NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen

Version 1.1

This paper provides the healthcare industry, in particular the pharmacy sector, with historical and background information on the patient risks associated with hidden sources of acetaminophen and recommendations for best practices to mitigate those risks through best practices in product labeling.

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NCPDP Recommendations
for Improved
Prescription Container Labels for
Medicines Containing Acetaminophen

Version 1.1

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Executive Summary

Since publication of Version 1.0 of this white paper in August of 2011, collaborative efforts among all key stakeholders have resulted in significant improved pharmacy container labeling of acetaminophen-containing prescription medicines.

Version 1.1 has been developed to inform all key stakeholders of the response to the National Council for Prescription Drug Programs (NCPDP) call to action and to provide additional guidance to facilitate their efforts to ensure full implementation of the NCPDP recommendations, necessary to improve safe and appropriate use of acetaminophen by the public.

NCPDP Stakeholder Call to Action

The NCPDP Acetaminophen Best Practices Task Group Call to Action (2010) to adopt, implement and adhere to the recommendations in this white paper remains directed to all pharmacy system stakeholders.

1. Completely spell all active ingredients in acetaminophen-containing medicines on all prescription container labels.

   a. Stakeholder Response:

      i. Pharmacy System Stakeholders: The major national drug database publishers have developed drug data files which provide for the complete spelling for all two-ingredient acetaminophen-containing prescription medicines (i.e., combinations with hydrocodone, oxycodone, tramadol, codeine). Two-ingredient acetaminophen-opioid combination medicines represent approximately 97% of all oral prescription acetaminophen-containing medicines dispensed in the United States (US) in 2011.

      ii. Major US pharmacy retailers, including CVS, Walgreens and Rite Aid, have implemented the NCPDP recommendation, and acetaminophen and the other active ingredients are completely spelled out for two-ingredient acetaminophen-opioid medicines dispensed by these retailers, accounting for approximately 45% of the US retail pharmacy market. Others, including WalMart, and two of the nation’s top commercial pharmacy system software companies, serving the independent and regional chain pharmacies in the US, are currently in the process of implementing the same recommendation, which will bring the total store count where change will have been implemented from 45% to 75% of the market.

      iii. The Institute of Safe Medication Practices (ISMP) added “APAP” to its “ISMP’s List of Error Prone Abbreviations, Symbols, and Dose Designations”, which have been reported to ISMP through the National Medication Errors Reporting Program as being frequently misinterpreted and involved in harmful medication errors. To help prevent serious and even potentially fatal mistakes and misinterpretations, ISMP’s list is intended to encourage stakeholders to never use any of the abbreviations, symbols, and dose designations from this list when communicating medical information. (April 2012)

      iv. Since Version 1.0 of the white paper was published, there have been simultaneous efforts by other key stakeholders to standardize all prescription...
container labels. These efforts are in alignment with the principles and goals of the white paper and included here because they support the need and value of consistency and standardization of medicine labels and endorse the efforts of the pharmacy system stakeholders who have recognized and taken steps to respond to the recommendations in the white paper. Additionally, any implementation of these parallel efforts will likely impact the labeling of acetaminophen-containing medicines and the pharmacy system industry.

- The US Pharmacopeial Convention (USP) released new standards, which provide a universal, patient-centered approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists to promote patient understanding. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the United States Pharmacopeia and the National Formulary, include: “Prominently display information that is critical for patients’ safe and effective use of the medicine”, and “at the top of the label specify the patient’s name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.” The NCPDP recommendation for complete spelling of acetaminophen and other active ingredients on prescription container labels is in alignment with the new USP standards. USP General Chapter <17> was published in USP 36 NF 31 in November 2012. The chapter will be official in May 2013, after which the states will have responsibility for the enforcement of the standards.

- The National Association of Boards of Pharmacy (NABP) passed Resolution No. 108-1-12, “Uniform Outpatient Pharmacy Prescription Container Labels Designed for Patient Safety” at their 108th Annual Meeting (May 2012). It resolves that NABP support the state boards of pharmacy in their efforts to require a standardized prescription container label.

b. Guidance for Continued Implementation

National drug database publishers and pharmacy system software companies who have not yet been able to provide complete spelling of active ingredients on pharmacy container labels for all two-ingredient acetaminophen containing prescription medicines will find additional guidance, including some examples, in Section 6.1.3 of this white paper.

2. Adopt a standard concomitant use and liver warning label which harmonizes with the label on over-the-counter (OTC) medicines and which is prioritized to print within the top 3 warning labels for acetaminophen-containing medicines.

a. Stakeholder Response

Since publication of Version 1.0 of this white paper, major national drug database publishers have introduced a standard acetaminophen warning label, in alignment with the recommendations in this white paper and in compliance with internal clinical guidelines. Their standard acetaminophen warning labels are programmed to print in the top 3 of all labels that print for prescription acetaminophen-containing medicines in their data files.
As a result, the vast majority of retail pharmacies print a standard acetaminophen warning label that prints within the top 3 warning labels for all prescription acetaminophen-containing medicines dispensed in their pharmacy.

b. Guidance for Continued Implementation

For pharmacies who have not yet implemented the standard warning label on their acetaminophen-containing prescription medicines, guidance is provided in Section 6.2.8. Warning labels which have been implemented by 3 major national drug database publishers for all acetaminophen-containing medicines and follow the guidance provided in this white paper with regard to key messages and their hierarchy are provided in Section 6.2.7.

3. Optimize pharmacy counseling, communication, and education at point-of-dispensing and point-of-use.

a. Stakeholder Response

National educational initiatives have arisen or have multiplied their efforts to provide the public with education on the safe use of acetaminophen and provide support to healthcare professionals in their attempts to educate their patients. All of these programs provide tools for the public and encourage the public to read their medicine labels and take action to make sure they do not take multiple medicines with acetaminophen simultaneously.

