House of Delegates

REPORT ON THE
VIRTUAL HOUSE OF DELEGATES

November 8-15, 2024

RESULTS OF THE VOTING

Between November 8 and 15, the ASHP House of Delegates (roster attached as Appendix A) voted on six policy recommendations. Delegates approved four policy recommendations including two discontinuations by 85% or more, the threshold for final approval. Two policy recommendations did not reach the threshold for approval, Clinical Significance of Accurate and Timely Height and Weight Measurements and Safety of Intranasal Route as an Alternative Route of Administration, and will be considered by the House of Delegates in 2025.

POLICY RECOMMENDATIONS APPROVED

The four policy recommendations **approved** are as follows (percentage of delegates voting to approve follows the policy title):

Pharmacist's Leadership Role in Anticoagulation Therapy Management (93.0%)
Source: Council on Pharmacy Practice
To discontinue ASHP policy 2006, Pharmacist's Leadership Role in Anticoagulation Therapy Management, which reads:

> To advocate that pharmacists provide leadership in caring for patients receiving drug products for anticoagulant therapy management; further,

> To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving drug products for anticoagulation therapy management; further,

> To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant drug product uses, drug interactions, reversal

therapies and strategies, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

Use of Two Patient Identifiers in the Provision of Patient Care (93.0%)
Source: Council on Pharmacy Practice
To encourage the use of two unique identifiers during the provision of patient care.

Pharmacy Drug Theft (93.9%)
Source: Council on Pharmacy Management
To discontinue ASHP policy 0303, Pharmacy Drug Theft, which reads:

> To support the development of policies and guidelines for health-system pharmacists designed to deter drug product theft and thereby enhance both the integrity of the drug distribution chain and the safety of the workplace; further,

> To encourage the development of systems that limit the diversion and abuse potential of medications, including high-cost drugs and controlled substances, and thereby reduce the likelihood that these products will be targets of theft.

ASHP Statement on Artificial Intelligence in Pharmacy (94.4%)
Source: Section of Pharmacy Informatics and Technology
To approve the ASHP Statement on Artificial Intelligence in Pharmacy (Appendix B).

POLICY RECOMMENDATIONS NOT APPROVED

The House **voted to not approve** the following policy recommendations (percentage of delegates voting to approve follows the policy title):

Clinical Significance of Accurate and Timely Height and Weight Measurements (75.5%)
Source: Council on Therapeutics

To encourage pharmacists to participate in interprofessional efforts to ensure accurate and timely patient height and weight measurements are recorded in the patient medical record to provide safe and effective drug therapy; further,

To encourage drug product manufacturers to conduct and publicly report pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes; further,

To advocate for federal and state laws and regulations to include weight, height, and date obtained as a required component of prescriptions for medications that are dosed based on height and weight.

Safety of Intranasal Route as an Alternative Route of Administration (76.0%)
Source: Council on Therapeutics

To encourage research on the pharmacokinetic and pharmacodynamic characteristics of drugs not approved for intranasal administration; further,

To encourage the development of institutional guidance and resources on the safe and effective use of drugs not approved for intranasal administration; further,

To encourage manufacturers to develop intranasal formulations in accordance with current regulatory standards to minimize the risk of medication errors, including ready-to-use devices.

NOTES ON VOTING

Over 91% (202) of delegates to the virtual House of Delegates participated in the voting.

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U.S. Public Health Service	Russ Gunter	Andrew Glatz Chenoa Shelton
Veterans Affairs	Julie Groppi	Heather Ourth

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ASHP Statement on Artificial Intelligence in Pharmacy

Position

1 Artificial intelligence (AI) has the potential to improve patient care and the medication-use

2 process by offering innovative methods to gather clinical, operational, and economic

3 knowledge; assist end users; enhance educational experiences; and streamline administrative

4 processes within pharmacy practice.[1] The pharmacy workforce is uniquely positioned to serve

5 as key contributors and domain experts in the advancement of AI in healthcare. They should

6 lead in decision-making, design, validation, implementation, and ongoing evaluation of AI-

7 related applications and technologies that affect medication-use processes and related tasks.[1]

8 Pharmacy leaders should use scientific approaches to define appropriate medication-related

9 use cases for AI-enabled technology and determine which aspects of the medication-use

10 process are best handled by the pharmacy workforce, by AI, or by the pharmacy workforce who

11 receive information or support from AI-based systems.

