

# Adopting an Easy-to-Read Medication Label in Wisconsin

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# Introduction

Effective medication use is essential to chronic disease control, population health management and health care cost reduction. Information printed on prescription medication labels offers the most readily available guidance to ensure the medications are being used effectively. Currently used medication labels and amber-cast pharmacy pill bottles have been in existence in the United States since World War II without much change. Yet these labels often can be confusing and, in some cases, even misleading.

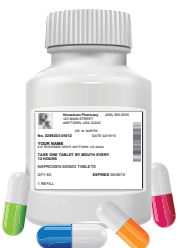
National standards for prescription medication labels do not exist. The lack of universal standards for labeling on prescription containers can lead to medication errors and adverse drug events (ADEs). The problem of misunderstanding medication use information can be particularly troublesome for individuals with limited literacy (difficulty reading text) and is more likely to be prevalent among groups at higher risk for low health literacy (difficulty understanding health information), such as older adults and patients with limited English proficiency. Misunderstanding of labels can lead to inadvertent misuse of medications and under or over dosing. To improve on this, it is essential for medication labeling to be more standardized and more easily understood.

Health literacy is a major factor in the ability of individuals to use medications properly. The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process and understand basic information and services needed to make appropriate decisions regarding their health.” In a 2011 systematic review of 96 studies, individuals with low health literacy had poorer health knowledge, poorer health status, and were less likely to take medications correctly.<sup>1</sup> More than half of U.S. adults find it difficult to understand and act on health information.<sup>2</sup>

In an effort to avoid misunderstanding of prescription medication information, it is essential for labeling to be constructed in a clear and easily understood manner. Emerging research is documenting the value of a more patient-centered label. In a recent study on use of the Universal Medication System (a method proposed by the Institute of Medicine which better describes how to take daily-use, pill-form medications) researchers found fewer medication errors with more complex prescription regimens and greater adherence to multi-daily dosing regimens, especially among adults with lower literacy. The benefits were especially pronounced among groups with limited English proficiency.<sup>3</sup>

In May 2013, the United States Pharmacopeia (USP) released a set of evidence-based guidelines for patient-centered medication labeling. Wisconsin Health Literacy and the University of Wisconsin School of Pharmacy undertook a project to determine barriers and facilitators to adoption of these new standards in Wisconsin.

*“Currently used medication label and amber-cast pharmacy pill bottles have been in existence in the United States since World War II without much change.”*



## Background/ Literature Review

Current research relating to prescription medication labeling that is easily understood by patients falls into two areas: label elements and design, and the impact of current labels on medication use and health outcomes.

### Label Elements and Design

National pharmacy chains have developed 31 different label styles, resulting in variability in the clarity and complexity of usage instructions.<sup>4</sup> One study found that the current labeling system emphasized information important to the health system (logo and prescription number) rather than information that aids the patient in understanding and use of the medication. Other studies have suggested a need for evidence-based standards that inform the content on the drug label, the formatting and font size to use, the best types of icons to support auxiliary instructions and how to better present dosage instructions on the drug label.<sup>5</sup>

The formatting especially can be problematic for those using multiple pharmacies where labels may vary dramatically. For example, the redesigned prescription bottles introduced by Target in 2005 have a larger, flat label which looks very different from the more traditional bottle and label design.

### Impact of Current Labels

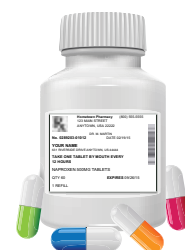
The understandability of most commonly used prescription labels is linked to poor health outcomes. Factors such as complex labeling language, unclear administration times, confusing label layout, and small font size have been shown to cause patient errors.<sup>1,4-9</sup> Such errors also have the potential to lead to increased emergency room visits, hospital admissions, morbidity and mortality.<sup>12</sup>

Research has shown that 75% of adults can't fully identify a prescription's indication for use. This lack of knowledge often results in improper use and poor clinical outcomes such as poor blood pressure and asthma control.<sup>13,14</sup> Research also has shown that misunderstanding of medication-related information leads to incorrect dosing linked to non-adherence, which was associated with a 20% greater risk of hospital readmission.<sup>16</sup>

Injuries related to medication use (ADEs) are responsible annually for 3.6 million office visits, 700,000 emergency room visits, and 117,000 hospitalizations.<sup>3, 7</sup> In one study, 46% of patients across all literacy levels misunderstood one or more medication dosage instructions and 54% misunderstood one or more auxiliary warnings that accompany medications.<sup>8</sup>