These educational coalitions and programs are organized, well-positioned, and poised to communicate to the public the importance of comparing medicine labels to avoid harm, as well as any other messages that become essential to enhance patient safety. An escalation of those efforts will be triggered when the public is fully able to identify the active ingredients in their acetaminophen-containing prescription medicines.

b. Guidance for Continued Implementation

This white paper offers guidance to facilitate pharmacies and pharmacy staff members’ efforts to educate their patients about the safe and appropriate use of prescription and OTC acetaminophen-containing medicines. Public education materials that can assist the healthcare professional in educating patients can be obtained in most cases at no cost or can be downloaded for use in counseling patients and for distribution. A variety of types and formats are available, and some also come in Spanish. See Section 7.2 for more information, and Section 10, Appendix D for online educational resources.

Background

In November 2010, the NCPDP approved a project to provide standard best practices and guidance for prescription container labels of acetaminophen-containing medicines. This project was assigned to the NCPDP Professional Pharmacy Services Work Group (WG10). The Work Group formed the “Acetaminophen Best Practices Task Group” to produce this white paper, “NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen.”

All stakeholders involved in the generation of prescription container labels and the dispensing of prescription medicines, as well as all stakeholders who currently play a
critical role in educating healthcare professionals, consumers and patients on appropriate use of medicines are audiences for this white paper.

Acetaminophen is one of the most commonly used and most important medicines in the US. When used according to the label directions, it has a well-established record of safety and efficacy. Although acetaminophen overdose is very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

Despite ongoing regulatory and educational efforts over the past several years to improve patient safety, intentional and unintentional acetaminophen overdose remains a significant public health problem.

Lack of patients' awareness regarding the content of their acetaminophen-containing prescription medicines has been identified as a contributing factor to unintentional overdose. Unclear prescription labels have been cited to be root causes for medication errors, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. In the case of acetaminophen-containing medicines, prescription container labels often list “APAP,” or an abbreviation or truncated version of acetaminophen that most patients don’t realize is used to represent acetaminophen.

The US Food and Drug Administration (FDA) regulation requires complete spelling of “acetaminophen” as well as a standard concomitant use and liver warning on the labels of all acetaminophen-containing OTC medicines. Without clear prescription labels, patients may take more than one medicine that contains acetaminophen without realizing they may be taking a potentially harmful overdose.

The recommendations in this white paper aim to improve prescription labeling practices by harmonizing with the labeling that already exists for OTC medicines that contain acetaminophen. A patient-centered approach is needed to make the messaging consistent and strengthen and reinforce the messaging for patients across all acetaminophen-containing medicines.
## Summary of Recommendations to Improve Prescription Container Labeling for Medicines Containing Acetaminophen

<table>
<thead>
<tr>
<th></th>
<th>Recommendation: Complete Spelling of Active Ingredients in Acetaminophen-Containing Prescription Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Completely spell all active ingredients in acetaminophen-containing medicine on the prescription container label. No acronyms, abbreviations, or truncations for acetaminophen or any other active ingredients should be used.</td>
</tr>
<tr>
<td></td>
<td>When a brand or branded generic medicine is dispensed, completely spell all active ingredients in addition to the branded name.</td>
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<thead>
<tr>
<th></th>
<th>Recommendation: Acetaminophen Concomitant Use and Liver Warning Label</th>
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<tbody>
<tr>
<td>2</td>
<td>Adopt one standard concomitant use and liver warning label in alignment with the OTC acetaminophen warnings on Drug Facts labels. This will make the messaging consistent and strengthen and reinforce the messaging for patients across all acetaminophen-containing medicines.</td>
</tr>
<tr>
<td></td>
<td>Adopt a standard hierarchy for the key messages on the warning label for these labels.</td>
</tr>
<tr>
<td></td>
<td>Delete all warning labels containing similar key messages from warning label data files to prevent duplication of key messages on prescription labels.</td>
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<tr>
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<th>Recommendation: Prioritization of Warning Label Printing</th>
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<tbody>
<tr>
<td>3</td>
<td>Prioritize the standard warning label to print within the top 3 warning labels to increase the probability the label will print and be applied to prescription containers.</td>
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<tr>
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<th>Recommendation: Icons on Pharmacy Warning Labels</th>
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<tbody>
<tr>
<td>4</td>
<td>Icons can be used on warning labels if testing has proven the icons improve consumer and patient understanding beyond simple explicit text alone.</td>
</tr>
<tr>
<td></td>
<td>Manufacturers of acetaminophen-containing medicines, working through Consumer Healthcare Products Association (CHPA) and in collaboration with academia, are currently conducting research to explore the effectiveness of an acetaminophen-ingredient icon for cross-industry inclusion on both OTC (Drug Facts label) and prescription container labels.</td>
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<th></th>
<th>Recommendation: Patient-Centered Pharmacy Warning Labels</th>
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<tr>
<td>5</td>
<td>Employ general health literacy and plain language principles on the warning label to promote patient readability and understanding.</td>
</tr>
<tr>
<td></td>
<td>Patient-centered labels should reflect strategies (simple, clear language; font type and size) that promote optimal readability of critical information, consistent with recommendations by health literacy experts, plain language experts, and other organizations that have addressed patient-centered approaches to labeling in order to maximize readability and patient comprehension.</td>
</tr>
</tbody>
</table>
Stakeholder Call to Action:

Adopt, Implement, Adhere, Communicate, and Educate

The NCPDP Acetaminophen Best Practices Task Group Call to Action is first and foremost directed to all pharmacy system stakeholders to:

- Adopt, implement and adhere to the recommendations in this white paper.
- Dialogue with pharmacy system stakeholders and those stakeholders that play a key role in consumer and patient education regarding appropriate use of medicines, with the aim to,
- Explore innovative patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point-of-dispensing and point-of-use, utilizing their state of the art clinical decision-support module systems.

Conclusions

Even though rare in the context of its widespread use, liver injury from acetaminophen overdose remains a serious public health problem. In particular, there has been a disproportionate increase in liver injury in recent years as a result of misuse of acetaminophen-containing prescription medicines.

