Universal standards proposed for prescription container labels to help reduce medication misuse

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For the first time, universal standards to guide the content, language, format and appearance of prescription medication labels to reflect how patients read and understand medication instructions are being proposed on a national level. These labels can vary significantly from pharmacy to pharmacy, even though they are intended to convey critical information for the safe use of medications. The new standards, developed by the U.S. Pharmacopeial Convention (USP)—the nonprofit scientific organization that sets FDA-enforceable standards for the quality, purity and strength of medicines in the United States—are the result of a broad effort led by the Institute of Medicine (IOM) to improve health literacy in the United States by bringing together government, industry, associations and other groups to advance practical strategies that can be implemented to maximize patient comprehension of health information. The new USP standards are being proposed for a 90-day public comment period, during which the organization will accept feedback from healthcare professionals, consumers and all other interested parties.

"As more patients enter the healthcare system, and as the nation becomes increasingly diverse, more patients will have difficulty understanding and using important healthcare information provided to them," said Roger L. Williams, M.D., chief executive officer of USP. "One key component of healthcare information is prescription container labels, which are a patient's best—and often only—source of instruction and background necessary for safely and appropriately using a medication.

Many studies have shown that patient misunderstanding is widespread, and lack of universal standards is a cause of this problem. These new standards were designed with the patient in mind, to bring clarity and consistency to the prescription labels they rely upon."

Developed by a multi-disciplinary group of independent experts convened by USP across the fields of pharmacy, medicine, health literacy, patient safety, human factors research, drug database software and chain drug retail operations, the standards could be adopted by state boards of pharmacy, other governmental authorities, or conformity assessment bodies into state laws, regulations, guidelines or other documents. Adoption of USP's standards at the state level is common, such as in the cases of USP's widely recognized standards for sterile and nonsterile pharmaceutical compounding to help ensure safe preparation of these customized medications. A few states, including California and New York, recently developed their own regulations for prescription container labeling.

Generally, the new standards propose that prescription container labels generated by pharmacies:

- Are organized in a patient-centered manner—Organized in a way that best reflects how most patients understand medication instructions, featuring the most important information for safe and effective understanding and use.

- Emphasize instructions and other important information to patients—Prominently display information that is critical to patient's safe and effective use of the medicine, such as, patient's name, drug name and strength, and clear directions for use. Less critical but important content (e.g., pharmacy name and number) should not supersede critical patient information.

- Give explicit instructions—Instructions should clearly separate the dose itself from the timing of each dose and use numeric characters (e.g., "Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily").

- Include purpose for use—The medication's purpose should be included on the label unless the patient prefers that it not appear. When included, use clear, simple terms (e.g., "for high blood pressure" rather than "for hypertension").

- Improve readability—The label type should use high-contrast print (e.g. black print on white background); large font size (e.g., minimum 12-point Times New Roman or 11-point Arial); and horizontal text only.

- Limit auxiliary information—Labels, stickers, or other supplemental information should be expressed in simple and explicit language that is minimized to avoid distracting patients with nonessential information.

Other recommendations include simplifying language, and eliminating Latin terms.

More information: To view detailed information on the proposed labeling standards, go to www.usp.org/USPNF/notices/generalChapter17.html

Provided by US Pharmacopeia

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