Seniors have a significantly greater risk of misunderstanding drug labels and misusing medications than other age groups, leading to ADEs such as allergic reactions, falls, and death. In 2009, almost 19% of Dane County seniors admitted to emergency rooms suffered

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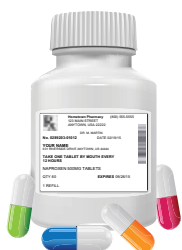
either a negative drug reaction or a fall, with drug reactions listed as a major risk factor for falls.<sup>9</sup> Research led by United Way of Dane County (Wisconsin) Delegation on Safe and Healthy Aging revealed that the average senior takes 6.4 medications daily.<sup>10</sup> One in three adults over age 65 taking five or more medications is likely to experience an adverse drug event each year, and medical attention will be needed for two-thirds of these ADEs.<sup>11</sup>

### **Introduction of New Label Standards**

The U.S. Food, Drug and Cosmetic Act (21 CFR 201.56) regulates the content of a prescription label, but there is no emphasis on the formatting and the spacing of the content on a fixed size label.<sup>16</sup> Additional content and formatting of the label is left to each state board of pharmacy, where there is a lot of flexibility. For example, the State of Wisconsin currently has no mandated standards for prescription label format. Wisconsin requirements now include only that a “legible” label affixed to the container must include the name/address of the facility dispensing the drug, the date, name of practitioner prescribing the drug, full name of patient, generic name and strength of the drug unless the practitioner requests omission, directions for use, and cautionary statements, if any.<sup>17</sup>

The USP, a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, appointed a Health Literacy and Prescription Container Labeling Advisory Panel for developing prescription labeling standards in 2008.<sup>18</sup> The advisory panel was charged with determining optimal prescription label content and format and with creating universal prescription label standards for format/appearance and content/language. USP published a set of standards for patient-centered medication labeling in November 2012 as General Chapter 17 in the USP’s National Formulary. These became official May 2013.<sup>19</sup> As a non-governmental organization, the USP does not mandate standards. Its standards, however, may be recognized in laws or adopted as a means of meeting certain regulatory criteria.

The USP labeling standards were developed based on hundreds of studies that have examined variability in medication labels and how they can enhance patient understanding. The new standards focused on emphasizing the most important information, improving readability, giving explicit instructions, identifying purpose for use, and addressing limited English proficiency and visual impairment. As of this writing, the USP has proposed revisions to Chapter 17 which include more specifics on addressing visual impairment, incorporation of the Universal Medication Schedule (UMS), standardizing directions, and utilization of metric devices for liquid medications.<sup>20</sup>



## Problem Statement

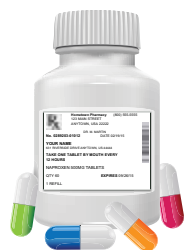
The National Association of Boards of Pharmacy (NABP) works closely with USP and recognizes its panel of experts as setting quality standards for the pharmacy profession. NABP was represented on the expert panel for the development of the label standards and adopted a resolution supporting state boards in requiring a standardized prescription container label in 2012.<sup>21</sup> In addition, the Institute for Safe Medication Practices (ISMP) and National Council for Prescription Drug Programs (NCPDC) also have supported the adoption of the USP patient-centered labeling standards.<sup>22</sup>

Although the new USP standards promote patient understanding of prescription medication labels, it was not known whether the adoption of these standards is practical or desirable to relevant stakeholders in Wisconsin.

Several unknowns guided the current project:

- How much do Wisconsin pharmacists know about the USP standards?
- If awareness is low, what efforts might be required to achieve sufficient awareness to lay the groundwork for adoption?
- By what means can the USP label standards be promoted most effectively?
- What are the perceived barriers and facilitators to adoption?
- What advocacy or action, if any, has been taken to adopt these or other label standards in Wisconsin?

This project focused on identifying the needs, current attitudes and values of key pharmacy stakeholders in Wisconsin regarding medication label standards. By exploring the above issues, a decision could be made as to the likelihood for success of launching a Wisconsin patient-centered labeling initiative and what approaches likely have the greatest chance of success.



# Research Methods

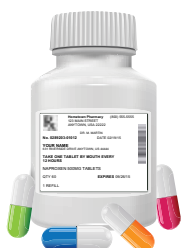
In order to explore potential adoption of the new patient-centered standards, semi-structured interviews were conducted among key stakeholders to identify the barriers and facilitators. The description of the stakeholders can be found in Table 1.