Over the past year, the pharmacy system industry’s voluntary responses to the NCPDP white paper have provided significant improvement to prescription container labels for acetaminophen-containing medicines.

However, continuing these efforts to implement the NCPDP recommendations needs to remain a priority for all stakeholders identified in the white paper. Consistency across OTC and prescription container labels is a critical first step to enable consumers and patients to identify and compare ingredients and take steps to improve their appropriate and safe use of acetaminophen.
1. Audience

The audience includes all stakeholders involved in the generation of prescription container labels and the dispensing of prescription medicines, including national drug database publishers, commercial and proprietary pharmacy system software companies (also known as “pharmacy practice management companies”), warning label companies, and pharmacies. Also included are all stakeholders who currently play a critical role in educating healthcare professionals, consumers, and patients on appropriate use of medicines.

2. Purpose

The purpose of Version 1.0 was to provide best practices and guidance for improved pharmacy-generated prescription container labels on medicines containing acetaminophen.

This version (Version 1.1) provides an overview of the stakeholder response to NCPDP’s recommendations and call to action in the first year following the publishing of Version 1.0 and provides supplemental guidance for stakeholders who have not yet been able to accommodate the recommendations.

Improved labels will help patients 1) identify when their prescription medicines contain acetaminophen, 2) compare active ingredients on their prescription and OTC medicine labels, and 3) avoid unintentional overdose.

Recommendations for developing prescription container labels in a patient-centered manner include:

- Complete spelling of acetaminophen and all other active ingredients on prescription labels, and
- The standardization of a concomitant use and liver damage warning label.

This white paper addresses only prescription labels for acetaminophen-containing medicines.

The NCPDP will implement a white paper dissemination strategy intended to engage all key stakeholders identified as the audiences for this version of the white paper.

3. Background

Acetaminophen is one of the most commonly used and most important medicines in the US. When used according to the label directions, it has a well-established record of safety and efficacy. Although very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.¹

Over the past several years, the US FDA has taken a number of steps to impact the factors that contribute to the incidence of liver injury resulting from unintentional

acetaminophen overdose. These actions include asking drug manufacturers to limit the amount of acetaminophen in prescription medicines that contain acetaminophen, mandating updated safety information on manufacturers’ labels for these medicines, updating the packaging and Drug Facts label for OTC medicines, and public education efforts. The FDA continues to consider additional measures for increasing patients’ safety.

Unclear prescription labels have been shown to be root causes for medication errors, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. As minimal standards and regulations exist for content and format and may vary across state lines, prescription container labels can differ between and within local and national pharmacies. The American College of Physicians Foundation (ACPF) Medication Labeling Technical Advisory Board has highlighted the importance of the container label as the most tangible and repeatedly used source of prescription drug instructions for use. Lack of patients’ awareness regarding the content of their acetaminophen-containing prescription medicines has been identified as a contributing factor to unintentional acetaminophen overdose. Since 2004, the FDA has taken steps to encourage state boards of pharmacy to improve prescription labels for acetaminophen-containing medicine to improve patients’ ability to recognize their prescription medicines contain acetaminophen.

In early 2010, the FDA Safe Use Initiative began a dialogue with the NABP about interventions to reduce unintentional overdoses involving acetaminophen-containing prescription medicines. Extensive parallel efforts among industry, pharmacy, patient safety, and healthcare professional organizations culminated in the FDA and NABP joining forces with these stakeholders with the shared goal of encouraging best practices for prescription labels of acetaminophen-containing medicines.

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In November 2010, the NCPDP approved a project to provide standard best practices and guidance for prescription labeling of acetaminophen-containing medicines. This project was assigned to the NCPDP Professional Pharmacy Services Work Group (WG 10). The Work Group formed the “Acetaminophen Best Practices Task Group.” The first mission of the Task Group was to produce this white paper, “NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen,” to communicate the recommendations of the Task Group to all relevant stakeholders.

4. Rationale

Acetaminophen is considered safe when used according to the directions on the labels of acetaminophen-containing OTC and prescription medicines. However, intentional and unintentional acetaminophen overdosing remains a significant public health problem.10 In particular, there has been a disproportionate increase in liver injury in recent years as a result of misuse of acetaminophen-containing prescription medicines as patients inadvertently overdose on acetaminophen while attempting to increase opioid doses.11

In a study that combined data from 22 specialty medical centers in the US, acetaminophen-related liver injury was the leading cause of acute liver failure for the years 1998 through 2003. Consumers and patients in this study were found to have taken too much acetaminophen from nonprescription medicines, prescription medicines, or both. Nearly half of these cases involved overdose in which the patient had not intended to take too much acetaminophen (unintentional overdoses). More than half (63%) of the unintentional overdose cases involved the use of prescription acetaminophen and narcotic combination medicines.12

The following are some factors which may contribute to unintentional acetaminophen overdoses.

- Taking more than the recommended maximum daily dose of acetaminophen (4 grams/day for adults, 75 mg/kg/day for children under the age of 12 years) is an overdose. An overdose may occur if a consumer or patient takes:13
  - More than the labeled dose of 1 acetaminophen medicine, or
  - More than one medicine containing acetaminophen (e.g., an OTC medicine that contains acetaminophen with a prescription medicine that contains acetaminophen).

- Acetaminophen is an active ingredient in more than 600 prescription and nonprescription medicines. IMS reports that 21 billion doses of acetaminophen-

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containing medicines were sold in 2011 (58% prescription and 42% OTC acetaminophen-containing dosages).\(^{14}\)

- Acetaminophen is combined with other active ingredients in prescription medicines primarily to help relieve pain.
- Acetaminophen is used as the single ingredient in OTC medicines to help relieve pain and reduce fever and it is combined with other active ingredients in OTC medicines to treat pain, symptoms of colds, flu, allergies, and sleeplessness.