12 The pharmacy workforce must assist in validating AI for clinical and operational uses and

13 identify strategies to mitigate unintended consequences of AI, especially recognizing the ethical

14 considerations that must guide the development and use in pharmacy practice.[1] Pharmacists

15 should engage in research efforts to generate data to support additional AI use cases and

16 identify potential risks. At a minimum, AI should be evaluated for accuracy, transparency, and

17 interpretability, with policies adopted for AI utilization and ongoing surveillance of AI-related

18 applications.[1] Additionally, the pharmacy workforce should actively pursue ongoing education

19 and training in AI, given its rapidly growing adoption.

20 Fully automated AI should be reserved for algorithmic tasks where AI performance is

21   comparable to that of its human counterpart. AI of proven value, particularly AI with proven

22   safety and efficacy, should be adopted and used so that the pharmacy workforce can make

23   informed and efficient decisions and focus their expertise on solving new and confounding

24   problems for patients, families, and healthcare professionals and organizations.[1]

25

26   **Background**

27   In 2020, the American Society of Health-System Pharmacists (ASHP) released a statement on

28   the use of AI in pharmacy.[2] Given the rapid advancements in AI technology,[3] this statement has

29   been developed to expand the scope to include generative AI, large language models (LLMs),

30   natural language processing (NLP), AI agents, and deep learning within the context of pharmacy

31   practice.

32   AI is the theory and development of computer systems to perform tasks previously

33   thought to require human intelligence, such as visual perception, language processing, learning,

34   and problem solving, by using machine learning to extrapolate from large collections of data.[4]

35   Deep learning, a form of machine learning, allows a network to understand concepts quickly,

36   learning from examples, similar to the way the human brain does.[5] LLMs use deep-learning

37   methods to process large data sets to construct natural-sounding text.[6] To put these concepts

38   together, generative AI is a type of AI trained using deep learning that can create content such

39   as text, images, and sound. As a result, text-based generative AI is a type of AI LLM that can

40   generate human-like text responses to written or spoken prompts, based on identified

41   patterns.[7]

42   AI-based technologies are being adopted by industries worldwide to improve efficiency

43   and outcomes. Healthcare has an opportunity to leverage AI to improve all aspects of the value

44   equation – outcomes, cost, and access. By increasing automation and improving workflow

45   efficiencies, AI has the potential to reduce time spent on manual and routine tasks, allowing

46   healthcare practitioners to optimize their scope of practice and improving clinician satisfaction,

47   both of which are vital in the context of ongoing clinician workforce shortages. AI adoption in

48   the healthcare system can also create new roles for the pharmacy workforce and alter the

49   scope of pharmacist patient care.[8] Therefore, pharmacy teams must be prepared to embrace

50   and lead efforts in selecting, implementing, safely using, and assessing AI technology use in the

51   medication-use process.

52   At its June 2024 meeting, the ASHP House of Delegates approved ASHP policy 2413, Role

53   of Artificial Intelligence in Pharmacy Practice.[1] The policy recognizes the potential for AI to

54   improve patient care, acknowledges the risks and ethical challenges associated with the use of

55   AI in healthcare settings, and supports the adoption of policies and procedures related to the

56   use of AI. This statement expands upon the ideals described in that policy and further defines

57   the roles and positions of the pharmacy workforce in the advancement of AI in the care of

58   patients. This statement was developed not simply to consider potential applications of AI

59   within the current practice of pharmacy but also to plan for how this technology will need to be

60   developed and implemented in coming years. Although this statement is similar to positions

61   held by other organizations of health professionals, it is uniquely focused on identifying

62   opportunities for AI to drive change specific to the practice of pharmacy. This statement is

63   based on consensus opinion and professional judgment among experts on AI in pharmacy and is

64   applicable to all pharmacy practice settings.

65

66   **Role of the pharmacy workforce in AI**

67   The pharmacy workforce serves in crucial roles in AI, including developing and validating

68   models, ensuring data quality, educating about implementation and use, and identifying

69   enhancement needs. As subject matter experts in medication-use processes, they bear

70   significant responsibility to ensure that AI contributes to safe, effective, and efficient outcomes.

71   In the same way they apply scientific rigor to medication formulary decision-making, they

72   should evaluate the deployment of AI capabilities and contribute to experimental design when

73   research gaps are identified.