**Table 1: Key Stakeholders Interviewed**

Category	Number of Respondents
Chain Pharmacists	2
Pharmacists at Independent Pharmacies	3
Chain Pharmacy Managers	4
Independent Pharmacy Managers	3
Physicians	3
Software Vendors	2

This study was approved by the University of Wisconsin-Madison Institutional Review Board. Purposive sampling was used to recruit stakeholders. Key stakeholders were identified through personal contacts with networks supporting research initiatives in the field of pharmacy and medicine. Each stakeholder was sent a reference packet after he or she consented to participate in the interview. The reference packet contained the USP label standards and a description of the standards to familiarize or remind study participants of the standards and to act as a reference tool at the time of the interview.

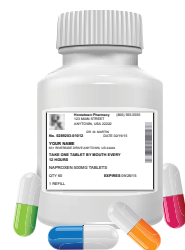
A semi-structured interview guide was developed to collect data on the barriers and facilitators of adopting the new patient centered USP label guidelines. Specifically the questions in the guide were constructed to identify stakeholder perceptions of attributes of the USP label standards that may affect adoption of these standards in practice. (See Appendix for interview guide.)



The Diffusion of Innovation Theory (Rogers, E. M., 1962) guided the development of the interview guide. The Diffusion of Innovation Theory explains how innovations are diffused throughout a population over time. Rogers describes attributes of innovations that affect adoption, including: relative advantage (is it better than what was there before?); compatibility (does it fit with the intended audience?); complexity (is it easy to use?); trialability (can it be tested before making a decision to adopt?); and observability (are the results visible and easily measurable?).<sup>1, 4</sup> In the context of the present study, the new USP label standards represent an innovation. Interview questions were constructed to measure perceptions of the attributes of the label standards that may influence their adoption in practice. The interview guide was customized to each stakeholder group.

The interviews were conducted primarily over the phone and were designed to take no more than 60 minutes. The same interviewer conducted all the interviews. All interviews were audio-recorded and transcribed verbatim. The transcribed interviews were independently analyzed by three of the authors using content analysis. The answers to each of the questions were coded based on their content, and constant comparison method was used to determine if newer codes needed to be created. Codes and sub-codes were organized into themes, and the themes were identified and grouped deductively based on the five constructs (i.e., attributes) of the Diffusion of Innovation Theory. The three authors who coded the transcripts met periodically to discuss their individual coding and resolve any discrepancies. Such discussions occurred for all the interview transcripts and continued until consensus was reached.

Data analysis was conducted concurrently with data collection. This procedure helped to highlight additional areas of clarification. For example, as a result of the first interview, the interviewer added a question and expanded probes in later interviews. Such concurrent data analysis allowed for a robust exploration of the topics as the study progressed.





## Research Findings

*“...this would make them look very similar from pharmacy to pharmacy. And that would be valuable, I think, in being able to look quickly at the information and understand.”*

*(Physician)*

*“...I would have to sit there and kind of scan through the label to try to find that information. It's located all over the place depending on the software you use.”*

*(Independent Pharmacy Manager)*

*“From a development viewpoint, I think it's a good thing... it's less that I have to maintain and support.”*

*(Software Vendor)*

*“Obvious advantage to the patient from a safety standpoint”*

*“...less confusion for the patient”*

*“...clearer in wording on labels makes a big difference.”*

*(Chain Pharmacy Manager)*

Seventeen semi-structured interviews were conducted with five different categories of stakeholders (See Table 1). The 12 pharmacists that were included were employed at pharmacies located in urban (n=8) and rural areas (n=4). These pharmacists came from diverse practice settings: traditional chain drug store pharmacies, grocery and discount retail stores, hospital or health care systems, closed staff HMOs, and privately owned pharmacies. Interviewed pharmacists reported using eight different software programs to process prescriptions. The physicians interviewed were all in family practice. One of the vendor interviewees was a software systems architect and the other was a compliance officer for a company with two different pharmacy software programs.

Several themes related to the five constructs of the Diffusion of Innovation Theory emerged from data analysis. The following section explains these themes and how they align with the theoretical constructs used.

### **Awareness and General Attitude toward the USP Standards:**

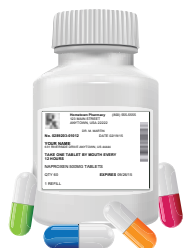
Although every key stakeholder valued guidelines developed by USP, a majority of them were unaware of the standards. Standardization and the merits associated with it was a key theme which emerged out of most of the interviews.