- Consumers and patients may not realize:
  - Their medicine contains the active ingredient acetaminophen.\(^{15,16,17}\)
  - Acetaminophen is a common ingredient in multiple OTC and prescription medicines.
  - An overdose of acetaminophen may cause liver toxicity.\(^{16,18}\)
  - The potential adverse consequences of taking 2 different acetaminophen-containing medicines simultaneously and from exceeding the maximum daily dose.\(^{19}\)

- It is difficult for patients to recognize acetaminophen as an ingredient in prescription medicines. Prescription medicines that contain acetaminophen often are not adequately labeled to identify acetaminophen as an active ingredient on prescription labels.
  - Acetaminophen often is labeled simply as “APAP” or with unclear abbreviations or truncated versions of acetaminophen (e.g., ACT, acetamin) which most patients do not realize are used to represent acetaminophen.\(^{17,20,21}\)
  - A prescription brand or branded generic medicine that contains acetaminophen may be dispensed with only the brand or branded generic name listed on the label and no active ingredients listed.\(^{20}\)

\(^{14}\) IMS Health. IMS National Prescription Audit (NPA). December 2012.


Without clear labels, consumers and patients may take more than one medicine that contains acetaminophen without realizing they may be taking a potentially harmful overdose.

As described in Section 5.1, clear labeling practices already exist for all acetaminophen-containing OTC medicines.\(^{22}\)

- The primary display panel (PDP) and the Drug Facts label on both the carton and the container for these medicines are required to contain complete spelling of “acetaminophen” and all other active ingredients.
- The Drug Facts label on both the carton and the container for these medicines are required to contain standardized concomitant use and liver warnings.

The best practices and guidance recommended in this white paper are intended to improve prescription container labels for acetaminophen-containing medicines by aligning with the labeling that already exists for OTC medicines that contain acetaminophen.

This includes:
- The complete spelling of “acetaminophen” and any other active ingredients, eliminating the use of abbreviations, acronyms, and truncations, and
- Incorporating a standard concomitant use and liver warning label

Broad-based, consistent implementation of these recommendations is essential in making it possible for patients to identify and compare active ingredients on their prescription and OTC medicine labels and to avoid taking 2 medicines which contain acetaminophen simultaneously. Clear labels will also increase the success and impact of ongoing collaborative efforts to educate consumers and patients on how to safely use acetaminophen-containing medicines.

5. Regulations and Authorities: Over-the-Counter and Prescription Labels for Acetaminophen-Containing Medicines

This section describes existing regulations and authorities for the labeling of both OTC and prescription acetaminophen-containing medicines.

The recommendations provided in this white paper are made in consideration of existing regulations and authorities with the aim of improving labeling practices and harmonizing prescription and OTC labels.

5.1 Over-the-Counter Medicine Labels\(^{22,23}\)

The current FDA OTC Drug Facts labeling standards have provided guidance in the development of the recommendations described in this white paper.
The OTC Drug Facts label regulation requires most OTC medicines to comply with format and content requirements and intends to make it easier for consumers to read and understand OTC medicine labels and use the medicines safely and effectively.

In addition, a 2009 FDA regulation requires increased prominence of “acetaminophen” as an active ingredient as well as a standard concomitant use and liver warning on the Drug Facts label for all acetaminophen-containing OTC medicines.

5.1.1 Principal Display Panel

All acetaminophen-containing medicines (single ingredient and combination) must have a statement of identity and the name "acetaminophen" must appear highlighted (e.g., in fluorescent or contrasting color) or in bold type and in prominent print size on the principal display panel. The highlighted printing is to make consumers aware that acetaminophen is present in the medicines they are using in an effort to prevent unintentional overdose.

5.1.2 Active Ingredient/Purpose Section

Under the “Active Ingredient” heading, the established name of each active ingredient and the quantity of each active ingredient per dosage unit is required. For acetaminophen-containing medicines, the information under the Active Ingredient and Purpose headings may appear highlighted. (In 2002, the OTC drug industry voluntarily adopted highlighting of “acetaminophen” under the “Active Ingredient/Purpose” heading on the Drug Facts label.) (See “Appendix B. Sample Acetaminophen Drug Facts Label Excerpt” for this section of the OTC Drug Facts label.)

5.1.3 Warnings Section

The 2009 regulation added a warning about the possibility of liver injury and a warning about concomitant use of acetaminophen-containing medicines. These new warnings are required to enhance consumer awareness and knowledge of the active ingredient. The aim is to reduce liver injury from unintentional overdosing and the incidence of adverse health outcomes. (See “Appendix B. Sample Acetaminophen Drug Facts Label Excerpt” for relevant portions of this section of the OTC Drug Facts label.)

5.1.3.1 Liver Warning

- For medicines labeled for adult use only, the liver warning states:

  "Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
  
  o more than [insert maximum number of daily dosage units] in 24 hours, which is the maximum daily amount [optional: `for this product']
  
  o with other drugs containing acetaminophen
  
  o 3 or more alcoholic drinks every day while using this product."

This liver warning must be the first warning under the "Warnings" heading. In July 2012, the FDA issued draft guidance to manufacturers of OTC acetaminophen-containing medicines to enhance consumer awareness and knowledge of the active ingredient. The aim is to reduce liver injury from unintentional overdosing and the incidence of adverse health outcomes.


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medicines which describes conditions under which alternative language may provide an option for the liver warning on medicines labeled for adult use only. This draft guidance does not affect the acetaminophen warning label recommendations in this white paper.\(^\text{25}\)

- **For medicines labeled only for children under 12 years of age, and**
- **For medicines labeled for adults and children under 12 years of age,**

refer to the regulation (also called the “final rule”) for the exact wording of the liver warning.

### 5.1.3.2 Concomitant Use Warning\(^\text{26}\)

- **For medicines labeled for adult use only**, the concomitant use warning states:
  - “Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.”
- **For medicines labeled only for children under 12 years of age, and**
- **For medicines labeled for adult and children under 12 years of age,**

refer the regulation (also called the “final rule”) for the exact wording of the concomitant use warning.