74   The pharmacy workforce can support the development of new AI models or the

75   implementation of prebuilt AI models, depending on the scope of the need. Pharmacy

76   informaticists, operations pharmacists, and clinical pharmacists possess diverse clinical and

77   technical skills, equipping them to collaborate with computer scientists to build or adjust

78   existing models. They can ensure data used in AI models are accurate and minimize bias, which

79   can impact outputs.[9] Among the 2023 ASHP Pharmacy Forecast panelists, 73% predicted that

80   health systems will be required to validate the safety and effectiveness of AI tools, while only

81   37% reported that they were prepared to perform the validation.[10] The pharmacy workforce

82   must be aware of pharmacy data sources, data classification, data quality and lineage,

83   intellectual property, and privacy management during model development and validation

84   stages. Once a model is established, the pharmacy workforce is responsible for testing it to

85   ensure it serves its intended function without errors.[11] Because it is important to define the

86   quality assurance and quality engineering processes that must occur to test AI accuracy as part

87 of the validation process, the pharmacy workforce will need to be trained on the evaluation and

88 validation of AI solutions, including failure modes and effects analysis.

89   The pharmacy workforce must also educate AI users, informing them of the AI model's

90 focus, scope, and boundaries. Generative AI models may require engineering to ensure that

91 prompts are crafted with the optimal textual inputs (i.e., appropriate words, phrases, sentence

92 structure, and punctuation). To be reliable and efficient, a generative AI tool will require a

93 clearly defined problem with a formulated prompt. Prompts can be built and standardized for

94 use. However, proper user education is required to ensure reliable outputs. Furthermore,

95 superusers can be designated among the pharmacy workforce to build credibility and advocate

96 for technology.

97   **Role of pharmacy informaticists**. Pharmacy informaticists play a vital role in creating,

98 supporting, and interfacing clinical information and technology to improve medication safety,

99 efficiency, and patient care.[12] Because that role typically includes oversight of data and

100 analytics, pharmacy informaticists should also have a robust understanding of AI, especially as it

101 pertains to medication-related applications. Pharmacy informaticists should have a deep

102 understanding of AI model types and variables.[13] They should assess models to align with

103 organizational policies to safeguard sensitive information, including protected health

104 information, personally identifiable information, and financial data. These individuals should be

105 responsible for ensuring models are trained, evaluated, corrected, and applied to data that

106 match clinical practice prior to implementation. Additionally, pharmacy informaticists should

107 also perform routine maintenance and monitoring of deployed AI models, as clinical practice,

108 data inputs, or data distributions change over time.[14] Pharmacists who have knowledge and

109   experience in informatics are well-suited for designing, implementing, and researching AI

110   applications in the future. As healthcare professionals, pharmacists can focus on AI and data

111   science as a specialty, going beyond the supportive role with data scientists and industry.

112

113   **AI education and training**

114   Education on AI is necessary across all pharmacy practice domains.[3,15] Pharmacy curricula

115   should introduce students to the essential concepts of data science, including the fundamentals

116   of AI, ethical use of generative AI, AI e-iatrogenesis, and AI model safety and efficacy

117   validation.[16,17] The pharmacy workforce must also be given the chance to expand their

118   understanding of AI through continuing education. Data science courses or pharmacy

119   residencies with a focus on AI topics should be available to pharmacists seeking advanced

120   training in these fields. Existing residencies could explore how to incorporate foundational AI

121   concepts into their learning experiences (e.g., pharmacy administration or informatics

122   electives).

123

124   **Role of AI in pharmacy practice**

125   **Informatics**. Pharmacy information systems, automation, and technology have been key

126   sources of data and analytics within health systems. These data should not only be an output

127   but should also be considered an agent to troubleshoot, enhance, and optimize pharmacy

128   technology to better suit the needs of end users.[18] Given the differing levels of data complexity

129   and organization, AI may aid pharmacy personnel in mining the vast amount of healthcare data

130   for actionable trends or patterns. Informaticists must also partner with their medical

131 technology vendors, advocating for continual, ethical advancement of AI applications to provide

132 the best possible patient outcomes.