### **Perceived Impact and Facilitators of Adoption:**

#### ***Relative Advantage of the New Label Guidelines over Old Labels:***

The new USP guidelines were perceived to be “patient centered” as intended by the USP. All the stakeholders felt that the newer USP guidelines would improve patient readability and reduce confusion related to the patients’ medications.

Specific characteristics of the new label guidelines such as bigger font, adequate white space, explicit directions and the purpose of the medication were perceived as advantageous over the current labels in different pharmacies. Standardizing the labels in terms of display of explicit directions (“take one in the morning and one in the evening” versus “twice daily”) was perceived to cause a reduction in medication-related errors. Further, labels printed in the language of the patient were perceived to have a high patient benefit and aid in patient readability and understanding. In particular, benefit to vulnerable populations such as older adults and patients with limited English proficiency was realized by most of our respondents. A potential issue with printing labels in languages other than English and Spanish was identified. Pharmacists could not verify or “proof” such labels if they themselves were not fluent in the foreign languages and found themselves to be reliant on web-based translation services.





The new USP label guidelines state that the purpose of the medication should be clearly present on the prescription label. All of our stakeholders unanimously agreed that patients would understand their medications much better if they know why they are taking them, especially in the case of older adults.

*"That's a question that we often get, especially from more elderly patients or if someone is picking up prescriptions for their mother or father who is elderly."  
(Chain Pharmacist)*

In the State of Wisconsin, pharmacists are not allowed to add the indications on the label unless given or approved by the prescribers. When asked about adding the indications to the prescription label, physicians interviewed mentioned that it's a "great idea" but they would need to be reminded of this addition while writing an e-prescription. They also acknowledged the challenge of off-label use.

*"...it would be super helpful if the structure of [the electronic medical record] changed a bit. Like if it flags me for an indication, I'll be more likely to put it on there..." (Physician)*

**Complexity and the Compatibility of the USP Guidelines:** Our key stakeholders expressed that the USP guidelines could be adopted in the current pharmacy practice. Some physicians perceived that the change from the current label to the newer label would involve "a lot of updating"; however, software vendors expressed that they create several iterations of the prescription labels and it depends on their clients (corporate level pharmacies) to select the most appropriate iteration. Some pharmacists mentioned that there may be some training of staff required to implement all the guidelines mentioned by the USP.

*"If anything, it'll actually make it a little bit easier at the counseling point, because if the label is simplified and more clear, it'll be easier when talking to the patient about a new prescription."  
(Chain Pharmacist)*

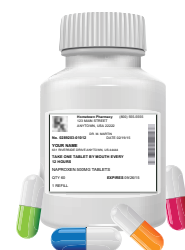
The newer label guidelines were perceived to be very compatible with the current workflow in the pharmacy. In fact, one pharmacist mentioned that the new label guidelines may serve as a "consultation aid" for them and help them save time in clarifying any confusion of the patient. Lastly, pharmacists mentioned that a patient-centered label would help them in keeping their patients more satisfied with their pharmacy.

*"Let's get it all done at the same time, so that we don't have to keep feeling like we're reinventing the wheel and I'm sure that the software people, the software vendors would rather: 'give me all the changes you want so that I can sit my programmers down and we're going to spend three months or six months or whatever changing the code, getting it all done, and then we're done'." (Independent Pharmacist)*

**Trialability and Observability of the New Label Guidelines:** Many stakeholders expressed that the new guidelines should be adopted all at once rather than selecting a guideline piece by piece. The rationale behind this was that if the software of the pharmacy would undergo a change in order to incorporate any of the recommended changes, then all the changes could be adopted at the same time.

*"Massive change for everything is not always accepted with wide open arms, so I think they should implement one change at a time."  
(Chain Pharmacist)*

However, a few pharmacists mentioned that adopting the entire gamut of changes may not be accepted very easily by pharmacists and their staff.



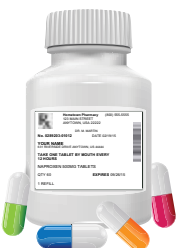
### **Barriers to Adoption:**

Limited label size or “real-estate” was cited as a strong barrier to adoption of USP guidelines. Fitting all this information in the current label was considered difficult. This is consistent with the reasoning behind Target Pharmacy’s larger prescription label called the ClearRx.<sup>21</sup> Target adopted this new label for a larger surface area, where they could fit in a large amount of information on the label. Our findings from the key stakeholders also suggest that adoption of the new USP guidelines will be aided by generating labels for bottles with a larger surface area. The software vendors especially spoke about how crucial information may get truncated on a prescription label, unless the size of the bottle is increased. Truncated information may further lead to patient confusion and poor readability. The software vendors also mentioned that older software programs, or “legacy systems,” which may be used in certain independent pharmacies pose an added barrier to the adoption of the new patient-centered guidelines.