### 5.2 Prescription Drug Labeling

The labeling requirements for prescription drugs describe the required content for the manufacturers’ package labels and prescription information intended primarily for healthcare professionals.\(^\text{27}\) This professional label is commonly called the “package insert” or “drug label” and is one of the primary references national drug database publishers use to generate their data files.

In January 2011, the FDA issued a Federal Register notice and a drug safety communication to announce new measures to help make acetaminophen-containing prescription medicines safer for patients.\(^\text{28}\) A new boxed warning\(^\text{29}\) required for these medicines highlights the potential for severe liver injury. The drug safety communication


\(^{27}\) 21 CFR §201 Subpart B Labeling Requirements for Prescription Drugs and/or Insulin.


\(^{29}\) A warning on the package insert for a prescription medicine that the FDA requires to appear in a box. Commonly referred to as a “black box warning,” it is bolded and boxed to highlight a contraindication or serious risk associated with the medicine. For more information, see 21 CFR §201.57 (c) (1).
addressed the need for healthcare professionals to educate consumers and patients about the importance of reading all prescription and OTC labels to ensure they are not taking multiple acetaminophen-containing medicines.

The FDA also asked drug manufacturers to limit the quantity of acetaminophen in prescription medicines, which are predominantly combinations of acetaminophen and opioids, to no more than 325 mg per tablet, capsule, or other dosage unit. With a reduced dosage, patients will be less likely to overdose on acetaminophen if they mistakenly take too many doses of an acetaminophen-containing prescription medicine.\(^{30}\)

5.3 Prescription Container Labels

5.3.1 Prescription Labels

The content of prescription labels is subject to both federal and state authorities.

- **Examples of federal statutes and regulations concerning prescription labels include:**
  - Food, Drug and Cosmetic Act\(^{31}\) – “Exemptions and consideration for certain drugs, devices, and biological products”
  - Controlled Substances Act – Labeling and Packaging\(^{32}\) which includes “Statement of required warning”\(^{33}\) and “Labeling of substances and filling of prescriptions”\(^{34}\)

- **Additional provisions are mandated by the individual state governments.**

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP Model Act)\(^{35}\) identify critical and important information for patients that must appear, as well as additional information that may appear, on all prescription labels.

5.3.2 Pharmacy Warning Labels

Prescription warning labels, also referred to as “auxiliary labels” or “auxiliary warning labels,” historically have not been standardized and are not regulated or reviewed by federal authorities. Most states offer only general guidance on warning labels.

The NABP Model Act provides that auxiliary information (i.e., relevant supplementary information that in the pharmacist’s professional judgment is important for the patient, including auxiliary labels) should appear on the label and that such information should

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\(^{31}\) 21 United States Code (USC) §353 (b) (2)

\(^{32}\) 21 USC §825 (c)

\(^{33}\) 21 CFR §290.5

\(^{34}\) 21 CFR §1306.24

be evidence based, standardized, and demonstrated to complement the prescription label.\textsuperscript{36}

The USP released new standards which provide a universal, patient-centered approach to the format, appearance, content and language of instructions for medicines in containers dispensed by pharmacists to promote patient understanding. Elements of the new USP standards, contained in General Chapter \textsf{<17> Prescription Container Labeling}, of the \textit{United States Pharmacopeia} and the \textit{National Formulary}, address the issue of warning labels, stating: "...there is great variability in the actual auxiliary warning and supplemental instructional information applied by individual practitioners to the same prescription." With regard to auxiliary information, USP General Chapter \textsf{<17>} states "...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."\textsuperscript{37}

The NCPDP recommendation to introduce a standard acetaminophen warning label on prescription container labels is in alignment with the new USP standards. USP General Chapter \textsf{<17>} was finalized, published, and made available to the public in USP 36 NF 31 in November 2012. The chapter will be official in May 2013, after which the states will have responsibility for the enforcement of the standards. (See also Section 6.2.)

\textbf{Warning Label Survey} Performed by the Acetaminophen Best Practices Task Group

In 2011 the Acetaminophen Best Practices Task Group conducted a survey of warning labels for acetaminophen-containing prescription medicines to assess the content and consistency of the warning labels available in the marketplace at that time. The labels reviewed were produced by three warning label companies and in use as of March 2011. The messages on these labels could be divided into the following four categories:

1) content (informing the medicine contains acetaminophen), 2) overdose, 3) liver injury, and 4) concomitant use. (See "\textit{Appendix A. Survey of Current Acetaminophen Warning Labels}" for the inventory.)

Three different combinations of the four categories were used by the companies, often in different text versions. A fourth label with a distinctly different message also was found.

- \textbf{Four messages combined on one label: content + overdose + liver injury + concomitant use} – Only one company distributed this label.

- \textbf{Three messages combined on one label: content + overdose + liver injury} – All three companies distributed the same text version of this combination label, but one added "(paracetamol)" as a modifier of "acetaminophen." All three companies also distributed a second text version of this combination.

- \textbf{Concomitant use message} – All three companies distributed different text versions of the concomitant use message, but included the phrase, "check all medicine labels carefully."

- \textbf{One label displays a distinctly different message} – Two of the three companies distribute this warning label: “Do not take aspirin or acetaminophen without checking with your doctor.”


In total, eight different labels were available from the three companies surveyed. The results of the survey demonstrated at least some of the variability in warning label content then available for acetaminophen-containing prescription medicines, including variety within individual companies. Note that the labels did not mirror the most recent warnings required on OTC acetaminophen-containing medicine labels (Section 5.1.3) or the required warnings on the prescription drug labeling (Section 5.2).

6. NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen

Prescription labels on containers dispensed in pharmacies are often the sole source of information patients use when they are taking their prescription medicine. Information that is critical for patients’ safe and effective use of the medicine should be prominently displayed on prescription container labels in a patient-centered manner.

