AI is not a threat to dismantle a workforce, but rather an opportunity to enhance human capabilities and achieve deeper connections with our patients. The integration of AI into specialty pharmacy services offers a transformative opportunity to enhance patient care, optimize operations, and drive innovation in the healthcare industry.

Our initiatives include testing and studying machine learning predictive index modeling to enhance decision support and natural language processing for task automation in operational workflows, designed to support human expertise in health system specialty pharmacies. Our implementation strategy involves phased rollouts with careful monitoring to ensure safety, efficacy, and appropriate data use throughout. These technologies are designed to enable our workforce to enhance patient care, improve access to medications, and provide coordinated, comprehensive support for complex medication therapies. As we progress, we will continuously evaluate and adjust our approaches based on feedback, emerging best practices, and evolving regulations in the AI field, always prioritizing the trust and well-being of our partners and the patients they serve, ensuring that our use of AI aligns with our values as a people-centered company dedicated to improving healthcare outcomes. We encourage the industry to continue collaboration and testing, when feasible, to advance our industry in the spirit of better patient care.

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ADDITIONAL ARTICLES AND RESOURCES

While this list is by no means comprehensive, it may be helpful in leading to further study as health system leaders consider the innovative possibilities of AI to improve patient outcomes and operational efficiency in specialty pharmacy and throughout their organizations.

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ABOUT SHIELDS HEALTH SOLUTIONS

Shields Health Solutions (Shields) is the premier specialty pharmacy accelerator in the country. The Shields Performance Platform, an integrated set of solutions, services and technology, is intentionally designed to elevate payer and drug access for specialty pharmacies, elevate health outcomes for complex patients, and elevate growth throughout the entire health system. As the foremost experts in the health system specialty pharmacy industry, Shields has a proven track record of success including access to over 90 percent of all limited distribution drugs (LDDs) and most (health insurance) payers in the nation; and a clinical model proven to lower total cost of care by 13%. In partnership with more than 80 health systems across the country through national-scale collaboration, Shields has a vested interest in delivering measurable clinical and financial results for health systems.



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