A barrier identified by physicians for the “directions for use” is that they often must “free text” to enter more specific instructions, and this takes too much time during the busy office day.

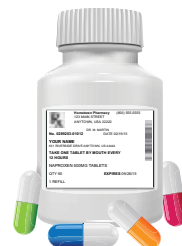
The pharmacists and pharmacy managers felt dependent on the software vendors to generate a label which would fit the needs of their patients. Certain software programs were considered more malleable than others on customization requests from the patients (such as font sizes, explicit directions). On the contrary, software vendors mentioned that they operate on client-centered models, and unless their client (corporate pharmacy) selects the USP label, they would not be able to produce or sell them.

Organizational and corporate level buy-in was considered as a barrier to adopt the new label guidelines. Some key stakeholders expressed that although the prescription label is the single most important piece of medication-related information from the perspective of the patient, they did not feel that a change in the label would be a top priority for the corporate pharmacy. Some key stakeholders felt that buy-in from consortiums of physicians such as the Wisconsin Academy of Family Physicians would help in encouraging the pharmacies to adopt the changes in the label.



### Additional Research Evidence:

Many of our key stakeholders could envision the benefits of adoption of these guidelines, especially to improve readability and understandability of medication instructions. Therefore, they did not require any additional research evidence to adopt the label. These stakeholders felt adoption of the label changes was contingent on corporate “buy-in.” Some stakeholders, such as the physicians, expressed the desire for additional evidence on the long term benefits of incorporating the new label and how it may help in improving patient adherence to medications and reducing overall cost. Cost was mentioned because adoption of all the recommended guidelines would be associated not only with updating software systems, but also potentially changing the size of bottles. Therefore, according to the stakeholders, corporate “buy-in” would be possible only if research is able to demonstrate a commercial viability of the new label guidelines.



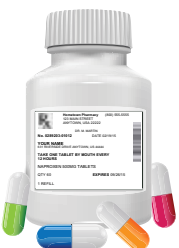
## Current State of Adoption of USP Label Standards

As of this writing, only three states have adopted a patient-friendly prescription label and none have made the USP standards mandatory in their entirety.

**California:** Prior to the announcement of USP standards, the California Board of Pharmacy adopted specific patient-centered label requirements, which went into effect Jan. 1, 2011. These included increasing the font size and dedicating 50% of the label space to information intended for the patient. Subsequently adopted revisions to the regulations included further increasing font size. To help patients with limited English proficiency, the regulations did not include language translation on labels but required pharmacies to have policies and procedures in place, including the availability of oral translation services in at least twelve languages. As part of the initial adoption, the California Board of Pharmacy's regulation listed standardized directions for taking medication in English and encouraged use of these standardized directions when appropriate in the dispensing pharmacist's judgment. The board also had these directions translated into five widely used languages other than English. However, the translations have not been greatly used. A proposal pending in the California Legislature would require pharmacies to use the translated directions on labels or on supplemental sheets when one of these non-English languages is requested by the patient. The legislation would also allow pharmacies to use their own translations for labels, instead of the Board's, if they prefer.<sup>24</sup>

The California standards cover most, but not all of the USP standards. Most notably absent is the USP standard to include medication purpose on the label. This was discussed; however, it was determined not feasible because of stakeholder concerns regarding the frequency of off-label use for certain medications.

One of the perceived barriers to adoption of a patient-centered label in California was the small size of most prescription labels. It was determined that this was not an issue, because medicine containers, in general, are larger now, due in part to the increased use of 90-day supplies and, in a few cases, redesigned bottles. Another barrier was the potential cost to the pharmacy resulting from destroying large quantities of labels not meeting the new requirements. To help with this, the implementation period for the new labels was extended before aggressive enforcement activities were initiated.