The recommended practices for prescription labels for acetaminophen-containing medicines aim to help decrease medication errors that result from the patient’s inability to recognize acetaminophen as the active ingredient in their prescription medicine.

The Task Group acknowledges that some recommendations under Sections 6.1 and 6.2 are more stringent than current NABP policy (NABP Model State Pharmacy Act and Model Rules) which calls for critical information never to be truncated, including the drug name. In July 2010, NABP specifically addressed the use of an acronym for acetaminophen when it released a public statement to the state boards of pharmacy recommending that they prohibit the use of “APAP” on prescription labels and require complete spelling of acetaminophen.

This section provides an overview of the stakeholder response to NCPDP’s recommendations and call to action to improve prescription container labels for medicines containing acetaminophen in the first year following the publishing of Version 1.0. While important progress has been made, certain technical challenges have impeded full implementation of the NCPDP recommendations as published in Version 1.0. This section also provides additional guidance for those pharmacy system stakeholders who have not yet been able to accommodate complete spelling of acetaminophen and all other active ingredients and/or implement and prioritize a standard warning label for acetaminophen-containing medicines.

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6.1 Prescription Container Labels

6.1.1 NCPDP Recommendation: Complete Spelling of Active Ingredients

To enable patients to recognize acetaminophen and all active ingredients in their medicines, the Task Group strongly recommends that the prescription labels for all medicines that contain acetaminophen, whether a brand, branded generic, or generic prescription medicine is dispensed, include the following information:

a. “Acetaminophen” and all other active ingredients should be completely spelled on the prescription label.

b. When a brand or branded generic is dispensed, acetaminophen and all other active ingredients should be completely spelled, in addition to the brand or branded generic name of the medicine. (See “Appendix C. Sample Acetaminophen Prescription Container Label”)

c. No abbreviation, acronym, or truncated version of acetaminophen or other active ingredients should be permitted on prescription labels. The length of the drug name field on prescription labels must accommodate the complete spelling of acetaminophen and all other active ingredients.

d. The amount of each active ingredient present in the medicine should appear clearly on the prescription label.

In order to promote patient understanding of prescription labels for acetaminophen-containing medicines, the Task Group recommends applying general principles of health literacy and plain language when implementing the recommendations. Use text features that increase readability and patients’ reading comprehension of critical information:

a. Use sentence case.

b. Restrict use of capital letters, all capitalized words, italics and stylized types. They slow reading. For example:
   i. “acetaminophen” is preferred over “Acetaminophen.”
   ii. Don’t use “ACETAMINOPHEN.”
   iii. Use “Brandname”; don’t use “BRANDNAME.”

c. Font size: Optimal font size for print reading is 12-14 points.

Current NABP policy recommends that critical information for patients be printed on the prescription label with emphasis (highlighted or bolded), in a sans serif typeface (such as “Arial”), minimum 11-point size, and in “sentence case.” The USP standard (General Chapter <17> Prescription Container Labeling) for prescription labels recommends use of a large font size (e.g., minimum 12-point Times Roman) for critical information.

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6.1.2 Stakeholder Response to the Recommendation: Complete Spelling of Active Ingredients

a. Pharmacy System Stakeholders:

i. Since publication of the white paper in August 2011, the major national drug database publishers have developed drug data files which provide for the complete spelling for all two-ingredient acetaminophen-containing prescription medicines (i.e., combinations with hydrocodone, oxycodone, tramadol, codeine). Two-ingredient acetaminophen-opioid combination medicines represent approximately 97% of all oral prescription acetaminophen-containing medicines dispensed in the US in 2011.45

ii. Major US pharmacy retailers, including CVS, Walgreens and Rite Aid, have implemented the NCPDP recommendation, and acetaminophen and the other active ingredients are completely spelled out for two-ingredient acetaminophen-opioid medicines dispensed by these retailers, accounting for approximately 45% of the US retail pharmacy market. Others, including WalMart, and two of the nation’s top commercial pharmacy system software companies, serving the independent and regional chain pharmacies in the US, are currently in the process of implementing the same recommendation, which will bring the total store count where change will have been implemented from 45% to 75% of the market.

b. Other Key Stakeholders:

i. Recently ISMP added “APAP” to its “ISMP’s List of Error Prone Abbreviations, Symbols, and Dose Designations.” ISMP’s list is intended to discourage stakeholders from using the entries on the list when communicating medical information. The abbreviations, symbols, and dose designations on the list, reported to ISMP through the National Medication Errors Reporting Program, are included because they are frequently misinterpreted and involved in harmful medication errors. (April 2012)46

ii. Since Version 1.0 of the white paper published, there have been simultaneous efforts by other key stakeholders to standardize all prescription container labels. These efforts are in alignment with the principles and goals of the white paper and included here because they support the need and value of consistency and standardization of medicine labels and endorse the efforts of the pharmacy system stakeholders who have recognized and taken steps to respond to the recommendations in the white paper. Additionally, any implementation of these parallel efforts will likely impact the labeling of acetaminophen-containing medicines and the pharmacy system industry.

- The USP released new standards, which provide the first universal, patient-centered approach to the format, appearance, content and

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language of instructions for medicines in containers dispensed by pharmacists to promote patient understanding.\textsuperscript{47} Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the United States Pharmacopeia and the National Formulary, include: “Prominently display information that is critical for patients’ safe and effective use of the medicine”, and “at the top of the label specify the patient’s name, drug name (spell out full generic and brand name) and strength, and explicit clear directions for use in simple language.”\textsuperscript{48} The NCPDP recommendation for complete spelling of acetaminophen and other active ingredients on prescription container labels is in alignment with the new USP standards. USP General Chapter <17> was published in USP 36 NF 31 in November 2012. The chapter will be official in May 2013, after which the states will have responsibility for the enforcement of the standards.

