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American Pharmacists Association  
House of Delegates – San Francisco, CA

## NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: LCDR Patrick Harper  
(Name)

02/21/2017  
(Date)

U.S. Public Health Service  
(Organization)

**Subject:** On-Label Indication and Medication Safety

**Motion:** Move to adopt the following policy statement,

1. APhA encourages pharmacists including the indication on prescription labels, using vocabulary appropriate for their unique practice sites and that addresses the needs of their specific patient populations, when such information is included by the prescriber on the prescription order or can be otherwise clearly and accurately discerned per the professional knowledge and judgement of the pharmacist.
2. APhA recognizes that the inclusion of on-label indications may not meet the wants and needs of every patient or may not be appropriate in all patient care situations and further encourages pharmacists' use of best judgement in executing self- or patient-initiated exclusion of on-label indication.

### Background:

The Principles of Practice for Pharmaceutical Care, published by the American Pharmacists Association in 1995, supports the need to develop and implement a plan with the patient that "[assures] that the patient has a thorough understanding of the disease and the therapy/medications prescribed in the plan" and is in line with a "patient's level of comprehension<sup>1</sup>." Despite major statutory requirements such as the Omnibus Budget Reconciliation Act (OBRA) of 1990 – which imposes pharmacist counseling obligations, prospective drug utilization reviews, and record-keep rules first applied to Medicaid patients and now found in standard practice -- it is common to find many patients still unsure of the purpose of their medications<sup>2</sup>. "Right indication" has been proposed as the "sixth right" alongside the right patient, drug, dose, time, and route to improve patient safety and meet desired outcomes<sup>3</sup>.

Patient knowledge impacts adherence to therapy<sup>4</sup>. Ignorance or misunderstanding of the reason a medication was prescribed has led to prescriber mistrust and refusal to take medication<sup>3,5</sup>. Not only do patients prefer a prescription

label with the indication, but as one of the patient's best source of information about their medication, prescription container bottles with on-label indications provide opportunity to enhance patient care<sup>6-9</sup>. In recognition of this, the United States Pharmacopoeia (USP) published, in November 2012, USP General Chapter <17> on prescription container labeling, stating the label should include a "purpose for use" based on patient preference<sup>9</sup>. As recently as November 2016, the Institute for Safe Medication Practices (ISMP) published agreement that "indications are the missing link connecting patients to their prescribed drugs, and that electronic prescribing systems must incorporate drug indications<sup>10</sup>." Thus, USP and ISMP join many providers, patients, and other key stakeholders in support of the inclusion of indication on prescription labels.

## References

1. Principles of Practice for Pharmaceutical Care [Internet].: American Pharmacists Association; 1995 [cited 1/22/2017]. Available from: <http://www.pharmacist.com/principles-practice-pharmaceutical-care#top>.
2. Omnibus Budget Reconciliation Act of 1990, 1990).
3. Schiff GD, Seoane-Vazquez E, Wright A. Incorporating Indications into Medication Ordering--Time to Enter the Age of Reason. *N Engl J Med*. 2016 Jul 28;375(4):306-9.
4. Kuntz JL, Safford MM, Singh JA, Phansalkar S, Slight SP, Her QL, et al. Patient-centered interventions to improve medication management and adherence: a qualitative review of research findings. *Patient Educ Couns*. 2014 Dec;97(3):310-26.
5. Is An Indication-Based Prescribing System in Our Future? [Internet].: Institute for Safe Medication Practices; 2016 [updated November 7, 2016; cited 1/22/2017]. Available from: <http://www.ismp.org/newsletters/acute/acute/showarticle.aspx?id=1153>.
6. Zargarzadeh AH, Law AV. Design and test of preference for a new prescription medication label. *Int J Clin Pharm*. 2011 Apr;33(2):252-9.
7. Sakharkar P, Zargarzadeh A, Law A. Examining preference of elderly for adding indication to the prescription label (Rx Label). *European Journal for Person Centered Healthcare*. 2014;2(4):523-32.
8. Burnside NL, Bardo JA, Bretz CJ, Busbee LA, Chrymko MM, Tuttle JA. Effects of including medication indications on prescription labels. *J Am Pharm Assoc (2003)*. 2007 Nov-Dec;47(6):756-8.
9. Key Issue: USP–NF General Chapter Prescription Container Labeling [Internet].: United States Pharmacopoeia; 2012 [updated November 13, 2012; cited 1/22/2017]. Available from: <http://www.usp.org/usp-nf/key-issues/usp-nf-general-chapter-prescription-container-labeling>.
10. ISMP. Is an Indication-based Prescribing System in Our Future? *ISMP Medication Safety Alert!* 2016 NOV 17.

## Current APhA Policy & Bylaws:

### 2010, 2001 Prescription Order Requirements

1. APhA supports the use of technology to facilitate the transmission of prescription order information from the prescriber to the pharmacist of the patient's choice at no additional cost to the pharmacy.
2. APhA supports the use of technology where appropriate standards for patient confidentiality and prescriber and pharmacist verification are established.
3. APhA supports the transmission of complete prescriber information on or with the prescription order that enables the pharmacist to readily identify and facilitate communication with the prescriber.
4. APhA supports the use of specific instructions with prescription orders. Use of potentially confusing terminology (such as "as directed", unclear use of Latin phrases, confusing abbreviations, etc.) should be avoided.

5. APhA supports the inclusion of the diagnosis or indication for use for which the medication is ordered on or with the transmission of the prescription order by use of standard diagnosis codes or within the directions for use. APhA further supports the inclusion of patient-specific information on or with the prescription order where appropriate.

6. APhA supports public education about the benefits and risks of technological advances in pharmacy practice.  
*(JAPhA NS41(5):Suppl. 1:S8 September/October 2001) (Reviewed 2007)(Reviewed 2009)(Reviewed 2010)(Reviewed 2012)*

### **2012 Medication Verification**

APhA encourages including a description of a medication's appearance on the pharmacy label or receipt as a means of reducing medication errors and distribution of counterfeit medications.

*(JAPhA NS52(4) 458 July/August 2012)*

**\*\*Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item Content.**

New Business Items are due to the Speaker of the House by **February 22, 2017** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at [hod@aphanet.org](mailto:hod@aphanet.org).