

VIA ELECTRONIC SUBMISSION

May 28, 2024

Micky Tripathi, Ph.D, M.P.P.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health
Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St., SW, Floor 7
Washington, DC 20201

Re: 2024-2030 Federal Health IT Strategic Plan Public Comment, Health IT
Feedback

Dear Dr. Tripathi,

On behalf of the United States Pharmacopeia (USP), I appreciate the opportunity to offer our comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the 2024-2030 Federal Health IT Strategic Plan. USP is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines. USP is governed by more than 400 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. A core pillar of USP's mission is to help strengthen the global pharmaceutical supply chain, from discovery and manufacturing of drugs to their distribution and use.

USP establishes, among other things, standards and solutions to help healthcare professionals tailor medicines for patients' personalized needs to deliver safe, quality patient care. USP standards are developed through an open, transparent, expert-based process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. The process utilizes the work of scientific and healthcare experts who volunteer their time on USP's standard-setting committees.¹

USP supports ONC's objective to establish expectations for data sharing. While the Cures Act requires ONC to establish certain Conditions and Maintenance of Certification requirements for health IT developers under the ONC Health IT Certification Program, there remains a need to provide solutions that improve medication safety and quality. We recommend ONC considers additional health information technology standards that provide guidance on how to properly maintain, operationalize, and transmit information related to medications. The USP Healthcare Information and Technology Expert Committee is dedicated to advancing health and promoting health equity and medication safety for people across the globe by

¹ USP standards are developed by Expert Bodies comprised of more than 750 scientific experts. These experts collaborate to develop USP standards through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology.

developing technology related standards and solutions that increase interoperability and strengthen data and information throughout global health electronic platforms.

USP supports ONC's 2024-2030 Federal Health IT Strategic Plan as a framework that will provide industry with guidance on person-centered inclusive design, safety and quality, privacy and security, data-led decision-making, increasing health equity across all populations, and encouraging innovation and competition.

USP appreciates the opportunity to provide comments related to Goal 1, to promote health and wellness, and Goal 2, to enhance the delivery and experience of care. The objectives of these goals can be further met by strengthening health care information practices related to the compounding of non-sterile preparations (CNSP's) and allergy and intolerance documentation and classification within electronic health records. USP is focused on the development of standards and other resources that support the delivery of safe, equitable, high-quality, and improved care. Our experts have identified several solutions that leverage existing prescribing standards and health IT clinical decision support systems to promote the exchange of discrete and uncoded/unmapped medication information across inpatient and outpatient platforms. Not only does this optimize patient care delivery, but it also reduces provider burden.

Promote Health and Wellness: Electronic Transmission of CNSP's

One of USP's strategic objectives is for all individuals to experience modern and equitable health care through information sharing and documentation practices for medications. While progress has been made in this area, opportunity for improvement and tailoring toward individual patient needs exists, particularly in the realm of electronic prescribing (e-prescribing) of medications that are not commercially available like compounded non-sterile preparations (CNSPs).

CNSP's are prescribed for a variety of reasons, including a non-compounded version being unavailable, allergies to dyes or preservatives in the non-compounded version, requiring a tailored dosage strength or to fulfill other medically necessary needs of a patient. Current e-prescribing interoperability of CNSPs demonstrate a lack of standardization of medication concentration, and lack of visibility around the ingredient and preparation formula during transitions of care. This lack of standardization and transparency contributes to increased patient risks for vulnerable populations, such as pediatric and geriatric populations. USP's 'Exchange of Compounded Drug Preparation Information in Health IT Systems' Expert Panel has conducted various efforts throughout the healthcare ecosystem to understand the benefits of standardizing e-prescribing practices of CNSPs.

To exchange CNSP prescriptions electronically, it is essential that key elements of the CNSP prescription be standardized to flow accurately, completely, and reproducibly throughout e-prescribing workflows. This standardization will also simplify and streamline documentation requirements for reimbursement of CNSP's. Currently, CNSP reimbursement practices remain widely inconsistent and lead to provider, prescriber, and patient challenges in dispensing and receiving CNSP's. Moreover, for the patient, CNSP e-prescribing standardization will optimize medication preparation by ensuring specific volumes translate to the same dose, regardless of patient setting. Thus, health and wellness will be enhanced, ensuring

that pediatric and other populations at risk or with special needs receive the intended doses and concentrations in the course of their health care.

Enhance the Delivery and Experience of Care

To enhance the delivery and experience of care, the health care workforce must be able to use health IT systems that have accurate patient information to ensure an optimal experience of care. Most systems today are proprietary and prevent the exchange of patient information across platforms. For example, patient allergy and reaction information does not move with the patient across inpatient and outpatient encounters resulting in an experience of care where the patient is responsible for providing at each care point information regarding their allergy history.

Adverse drug event (ADE) documentation improvement is an important component of modernizing approaches to allergy identification, documentation, capture, and prevention with high-impact potential for patients, providers, and health care operations. The clinical burden of ADE documentation remains high with estimates that clinicians annually spend 175,000 hours responding to 78.8 million alerts, equating to a financial cost of \$16.9 million.²

Current ADE capture practices within electronic health records (EHRs) remain widely inconsistent and can be made more actionable through terminology standardization and interoperability. One solution to enhance ADE terminology standardization and interoperability is the use of a value set, which is a list of specific values, terms, and their codes, used to describe clinical and administrative concepts in quality measures. The development of a more tailored value set addressing high-risk ADEs can standardize data entry across health IT systems and recording for more accurate use in clinical decision support (CDS) and facilitate interoperability across various EHR, pharmacy and clinical platforms. The USP Allergy and Intolerance Documentation and Classification Expert Panel has proposed the implementation of a value set to electronically map drug products to clinical manifestations.

By electronically mapping drug products to clinical manifestations, clinicians will have more accurate information that can establish whether a clinical manifestation or reaction is likely to occur due to a specific chemical entity (active ingredient vs. excipient). Improving data collection and information practices of ADE's will standardize ADE documentation, improve documentation and interoperability of ADE information, provide more targeted CDS, inform the frequency of ADE's, and reveal previously undocumented ADE's. Enhancing the standardization of ADE documentation will also aid in improving person-centered inclusive design, safety and quality, data-led decision making, health equity, and innovation within healthcare.

USP welcomes the opportunity to discuss and/or convene around the best solutions and future roles in supporting electronic transmission of compounded medication preparations and strengthening allergy and intolerance classification and clinical

² Sarah Slight, "The National Cost of Adverse Drug Events Resulting From Inappropriate Medication-Related Alert Overrides in the United States," Journal of the American Medical Informatics Association, September 1, 2018. [https://pubmed.ncbi.nlm.nih.gov/29939271/#:~:text=Taking%20the%20basic%20model%20\(78.8,billion%20for%20tr eating%20preventable%20ADEs.](https://pubmed.ncbi.nlm.nih.gov/29939271/#:~:text=Taking%20the%20basic%20model%20(78.8,billion%20for%20tr eating%20preventable%20ADEs.)



decision support. For more information, please contact Nakia Eldridge, Director, Healthcare Patient Safety Information, at (301) 692-3486 or nakia.eldridge@usp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony Lakavage". The signature is fluid and cursive, with a prominent initial "A" and a long, sweeping underline.

Anthony Lakavage, J.D.
Senior Vice President, Global External Affairs
Secretary, USP Convention and Board of Trustees