**New York:** In 2013 the State of New York adopted *Pharmacy Laws Rules and Regulations, Section 6829* directing each pharmacy to provide oral interpretation services at the time of service. This section also directed the Commissioner of Health to develop rules and regulations for standardized patient-centered data elements on labels. Part 63.12 was added, requiring labels to highlight *critical elements* (patient name, directions, drug name/strength) and to use at least 12-point font. *Important elements* (pharmacy information, patient address, prescriber name, date of filling and prescription number) were to be “legible” but not to be presented in a way that undermines emphasis on critical elements. The standards were adopted without much comment from pharmacists and there was little resistance. There are no changes planned as of this writing.<sup>25</sup>

**Utah:** On December 23, 2013, Utah became the first and only state to formally adopt the USP standards when its Board of Pharmacy adopted Administrative Code rules stating that it is “unprofessional conduct” for a pharmacy or pharmacist to fail to comply with the USP Chapter 17 standards. The issue initially was raised by a state legislator who wanted it mandatory to have the medication indication on the label. All pharmacies were to be in compliance by November 30, 2014. This action resulted in numerous calls to the Board of Pharmacy on how to interpret these standards, with the suggestion that some of the language used was subjective and unclear, thus difficult to enforce. The feedback focused on the standards’ consistent use of the word “should” rather than “shall.” The label size was not considered to be a major barrier.

On November 21, 2014, the Utah Board of Pharmacy and Utah Division of Occupational and Professional Licensing (DOPL) announced the decision “not to enforce prescription container labeling standards established in the United States Pharmacopeia General Chapter 17.” They further stated, “Although pharmacies are not required to comply with USP 17, DOPL and the Board recommend that pharmacies use it as a guide to help prevent medication misuse.”<sup>26, 27</sup>



## Implications of Study

This project revealed three significant challenges for implementing the USP prescription label standards in Wisconsin.

First, there is lack of awareness of the USP standards among pharmacists. When the standards were introduced, the Pharmacy Society of Wisconsin communicated them to its membership through newsletters and presentations. Our research, however, suggests little current awareness among pharmacists (see research findings, page 8).

Second, there is little public advocacy for this issue, which is consistent with the lack of awareness. Pharmacists interviewed for this project see the standardization of labels as important. Those unfamiliar with the new standards were quick to support them once informed (see research findings, page 8). Yet, there has been no widespread advocacy for adoption.

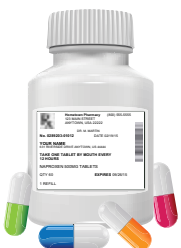
The minimal advocacy may be related to the perceived inability of pharmacists to effect adoption. Pharmacists viewed the implementation of the standards in Wisconsin as out of their control. More specifically, pharmacists felt the necessary changes can't occur without actions by others, including software developers, pharmacy/store managers and pharmacy owners.

Third, there has been no apparent action by private organizations or government bodies to adopt or adapt the USP standards for implementation in Wisconsin. The most likely action on the USP standards would come from the Wisconsin Pharmacy Examining Board (PEB) in the Department of Safety and Professional Services. However, we are not aware of any action taken by the PEB. A letter request for participation and the proposed interview questions were sent to the Wisconsin PEB as part of this project. However, the Wisconsin PEB subsequently declined to participate.

### Proposed Solution

To achieve implementation of a patient-centered prescription label in Wisconsin, a multi-pronged effort will be required to increase awareness of the standards, leverage existing support of label standardization in general, and establish the building blocks for system change.

Our goal is for Wisconsin pharmacies to adopt the USP standards for patient-centered labeling to enable patients to more easily understand the information and effectively follow directions on the label.



The strategy and some of the anticipated action steps include the following:

1. *Utilize the research knowledge base and experience of other states to inform the adoption process.* This strategy could include: identifying synergies with national patient centered labeling researchers and inviting patient-centered labeling initiative leaders from California, Utah, and New York to Wisconsin to share their experiences and recommendations.
2. *Build awareness and knowledge of USP standards and benefits among stakeholder constituencies, including patients, health care providers and pharmacists.* This strategy could include: development of prototype labels using the USP standards; distribution of this White Paper to pharmacy stakeholders, physician networks, and state health policy leaders, and presentations to professional groups and direct communication to target audiences.
3. *Work with regulatory agencies, governmental officials, national organizations and pharmacy software vendors to identify solutions to facilitate implementation of the standards.* This strategy could include: meetings with key Wisconsin stakeholder organizations, identification of liaisons from national organizations with an interest in patient-centered labeling (such as the National Academy of Medicine's Health Literacy Committee) and a "help our patients understand" initiative with chain pharmacies.
4. *Encourage, organize and support advocacy by pharmacists, health care providers, professional groups and consumers.* Activities for this strategy could include: development of a patient advocacy group, creation of a Wisconsin Patient-Centered Medication Label Advisory Council and implementation of a Wisconsin Summit on Patient-Centered Medication Labeling (inviting all key stakeholders and health professional groups).
5. *Implement the new standards at one or more pilot sites.* This could include: identifying health systems and/or pharmacies willing to pilot adoption of some or all standards.
6. *Implement communications campaign to encourage adoption of standards.* This could include: media relations, grassroots advocacy, formal communications and endorsement by pharmacy and other professional organizations.