133   **Clinical applications.** Historically, AI has been used in pharmacy to perform repetitive

134 tasks and translate large quantities of data into easily digestible patterns or trends.[18] More

135 recent literature has emerged describing clinical applications of AI. For example, AI has proven

136 useful in interpreting diagnostic imaging,[19] conducting pharmacovigilance,[20] and designing

137 treatment plans.[18] Generative AI has the potential to offer additional benefits, including clinical

138 documentation, patient chart analysis, patient education, drug information, clinical protocol

139 development, and publication support. Future clinical applications of AI may intersect with

140 other growing fields in pharmacy, including pharmacogenomics, population health, drug

141 development, and telehealth pharmacy practice. A common feature of current and future use

142 cases is that they are designed to augment clinical pharmacy services, not replace the pharmacy

143 workforce. Pharmacists should be open to changing traditional clinical workflows to include AI

144 and AI-enabled clinical decision support systems that improve patient care. Pharmacy

145 departments should support efforts to integrate emerging AI-enabled tools to evaluate models,

146 improve care, improve access, lower costs, and provide comprehensive medication

147 management for patients.

148   **Pharmacy practice.** From an operational standpoint, AI platforms can improve inventory

149 management, facilitate product verification, assess medication adherence, and help

150 pharmacists perform at the top of their skill set.[20,21] Generative AI can assist with pharmacy

151 administration documentation requirements, such as staffing memos, human resource

152 management tasks, and medication safety event analysis.[22,23] As AI becomes more reliable,

153   standard pharmacy operations will become increasingly automated, allowing pharmacists to

154   focus more on high-value patient-care activities. Furthermore, it may also enable pharmacy

155   technicians to assume operational tasks historically performed by pharmacists (e.g., medication

156   optimization, medication safety and quality surveillance, and drug diversion monitoring),

157   supporting pharmacists' ability to provide direct patient care.

158   Rather than just adopting AI, pharmacy executives should lead the effort to define the

159   future of pharmacy and educate their healthcare colleagues and administrators on the role of

160   the pharmacy workforce in an environment in which AI is pervasive.

161   **Educational applications.** Generative AI has been used in various settings to provide

162   patient education.[7,24,25] Because pharmacists are often the most accessible healthcare

163   professionals, they must be willing and able to address concerns and comprehension challenges

164   when AI technologies are used for primary patient education. Ultimately, as technologies

165   rapidly evolve, the pharmacy education system must remain agile to ensure our profession is

166   equipped to steward these transformations of care, including educating patients on safe use of

167   generative AI drug information.

168   In addition to patient education, AI capabilities may be leveraged to support education

169   of the pharmacy workforce, including students and residents. AI applications have already been

170   used in the pharmacy curriculum, including in skills-based courses, exam writing, and school

171   admissions decision support, among other use cases.[26-28] These capabilities may allow for

172   pharmacy instructors to streamline administrative tasks and optimize their time with pharmacy

173   trainees. Pharmacy educators should evaluate AI capabilities to determine which are most

174   appropriate to deploy within the classroom, skills laboratory, and experiential training

175   environments.

176

177   **Ethical considerations and unintended consequences of AI**

178   While AI is poised to bring significant benefits to patient care, it also has its limitations. An

179   effective AI system relies on a repository of high-quality data. In the absence of high-quality

180   data, AI systems can easily perpetuate bias due to limited training data, population size, or

181   human bias. Medicine is vulnerable to those risks, as evidence-based clinical practice and

182   measures are often based on data from study populations skewed towards certain groups.[29]

183   Healthcare organizations must ensure that AI models are based on high-quality and expansive

184   data sets that include other objective measures to minimize perpetuating biases.

185   Generative AI also poses the risk of creating content that is false or misleading. These

186   models should be developed to minimize the probability of creating misleading content, such as

187   setting constraints on possible responses.[30] Operating these tools with human oversight is

188   crucial; AI should serve as a valuable aid to support the pharmacy workforce, rather than as a

189   proxy for them.[31]

190   These risks have been well recognized nationally. Recently, an executive order outlined

191   the risks, requirements, responsibilities, and accountability measures for the "safe, secure, and

192   trustworthy development of artificial intelligence."[32] One outcome of this executive order was

193   designating the National Institute of Standards and Technology (NIST) as the lead organization

194   for development of guidelines, standards, and best practices for AI safety and security. NIST has

195   already constructed an AI risk management framework, which includes guidelines on general AI

196   risk management and a companion framework on generative AI risk management.[33] Within

197   these frameworks, NIST tackles many common unintended consequences of AI, including

198   harmful bias, homogenization, data privacy, information integrity, and transparency.[33]

199   Organizations should establish AI governance committees to evaluate and ensure compliance

200   with these guidelines, standards, and best practices.

