



Report of the Task Force on Uniform Prescription Labeling Requirements

Members Present:

Michael J. Romano (PA), *chair*; Barry J. Boudreaux (NV); Karen DiStefano (RI); Patricia Donato (NY); Virginia Herold (CA); Ronald Huether (SD); William Prather (GA); Leo H. Ross (VA)

Others Present:

Karen M. Ryle, *executive committee liaison*; Carmen Catizone, Melissa Madigan, Larissa Doucette, *NABP staff*

Guests:

Colleen Brennan, *United States Pharmacopeia*; Darren K. Townzen, *National Council for Prescription Drug Programs*

The Task Force on Uniform Prescription Labeling Requirements met December 6, 2008 at the JW Marriott Starr Pass Hotel, Tucson, AZ.

This task force was established in response to Resolution 104-3-08, Task Force on Uniform Prescription Labeling Requirements, which was approved by the NABP membership at the Association's 104th Annual Meeting in May 2008.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate current state and federal laws and regulations addressing prescription label format and content.
2. Review the results of the findings of both state and federal studies regarding prescription labeling.
3. Study the feasibility of implementing standardized state requirements for prescription label format and content and for patient medication information.
4. Recommend revisions, if necessary, to the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act*) addressing these issues so as to increase readability and comprehension of labels by patients.

Recommendation 1: Endorse and disseminate statement on prescription labeling.

The task force recommends that the NABP Executive Committee endorse the following statement on the issue of prescription labeling and disseminate it to all interested stakeholders:

The purpose of the prescription label is to provide critical information to the patient so that he or she may use the medication appropriately and comply with the medication regimen. The label should be patient-centered. The label should not be used as an audit mechanism by third-party payers, nor should it be used for promotional purposes by dispensing pharmacies. Further, the label should not be used as a sole means to determine compliance with pharmacy laws and regulations by pharmacy regulators.

The prescription label cannot and should not replace critical pharmacist care responsibilities, such as appropriately identifying the patient at the time of dispensing and providing patient counseling.

Background:

Upon review and discussion of the issue of prescription labeling and concerns related to patients' understanding of such labeling, the task force determined it is important to clearly identify for what purposes prescription labels should and should not be used. As stated above, members felt that labels should be used solely to provide patients with important information about medication use. They agreed that prescription labels should not replace critical pharmacist care responsibilities. Identified were two such primary responsibilities: patient identification and patient counseling. On these issues, the task force stated the following:

1. Patient Identification – Patient data elements, such as address, are important identifiers but do not warrant inclusion on the label; instead, such information should be contained in other patient identification systems upon which a pharmacist relies to ensure that the patient receives his or her medication and to avoid confusion among patients with similar names or whose names may bear suffixes such as “Jr” or “Sr” within a family group.
2. Patient Counseling – The single most effective component to increase and improve patient compliance and avoid medication errors, as documented in numerous studies, is appropriate patient counseling. The prescription label is designed to supplement this critical pharmacist responsibility and not replace it in any way. Pharmacists cannot avoid their legal and professional responsibilities by deferring counseling activities to the prescription label. Further, boards of pharmacy cannot regulate counseling activities through the prescription label.

Recommendation 2: Amend the NABP Model Act language addressing prescription drug labeling.

The task force recommends that NABP Executive Committee approve amendments to the *Model Act* that will ensure prescription labels are organized in a patient-centered manner and that mandate the following data elements appear on the prescription label. The task force has consciously removed some data elements historically included on prescription labels to make room for the most critical patient information.

- A. Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif (such as “arial”), minimum 12-point

font, and in “sentence case.” Field size and font size may be increased in the best interest of patient care. Critical information text should never be truncated.