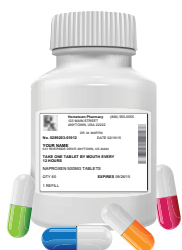




## Appendix

### New Label vs. Old Label

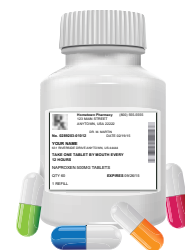
Drivers of Change	New Label	Old Label
Font Size	Large font size (e.g., minimum 12-point Times Roman or 11-point Arial) for critical information	No standardized regulations
Background	White space between lines of text (i.e., 25-30% of the point size)	No standardized regulations
Alignment of Information and Topography	Box for warnings and precautions Spacing of information--patient name, drug name on top	No standardized regulations
English Proficiency	Addresses low English proficiency, patient's preferred language used	No standardized regulations
Advantages	Addresses visually impaired	No standardized regulations
Types of Information Displayed	Explicit directions for administration Adds indications of medication	No standardized regulations



## Appendix (cont.) Interview Questions

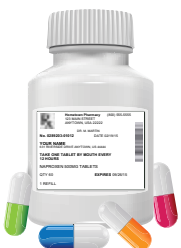
(customized for each  
stakeholder group)

1. Are you aware of the new USP patient-centered label standards and, if so, when and how did you learn of them?
2. Do you value the USP and the standards recommended by them?
3. How do the new USP medication label standards compare to the current medication labels being used in pharmacies today?
  - a. What struck you the most when you went through the USP new label guidelines?
  - b. What, if any aspects of the new standards are better than the current practice?
4. What do you think could be the overall impact of adopting the new label?
5. How do the new USP medication label standards fit within pharmacy practice?
  - a. Do the new standards fit within the pharmacy workflow? Why (why not)?
  - b. Do the new standards fit within the priorities of management/owners? Why (why not)?
  - c. Do the new standards fit within the priorities of payers (insurance companies)? Why (why not)?
  - d. Do the new standards fit within the priorities of regulators? Why (why not)?
  - e. Do the new standards fit within the priorities of patients? Why (why not)?
6. Have patients ever asked for customized labels? If so, what was requested?
7. What do you think about the ease or difficulty of which the new USP medication label standards could be used in pharmacy practice?
  - a. Would it be easy/ hard to implement the new standards? Why (why not)?
  - b. What are some possible hindrances to the adoption of the label?
  - c. Would it be easier to implement the new standards one component at a time? Why (why not)?
8. What do you think about the degree of ease or difficulty with which the new standards could be implemented on a trial basis?
9. Have you ever tried customizations in your labels by requests from customers (e.g., font change)? How easy has that process been?
10. What type of additional evidence would you like to see in order to adopt the label?