201   Having educated, competent staff using these models helps organizations mitigate

202   potential liability. Generally, individuals or groups are not found liable when the standard of

203   care is followed.[34] However, there are two scenarios in which liability may occur: when the AI

204   tool makes a recommendation that aligns with the standard of care, or optimal care, but is

205   dismissed, or when it erroneously makes a recommendation that is not the standard of care

206   and is accepted. In both situations, staff using the AI model must be educated and competent,

207   not only in the current subject in which AI is being applied, but also in the strengths and

208   weaknesses of the model itself.

209   As with any technology used to assist the practice of pharmacy, contingency plans must

210   be developed in the event of unexpected downtimes, breaches, or recalls.[35] Organizations

211   should answer such questions as: How are patient safety risks identified and handled? If the

212   model is unavailable, what processes should staff fall back to in its absence? Mitigation

213   strategies for unintended consequences of AI must be proactively identified and included

214   within an organization's AI policies and procedures.

215   In 2021, the World Health Organization published a set of ethical considerations that

216   should be observed in the application of healthcare AI.[36] These considerations include the

217   preservation of human autonomy within AI-supported medical decision-making and uses of

218   protected health information, the avoidance of harm, and the responsibility to provide the

219   maximum possible unbiased benefit across diverse patient populations. Pharmacy leaders

220   should address these considerations when AI is implemented.

221

222   **AI regulation**

223   Rapid expansion of AI use in health information technology has highlighted the need for federal

224   agency standards and policy to support safe use, encourage responsible development, improve

225   trust, and promote adoption. In January 2021, the FDA released its first AI/ML-Based Software

226   as a Medical Device (SaMD) Action Plan, outlining the agency's plans to develop a SaMD

227   regulatory framework for AI while also establishing best practices for development,

228   implementation, and monitoring of AI capabilities.[37] In December 2023, the Office of the

229   National Coordinator for Health Information Technology (ONC) issued the Health Data,

230   Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and

231   Information Sharing (HTI-1) Final Rule.[38] This rule established new standards for algorithm

232   transparency and risk management expectations for AI-enabled decision support interventions.

233   Additionally, it advanced interoperability standards designed to promote health equity and

234   established interoperability-focused reporting metrics.

235   Interoperability and AI are uniquely related. A common barrier to health information

236   exchange is the lack of standardized documentation or use of data standards. AI and machine

237   learning can improve interoperability by allowing the use of streamlined data standards to

238   provide for semantic exchange of health information. Given the fundamental role of data sets

239   and LLMs in AI, improving health information exchange will be a key goal of AI technology

240   development and optimization. In December 2023, the ONC also announced that the Trusted

241   Exchange Framework and Common Agreement (TEFCA) had become operational.[39] TEFCA is a

242   new interoperability framework supporting nationwide exchange of health information that

243   may support the facilitation of AI in healthcare due to simplification of connectivity and

244   increased flexibility for the exchange of data[40].

245   As AI and interoperable exchange of information continue to rapidly evolve, pharmacy

246   leaders are uniquely positioned to contribute to the regulatory efforts and ethical

247   considerations for applications related to medication use. Pharmacy leaders must embed

248   themselves in all arenas (organizational, regional, and national) of AI policymaking, governance,

249   and data stewardship to promote personalized, continuous, and preventive care.[15]

250

251   **Conclusion**

252   Advances in AI technologies will continue at a rapid pace, as will the opportunities to leverage

253   AI in all aspects of pharmacy practice. This evolving landscape presents pharmacy professionals

254   with the opportunity to embed themselves in processes to investigate, implement, maintain,

255   and optimize the use of AI technologies within their respective organizations. Pharmacy

256   workforce engagement in these processes is necessary to ensure that the use of AI technologies

257   results in safe and effective tools for improved patient care. To see this vision come to fruition,

258   pharmacy leaders must ensure sufficient education regarding AI technologies is available to

259   current and future pharmacy professionals. The incorporation of AI technologies within

260   pharmacy practice is inevitable, and pharmacists have the potential to significantly impact

261   patient care and the profession's future.

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