VIA Electronic Submission to 17PrescriptionContainerLabeling@usp.org

March 31, 2011

Shawn C. Becker, M.S., R.N.
Director, Healthcare Quality Standards
U.S. Pharmacopeia
12601 Twinbrook Parkway
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Re: Proposed General Chapter <17> Prescription Container Labeling

Dear Ms. Becker:

Thank you for the opportunity to submit our comments on the U.S. Pharmacopeia's (USP) newly proposed chapter. As USP considers finalizing a draft of General Chapter <17> Prescription Container Labeling, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

The National Community Pharmacists Association (NCPA®) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Patient safety is of the utmost importance, and independent pharmacists take the utmost care in ensuring their patients are presented with the most comprehensible and concise information possible to help them best adhere to their medication therapies.

Given the primary role that NCPA members play with regard to providing prescription services to patients, we believe that it is important that the newly proposed USP General Chapter <17> Prescription Container Labeling standards be feasible and easily implemented by community pharmacies. Labeling standards should take into consideration the state and federal regulations that oversee the practice of pharmacy, and NCPA recommends that USP clearly indicate that the purpose of the label is for the benefit of the patient. Accordingly, NCPA urges USP to consider the following suggested improvements to the proposed General Chapter <17> Prescription Container Labeling chapter.

Sections: Simplify language, Give explicit instructions, and Include purpose for use

> "[s]tandardized patient-centered translations of common prescribing directions to patient (SIG) should be used."

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> "[c]learly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when"
>
> "Determine what the patient prefers, and include the purpose of the medication on the label unless the patient prefers that it not appear."

NCPA believes that a heavy responsibility of implementing prescription container labeling standards lies with prescribers to ensure prescriptions are being written in conjunction with the standards made in the update. NCPA believes that the prescriber should write the indication on the prescription however, currently, the majority of prescribers do not write the indication on the prescription to increase safety and patient awareness of the medication purpose.

A pharmacist uses their professional judgment to assist the patient with taking their medications appropriately, but the precise wording to appear on the label must come from the prescriber. It is unreasonable to request that a patient stand by while the pharmacist spends significant time contacting prescribers to ask them for the prescription's indication. Improperly written prescriptions could lead to reduced adherence through an increased number of abandoned prescriptions by frustrated patients and a significant portion of the pharmacist's time being spent contacting prescribers in order to clarify prescriptions – time that NCPA contends should be spent on direct patient care.

Section: Limit Auxiliary Information

> "Evidence-based auxiliary information, both text and icons, should be standardized so that it is applied consistently and does not depend on individual practitioner choice"

Community pharmacists are licensed healthcare professionals, who have the ability to use professional judgment when it comes to auxiliary labels. Use of certain labels can be appropriate in one population and inappropriate in others. Therefore, auxiliary label placement should be left to the judgment of the pharmacist.

Section: Address Limited English Proficiency

> "[p]rescription container labeling should be provided in an individual's preferred language."
>
> "Translation of prescription medication labels should be produced using a high-quality translation process."

NCPA agrees that patients should clearly understand instructions for use contained on their prescription vials. However, which languages should be considered essential for pharmacy software systems? Languages such as Spanish that are more widely spoken may be appropriate in instances; however, various locations throughout the country may have widely varying language usage. Also, which programs can be considered to yield "high-quality translation"?

This section imposes unrealistic requirements for translated labels that could subject individual pharmacists to increased liability and ultimately jeopardize patient safety. At the present time, there are no standardized medical translation services that will guarantee the accuracy of translated labels. Cultural differences in translation are difficult to capture and may lead to misinterpretation of the label instructions. This would place individual pharmacists in an untenable situation in which they would be required to deliver drug information and instructions in a language that they do not understand and have no way to verify the accuracy of the translation.

Implementing software that caters to several different languages can be costly, can pose risks to patient safety if not high quality, and can place large financial burden on independent pharmacies, ultimately decreasing the level of patient services that can be offered.

Section: Improve Readability

"Optimize typography by using the following techniques:

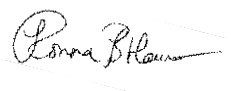
- High-contrast print (e.g., black print on white background).
- Simple, uncondensed familiar fonts with sufficient space within letters and between letters (e.g., Times Roman or Arial).
- Sentence case (i.e., punctuated like a sentence in English: initial capital followed by lower-case words except proper nouns).
- Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information."

NCPA believes that promoting patient safety by ensuring prescription labels are clearly understood is extremely important. However, this requirement could necessitate the use of larger prescription vials which may result in consumers taking their medication out of the larger, unwieldy bottle and putting it into a smaller, unlabeled bottle. There are no states that currently require a 12-point font and only one state mandates even a 10-point font size for prescription labels.

In addition, the issue of sig codes longer than the allotted space has not been addressed. For example, steroid tapers that require lengthy patient instructions that are often times abbreviated by the letter "x", i.e. "3 tablets by mouth x 2 days". Such issues are not addressed in the updated guideline and require clarification prior to recommending a specific labeling strategy.

NCPA appreciates the opportunity to comment on the Proposed General Chapter <17> Prescription Container Labeling standards. Please do not hesitate to me, by email at ronna.hauser@ncpanet.org, or by telephone at (703) 838-2691, if you have any questions.

Sincerely,



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