## References

- <sup>1</sup> Berkman, Nancy D.; Sheridan, Stacey L.; Donahue, Katrina E.; Halpern, David J.; and Crotty, Karen. July 2011. *Ann Intern Med* 155(2): 97-107.
- <sup>2</sup> National Center for Education Statistics. 2003. National Assessment of Adult Literacy.
- <sup>3</sup> Wolf, Michael. A Better Prescription...Improving Health Literacy for All Patients. Plenary Presentation, 2015 Wisconsin Health Literacy Summit, Madison, WI, April 14-15, 2015.
- <sup>4</sup> ACPF (American College of Physicians Foundation). 2007. *Improving prescription drug container labeling in the United States: A health literacy and medication safety initiative*. Washington, D.C.: ACPF.
- <sup>5</sup> Institute of Medicine of the National Academies. 2008. *Standardizing Medication Labels: Confusing Patients Less*. The National Academies Press, Washington D.C.
- <sup>6</sup> Budnitz, D.S., Pollack, D.A; Weidenback, K.N.; Mendelsohn, A.B.; Schroeder, T.J., and Annet, J.L. 2006. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA* 296: 1858-1866.
- <sup>7</sup> Zhan, C.; I. Arispe; E. Kelley, T. Ding, C.W. Burt; J. Shinogle, and D. Stryer. 2005. Ambulatory care visits for treating adverse drug effects in the United States, 1995-2001. *Jt Comm J Qual Patient Saf* 31: 372-378.
- <sup>8</sup> Wolf, M.S.; Davis, T.C.; Bass, P.F.; Tilson, H.; Parker, R.M. 2006b. Misunderstanding prescription drug warning labels among patients with low literacy. *Am J Health System Pharm* 63: 1048-1055.
- <sup>9</sup> "Safe Healthy Aging." *Is Your Loved One At Risk?* United Way of Dane County. Web. 01 June 2012. <<http://www.unitedwaydanecounty.org/safe-and-healthy-aging-initiative/>>.
- <sup>10</sup> *Safe Healthy Aging Mobilization Plan*. United Way of Dane County. January 2011.
- <sup>11</sup> Pham, Cung B, and Dickman, Robert L. 2007. Minimizing adverse drug events in older persons. *American Family Physician* 76 (12): 1837-1844.
- <sup>12</sup> Zed PJ, RB Abu-Laban, RM Balen, PS Loewen, CM Hohl, JR Brubacher, et al. Incidence, severity and preventability of medication-related visits to the emergency department: a prospective study. *CMAJ* 2008;178, 1563-9.
- <sup>13</sup> Persell SD, SC Bailey, J Tang, TC Davis, MS Wolf. Medication reconciliation and hypertension control. *The American Journal of Medicine* 123 (2), February 2010, 182.e9-182.e15. Lenahan JL, DM McCarthy, TC Davis, LM Curtis, M Serper, MS Wolf. A drug by any other name: patients' ability to identify medication regimens and its association with adherence and health outcomes. *Journal of Health Communication* 18, Iss. sup1, 2013.
- <sup>14</sup> Farber HJ, AM Capra, JA Finkelstein, P Lozano, CP Quesenberry, NG Jensvold, FW Chi, TA Lieu. Misunderstanding of asthma controller medications: association with nonadherence. *Journal of Asthma* 40 (1), 2003.



- <sup>15</sup> Lindquist LA, L Go, J Fleisher, N Jain, E Friesema, D Baker, Relationship of health literacy to intentional and unintentional non-adherence of hospital discharge medications. *Journal of General Internal Medicine*. 2012;27 (2):173-178.
- <sup>16</sup> US FDA website: Accessed MAY 2015 on [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)
- <sup>17</sup> "Standards for Dispensing and Prescribing Drugs." *Administrative Code*. No. 528 ed. Chapter 17. Madison, WI: Wisconsin State Legislature, December, 1999, Print.
- <sup>18</sup> "Recommendations on Prescription Container Labeling." USP.org. April 26, 2010. Accessed March 8, 2015.
- <sup>19</sup> "Key Issue: USP–NF General Chapter Prescription Container Labeling." USB.org. November 13, 2012. Accessed March 8, 2015.
- <sup>20</sup> Bohannon, Donna. "USP Patient-Centered Label Standards." Telephone interview by Steven Sparks. May 27, 2015.
- <sup>21</sup> NABP Professional Affairs. "NABP and USP Standards." E-mail interview by Steven Sparks. May 12, 2015.
- <sup>22</sup> McEvoy, Pharm.D., Gerald. "Creating a Standard for Medication Prescription Labels." Roundtable on Health Literacy "Health Literacy Past, Present, and Future". Institute of Medicine, Washington, D.C. 6 Nov. 2014. Speech.
- <sup>23</sup> "Right On Target with Safer Labels." ISMP.org. May, 2005. Accessed July 9, 2015.
- <sup>24</sup> Herold, Virginia. "California Board of Pharmacy Patient-Centered Labeling Standards." Telephone interview by Steven Sparks. May 11, 2015.
- <sup>25</sup> New York State Board of Pharmacy. "Patient-Centered Labeling Standards." E-mail interview by Steven Sparks. June 11, 2015.
- <sup>26</sup> "Utah – DOPL Label Requirements Dropped." Foundation Systems Support. November 21, 2014. Accessed July 8, 2015.
- <sup>27</sup> Garn, Derek (Chair, Utah Board of Pharmacy). "Patient-Centered Labeling Standards." Telephone interview by Steven Sparks. June 11, 2015.

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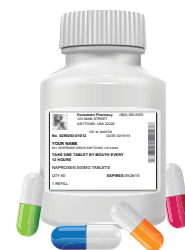
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