Commentary – *USP 36-NF 31*

Excerpt Related to General Chapter <17> *Prescription Container Labeling*

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The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference between the contents of the *Commentary* and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary*, shall prevail.

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General Chapter/Section(s):	General Chapter <17> *Prescription Container Labeling*
Expert Committee(s):	Nomenclature, Safety and Labeling
No. of Commenters:	193

Introduction and General Comments

Comment Summary #1: Several commenters suggested that responsibility and oversight be assigned for creation and maintenance of standardized formats, dictionaries, and glossaries.

[1] The Commentary for General Chapter <17> *Prescription Container Labeling* is being posted early to correspond with the early posting of the final General Chapter.

Response: Comment not incorporated. The jurisdiction of prescription container labeling is state by state and thus may vary.
Comment Summary #2: Several commenters indicated that compressed gas is exempted from prescription container labeling according to 21CFR and should also be exempt from the standard.
Response: Comment incorporated.
Comment Summary #3: Several commenters suggested that specific technologies be applied to manage the patient centered label.
Response: Comment not incorporated. The Expert Committee does not endorse any particular type of technology to allow for flexibility and cost considerations to accomplish compliance with the standards.
Comment Summary #4: Several commenters suggested that the General Chapter emphasize that the standards pertain to prescription containers that are directly dispensed to patients.
Response: Comment incorporated.
Comment Summary #5: Several commenters suggested that the label specifications in the standards be compliant with federal and state laws.
Response: Comment incorporated.
Comment Summary #6: Several commenters suggested the patient has the right to know the country of origin of the drug.
Response: Comment not incorporated. This is a supply chain issue and will be considered for incorporation in the General Chapter related to supply chain management.
Comment Summary #7: Several commenters suggested that the brand name and the generic name be included on the prescription container label.
Response: Comment incorporated.
Comment Summary #8: A commenter suggested that the written medication description and picture be required on the prescription container label.
Response: Comment not incorporated. The General Chapter allows for flexibility in the manner in which a patient centered label can be accomplished but does not require a written medication description or picture.
Comment Summary #9: A commenter suggested that the use of standardized color and shape be required on the patient centered label to identify medication.
Response: Comment not incorporated. The General Chapter allows for flexibility in the manner in which a patient centered label can be accomplished but does not require the use of color or shape.
Comment Summary #10: A commenter suggested that the General Chapter be numbered over 1000 to be considered as a voluntary guideline rather than an enforceable chapter (numbered below 1000).
Response: Comment not incorporated. The root cause for patient misunderstanding, non-adherence, and medication errors is a lack of universal standards for labeling on dispensed prescription containers. The standard will be more readily adopted by state regulatory agencies if the chapter is numbered below 1000.
Comment Summary #11: A commenter suggested that the gluten status of the medication be included on the prescription container label.

Response: Comment not incorporated. There are currently no standards related to gluten content in drugs.
Comment Summary #12: Several commenters suggested that the General Chapter be eliminated due to unjust financial impact to vendors, pharmacies, and patients.
Response: Comment not incorporated. The prescription container labeling standards were developed to promote patient understanding and prevent medication misuse, nonadherance, and medication errors.

Organize Prescription Label in Patient Centered Manner
Comment Summary #1: A commenter suggested that the organization of the label not be specified.
Response: Comment not incorporated. Information shall be organized in a way that best reflects how most patients seek out and understand medication instructions.
Comment Summary #2: One commenter suggested that the patient centered label be field tested.
Response: Comment not incorporated. Two states have adopted patient centered labels that were reviewed by the Expert Committee.
Comment Summary #3: Several commenters suggested that examples of patient centered labels be incorporated in the General Chapter.
Response: Comment not incorporated. The General Chapter allows flexibility in the manner in which the patient center label can be accomplished.

Emphasize Instructions to Patients
Comment Summary #1: Several commenters suggested prescriber contact information be included as critically important information.
Response: Comment not incorporated. The Expert Committee acknowledges the importance of prescriber contact information but this should not supersede information critical to the patient's safe and effective use of the medicine.
Comment Summary #2: A commenter suggested that the medication picture be required on the patient centered label.
Response: Comment not incorporated. The General Chapter allows for flexibility in the manner in which a patient centered label can be accomplished.

Simplify Language
Comment Summary #1: Several commenters suggested that "SIG" be defined.
Response: Comment incorporated.
Comment Summary #2: Several commenters suggested that the SIGs (signature, directions) be standardized.
Response: Comment not incorporated. The Expert Committee agrees standard directions should be used whenever possible but standardizing the SIG did not fall within the scope of this revision. The Expert Committee will review further studies.

Give Explicit Instructions
Comment Summary #1: A commenter suggested that the principles of Doak, Doak be defined.