- a. Patient name.
 - i. Legal name of the patient. If patient is an animal, include the last name of the owner, name of the animal, and animal species.
 - b. Directions for use.
 - i. The directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order.
 1. Boards of pharmacy and licensees should recognize that “take as directed” may not provide sufficient information for the appropriate use of the medication. “Take as directed” is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. “Take as directed” should not be used in lieu of patient counseling.
 2. It is understood that prescription drug orders often do not include the indication for use.
 - ii. Language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.
 - c. Drug name.
 - i. Name of the drug.
 - ii. If written for a brand name and a generic drug is dispensed, include phrase “Generic for [brand name].”
 - iii. If a fixed combination generic product is dispensed, use the United States Pharmacopeia (USP) publication of Pharmacy Equivalent Names (PEN) abbreviation. If no PEN has been officially issued by the USP, label the medication *secundum artem*.
 - iv. Include drug name suffixes, such as CD, SR, XL, XR, etc.
 - d. Drug strength.
 - i. Strength of the drug.
 - e. “Use by” date.
 - i. Date by which medication should be used; not expiration date of medication or expiration date of prescription.
 - ii. Format as: “Use by: MM/DD/YY.”
- B. Important Information for Patients – Must appear on the label but should not supersede Critical Information for Patients.
- a. Pharmacy name.
 - i. Name of the dispensing pharmacy. Boards of pharmacy should recognize that some pharmacies “do business as” a name other than the corporate name.
 - b. Pharmacy telephone number.
 - i. Phone number of the dispensing pharmacy. Recognizing that a central fill pharmacy may be involved in the filling process, boards of pharmacy should not require more than one telephone number on the label.

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- c. Prescriber name.
 - i. Name of the prescriber.
 - ii. Format – “Prescriber: [prescriber name].”
- d. “Fill date.”
 - i. Date the prescription is dispensed, which will change with each subsequent refill. Format – “Date filled: MM/DD/YY.”
 - ii. The “fill date” and “use by” date should be the only dates appearing on the prescription label. Other dates often found on labels, such as the original and expiration dates of the prescription drug order can be misunderstood by patients and clutter the label with unnecessary information.
 - iii. The term “fill date” should be defined in the *Model Act*.
- e. Prescription number.
 - i. Identifies the number of the pharmacy record under which the prescription information is recorded.
- f. Drug quantity.
 - i. Quantity of drug dispensed.
 - ii. Format – “Qty: [number].”
- g. Number of refills.
 - i. Number of remaining refills.
 - ii. Format – “Refills: [number remaining]” or “No refills,” using whole numbers only and managing partial fills through the pharmacy recordkeeping system.
- h. Product description.
 - i. Written or graphic description of medication dosage form.
- i. Auxiliary information.
 - i. Auxiliary labels – information should be evidence based, standardized, and demonstrated to complement the prescription label.

Examples of compliant labels include the following:

Pharmacy Name: Phone:	Date Filled: MM/DD/YY Rx No.:	Cautions:
Purpose:		
Patient Q. Name		
Prescriber:		
Take 1 tablet in the morning and 2 tablets at bedtime.		Description:
Drug Name and Strength		
Generic for:	Qty:	
Use by: MM/DD/YY	Refills:	

Pharmacy Name: Phone: Patient Q. Name Rx No.: Date Filled: MM/DD/YY Prescriber: Drug Name and Strength Generic for: Qty: Refills: Use by: MM/DD/YY	Purpose: Take 1 tablet in the morning and 2 tablets at bedtime. Cautions: Description:
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Recommendation 3:

The task force recommends that NABP work with federal and state agencies and pharmacy stakeholders to advocate for and ultimately achieve changes in state or federal laws and regulations and industry standards to support a patient-centered label.

Background:

The task force recognized that Recommendation 2 represents a significant change in the philosophy of what defines a prescription label and the purpose of the prescription label. In some situations, this recommendation will be contrary to existing federal and state laws and regulations and industry standards. The *Model Act* cannot and is not intended to contravene state and/or federal laws or regulations. The task force understands this and supports NABP working with relevant agencies and organizations to allow the use of a patient-centered label.

Recommendation 4:

The task force recommends that the NABP Executive Committee approve amendments to the *Model Act* to note that the following additional data elements may appear on the prescription label:

- Bar codes
- Pharmacy address
- Pharmacy store number

Background:

The task force wanted to give states the option to allow pharmacies to include these elements on the label if they felt they were necessary.

Recommendation 5:

The task force recommends that NABP work with relevant organizations, including the American Medical Association, the Federation of State Medical Boards, and the Centers for Medicare and Medicaid Services (CMS), to require that medication indications be included on all prescriptions including but not limited to written and electronic prescription drug orders.

Background:

Task force members agreed that this item of information is vital for appropriate medication counseling. It was felt that this was a good time to approach CMS about the possibility of requiring prescribers to include such information in order to be reimbursed for their services.