Response: Comment not incorporated. Doak, Doak and Root reference were removed and replaced with other health literacy references that are more accessible.
Comment Summary #2: A commenter suggested that a direction schema be developed and incorporated into the prescription container label standards.
Response: Comment not incorporated. There is continuing research in this area. Best practices will be considered for future revisions as evidence becomes available.
Comment Summary #3: Several commenters suggested that the instructions should take into account a patient's lifestyle, e.g., different shift work hours.
Response: Comment incorporated. The Expert Committee acknowledges that dosing by precise hours may present greater adherence issues due to individual lifestyle patterns and general time frames such as in the morning may be more easily understood.

Include Purpose for Use
Comment Summary #1: Several commenters suggested that Include Purpose for Use not be required in the standard.
Response: Comment not incorporated. The Expert Committee decided that if the purpose of the medication is included on the prescription, then it should be included on the prescription container label.
Comment Summary #2: Several commenters suggested that the prescriber be required to write the purpose for use on the prescription.
Response: Comment not incorporated. The General Chapter does not address how a prescription should be written.
Comment Summary #3: Several commenters suggested that patient preference for inclusion of the purpose for use be excluded.
Response: Comment not incorporated. The label is meant to be patient-centered to allow for patient preference.
Comment Summary #4: A commenter suggested that prescription container labeling should include contraindications, side effects, interactions with other medications, directions for use and the drug's purpose for use as approved by the Food and Drug Administration (FDA).
Response: Comment not incorporated. The Expert Committee decided that if the FDA-approved purpose of the medication is included on the prescription, then it should be included on the prescription container label. The prescription container label should feature only the most important patient information needed for safe and effective understanding and use. Less critical but important content should be placed away from dosing instructions because it distracts patients, and this can impair patients' recognition and understanding. Medication guides that accompany the prescription are still appropriate for elements such as FDA approved use, contraindications, side effects, and drug interactions.

Limit Auxiliary Information
Comment Summary #1: A commenter suggested getting patient feedback (which is important to the patient) should be included on the auxiliary information.

Response: Comment not incorporated. The General Chapter recommends getting patient feedback on simplified language on the patient-centered label. If the auxiliary information is printed on the label, the standard would apply.
Comment Summary #2: One commenter suggested adding pregnancy and lactation status of the drug product with accompanying side effects, contraindications and interactions.
Response: Comment not incorporated. The items requested are beyond the scope of the prescription container label and would be listed in the medication guide given with the prescription at time of dispensing.
Comment Summary #3: Several commenters suggested that a clear statement referring the patient to supplemental instructions be stated on the label.
Response: Comment not incorporated. The General Chapter allows flexibility in the manner in which a patient centered label can be accomplished.

Address Limited English Proficiency
Comment Summary #1: Several commenters suggested that the label specifications address patients with low English proficiency.
Response: Comment incorporated.
Comment Summary #2: Several commenters suggested that the label be produced in a language that the patient understands.
Response: Comment not incorporated. Whenever possible, the directions for use should be provided in the patient's preferred language.

Improve Readability
Comment Summary #1: A commenter suggested that a minimum font size be included for "non-critical information."
Response: Comment incorporated.
Comment Summary #2: Several commenters suggested that the font on the entire label be 12 pt.
Response: Comment not incorporated. 12 pt font size (New Times Roman) or 11 pt Arial are to be used for critical information.
Comment Summary #3: Several commenters suggested that the use of 12 pt font would result in the use of larger labels and containers.
Response: Comment not incorporated. The General Chapter allows flexibility in the manner in which a patient centered label can be accomplished.
Comment Summary #4: A commenter suggested that a statement be included to provide adequate space between words and numerals.
Response: Comment not incorporated. The typography of the label shall be optimized to include white space to distinguish sections on the label, but does not require a statement to provide adequate space between words and numerals.
Comment Summary #5: A commenter suggested the use of two labels on prescription containers.
Response: Comment not incorporated. The General Chapter allows for flexibility in the manner in which a patient centered label can be accomplished.
Comment Summary #6: A commenter suggested a standardized location on the prescription label for prescription date and beyond use date.

Response: Comment not incorporated. The General Chapter allows for flexibility in the manner in which a patient centered label can be accomplished.
Comment Summary #7: Several commenters suggested that the prescription container labeling address access for the visually impaired.
Response: Comment incorporated.
Comment Summary #8: A commenter suggested that the lot number and or expiration date be standard information on the label.
Response: Comment not incorporated. The General Chapter allows flexibility in the manner in which a patient centered label can be accomplished.
Comment Summary #9: A commenter suggested that the barcode be required as standard information on the label.
Response: Comment not incorporated. The General Chapter allows flexibility in the manner in which a patient centered label can be accomplished. Barcode technology currently is not universally available in all practice settings.
Comment Summary #10: A commenter suggested that while the specific hour for dosing emphasizes patient understanding, it is not within the realm of pharmacy practice to convert or interpret the prescription.
Response: Comment not incorporated. The General Chapter states, “whenever available, use standardized directions” and recognizes that regulations and authoritative bodies will determine how the standards will be adopted
Comment Summary #11: A commenter suggested the General Chapter highlight further research being done to test proposed changes.
Response: Comment not incorporated. The General Chapter is dynamic and will incorporate evidence based information in future revisions if warranted.