- The NABP passed Resolution No. 108-1-12, “Uniform Outpatient Pharmacy Prescription Container Labels Designed for Patient Safety” at their 108th Annual Meeting (May 2012). It resolves that NABP support the state boards of pharmacy in their efforts to require a standardized prescription container label.\textsuperscript{49}

### 6.1.3 Guidance for Pharmacy System Stakeholders: Complete Spelling of Active Ingredients

The drug name field for active ingredients on a pharmacy prescription container label is sourced from a national drug database publisher and created by commercial or proprietary pharmacy system software companies. Alternatively such content can be sourced from a national drug database publisher but manually manipulated or changed by the pharmacy.

Drug data files as provided by national drug database publishers may contain multiple drug name, label names, and/or ingredient (active and/or inactive) fields. The type, size, and naming conventions are different between national drug database publishers. Each of these “name” fields may be of varying length, e.g., from 10 characters to over 100 characters.

To ensure the prescription container label includes the complete spelling of acetaminophen and all other active ingredients, the Task Group recommends the following for pharmacy system stakeholders.

\textsuperscript{47} USP press release October 9, 2012: First Universal Standards Guiding Content, Appearance of Prescription Container Labels to Promote Patient Understanding of Medication Instructions; Nearly Half of Patients Misunderstand One or More Dosage Instructions Pharmacies Across the Country Urged to Adopt “Patient-Centered” Labels. [http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010]


a. The national drug database publisher:
   i. Provides multiple drug name fields including label names, and/or ingredient (active and/or inactive) fields. The type, size, and naming conventions are different among publishers. Each of these “name” fields may be of varying length from 10 characters to over 100 characters.
   ii. Provides publisher-specific guidance for each of their pharmacy system software companies to assist the companies in selecting the appropriate choices from the available options in order to support adherence to the white paper recommendations.

b. The pharmacy system software company:
   i. Reviews the “name” field options for labeling to ensure sufficient length of the field to allow complete spelling of acetaminophen and all other active ingredients on prescription labels of acetaminophen-containing medicines as described in Section 6.1.1.
   ii. Reviews the appropriate choice of data options from its national drug database publisher in order to provide the full spelling of acetaminophen and all other active ingredients.
   iii. Reviews any manual drug name creation or national drug database publisher overrides which either truncate or abbreviate acetaminophen or other active ingredients.
   iv. Assists customers with updating any available custom drug name fields.
   v. Provides company-specific guidance to customers on name/ingredient/warning label databases to support adherence to the white paper recommendations.

c. Examples of different types of name fields:
   i. Vicodin ES (Abbott Laboratories)
      a) Product label name: Vicodin ES Oral Tablet 7.5-750 mg
      b) Generic Name: Hydrocodone-Acetaminophen Tab 7.5-750 mg
      c) Ingredients:
         o acetaminophen 750 mg
         o hydrocodone bitartrate 7.5 mg
   ii. Acetaminophen-Codeine #3 (Teva Pharmaceuticals-ANDA)
      a) Product label name: Acetaminophen-Codeine #3 Oral Tablet 300-30mg
      b) Generic name: Acetaminophen-Codeine #3 Oral Tablet 300-30 mg
      c) Ingredients:
         o acetaminophen 300 mg
         o codeine phosphate 30 mg
6.2 Standard Pharmacy Warning Labels

6.2.1 NCPDP Recommendation: Standard Acetaminophen Warning Label with Prioritized Printing

Multiple, inconsistent acetaminophen warning labels have historically been in use. (See Section 5.3.2, “Pharmacy Warning Labels”) In the absence of regulations for standardizing and prioritizing pharmacy warning labels, this white paper recommends that industry collaborate to adopt a standard warning label. The acetaminophen warning label should be prioritized to print within the top 3 warning labels that print for the acetaminophen medicine. This prioritization increases the probability that this warning label will print and be applied to prescription containers. Pharmacy systems should be programmed to ensure adequate prioritization.

6.2.2 Develop Patient-Centered Pharmacy Warning Labels

This white paper provides guidance for the hierarchy and wording of key messages that should be included on standard acetaminophen warning labels through application of plain language and health literacy principles in order to:

- Align with the FDA-approved concomitant use and liver warning requirements for the OTC Drug Facts label for acetaminophen-containing OTC medicine.\(^{50}\)
- Promote optimal patient understanding of the warnings on warning labels while taking into account the limited space available.

6.2.3 Use a Hierarchy of Key Messages within the Warning Label

The Task Group recommends a standard hierarchy of key messages within the warning label. This list presents the key messages in decreasing order of importance (1-4).

1. Content message – Active ingredient
2. Action and warning message – Concomitant use warning (prescription and nonprescription)
3. Risk and consequence message – Overdose and liver warning
4. Healthcare professional message – Where to address questions

6.2.4 Apply Plain Language and Health Literacy Principles

In order to promote patient understanding of prescription labels for acetaminophen-containing medicine, the Task Group recommends industry use general principles of health literacy and plain language when implementing the recommendations put forth in this white paper, such as those described in the Federal Plain Language Guidelines.\(^{51}\)

Use features that increase readability and reading comprehension of critical information:

a. Use sentence case.

i. Restrict use of capitalized words, all capital letters in a word, italics and stylized font types. They slow reading. Some examples are:

\(^{50}\) 21 CFR §201.61 and §201.66(c)(2) and (3) Labeling requirements for Over-the-Counter Drugs.

NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen

- “acetaminophen” is preferred over “Acetaminophen.”
- Don’t use “ACETAMINOPHEN.”

b. Don’t hyphenate words between lines.

c. Use large font size for critical information (e.g., 11 point Arial).\textsuperscript{52}

d. Explicitly state desired behaviors. General concepts don’t lead to action.

  i. Use every day words, limit the use of medical and science terms and use short sentences.

  ii. Be concise – leave out unnecessary words. Don’t use jargon or technical terms when everyday words have the same meaning.

  iii. Use words and terms consistently throughout.\textsuperscript{52}

### 6.2.5 Recommended Language for Key Messages

<table>
<thead>
<tr>
<th>Key Message</th>
<th>Avoid Using:</th>
<th>Do Use:</th>
<th>Recommended Language:</th>
</tr>
</thead>
</table>
| 1 Content   | - All capital letters, e.g., “ACETAMINOPHEN”<br>- Capitalized words, e.g., “Acetaminophen”<br>- *Italics* and **bolding**<br>- Different terms for the same thing, like drugs and medicines | - No capitals<br>- Sentence case<br>- Simple, familiar words, such as “has” instead of “contains.” These are better understood by patients. | - Has acetaminophen.  
- This has acetaminophen. |
| 2 Action and Warning | - Passive voice<br>- Unclear statements that may confuse patients as to what they need to do to improve their safety<br>- “Do not”.<br>- “acetaminophen-containing drugs”<br>- Slashes (e.g., prescription/nonprescription) | - Active voice<br>- Direct, clear directions for the action patients should take. Place action up front on label.<br>- Contractions to minimize chance patients will miss the “not”<br>- Consistent terms. “Medicines” (3 syllables) is preferable to medications (4 syllables). “Drugs” may be preferred if space is restricted.<br>- “Drugs that have acetaminophen” “or” or “and” | - Don’t use with other drugs that have acetaminophen (prescription or nonprescription).<br>- Don’t take with any other medicines that have acetaminophen (prescription or nonprescription). |
| 3 Risk and Consequence | - Non-descriptive or vague terms for severity or consequences that patients may not understand (e.g., “liver problems”)<br>- Metric abbreviations patients may not understand (e.g., “mg” or “G”)<br>- References to quantities that would require patients to do calculations (e.g., “more than 4000 mg”) | - Language to give explicit consequences from “misbehavior” so patients understand their risks and the rationale for and importance of adherence<br>- Use language consistent with the Drug Facts label whenever possible (e.g., liver damage) | - Too much can cause liver damage.  
- Too much acetaminophen can cause severe liver damage. |
| 4 Healthcare professional | - Non-descriptive terms or titles | - Active voice<br>- Pronouns that can help personalize the message, when there is room | - Questions? Ask your doctor or pharmacist.  
- If you have questions, ask your doctor or pharmacist. |
6.2.6 Stakeholder Response to the Recommendation: Standard Acetaminophen Warning Label with Prioritized Printing

Since publication of Version 1.0 of this white paper, major national drug database publishers have introduced a standard acetaminophen warning label, in alignment with the recommendations in this white paper and in compliance with company, internal clinical guidelines. Their standard acetaminophen warning labels are programmed to print in the top three of all labels that print for prescription acetaminophen-containing medicines in their data files.

6.2.7 Implemented Acetaminophen Warning Labels

Warning labels which have been implemented by the three major national drug database publishers for all acetaminophen containing medicines are provided below. These follow the guidance provided in the white paper with regard to key messages and their hierarchy. One national drug database publisher chose to incorporate the key messages into two standard warning labels in its warning label library. However, both of these warning labels (Warning label 2a and 2b) are programmed to print within the top three warning labels for acetaminophen medicines.

**Warning label 1:**
This has acetaminophen. Don’t take with other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage. Questions? Ask your doctor or pharmacist.

**Warning label 2:**


b. Do Not Take Other Medicines That Have Acetaminophen (Prescription Or Nonprescription) Without Checking With Your Doctor.

**Warning label 3:**
This has acetaminophen. Don’t take with any other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage.

Label comprehension research can help assess patient understanding of the new standard warning label.\(^{53}\) However, a recommendation for label comprehension testing is outside of the scope of this white paper.

6.2.8 Guidance for Pharmacy System Stakeholders: Standard Acetaminophen Warning Label with Prioritized Printing

All pharmacies are encouraged to ensure they are using the most up-to-date warning label libraries provided by their pharmacy system software company and warning label company. Older acetaminophen warning label combinations may still print on pharmacy container labels in those pharmacies, where pharmacists use font cards, which are not automatically updated. Examples of language of the standard acetaminophen warning labels currently provided by national drug database publishers which respond to the

white paper recommendations for messages and hierarchy of messages are provided in Section 6.2.7 of this white paper.

6.2.9 Use of Icons on the Standard Acetaminophen Pharmacy Warning Label

It is common practice for warning label companies to develop and include icons or pictograms on pharmacy warning labels. Icons can help improve patient understanding of complex health information. As noted in the USP standard for prescription labeling, icons should be used only when there is “adequate evidence, through consumer testing, that they improve patient understanding about correct use.” The Task Group, in alignment with USP, recommends using icons only when testing proves improved consumer and patient understanding beyond simple, explicit text alone.

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.

Manufacturers of acetaminophen-containing medicines, working through Consumer Healthcare Products Association (CHPA) and in collaboration with academia, are currently conducting research to explore the effectiveness of a uniform acetaminophen-ingredient icon for cross-industry inclusion on both OTC (Drug Facts label) and prescription container labels. The goal of the acetaminophen-ingredient icon is to help consumers and patients further recognize acetaminophen as the active ingredient in their medicines. The pharmacy warning label companies have agreed to work with the OTC manufacturers to add the uniform research-based acetaminophen-ingredient icon to the standard acetaminophen warning label once its effectiveness has been confirmed in quantitative testing on both prescription and nonprescription (OTC) medicines.

6.3 Prescription Labels for Prescribed Over-the-Counter Medicine

a. Pharmacist dispenses the product in the manufacturer’s original packaging:

Pharmacy staff should take care to apply the prescription label in such a way as to preserve the integrity of the critical acetaminophen safety information contained in the Drug Facts label. This includes the active ingredients, the strength, and warnings section in their entirety.

b. Pharmacist dispenses the product in a container other than the manufacturer’s original packaging:

Pharmacy staff should follow the recommendation put forth in this white paper, including the recommendation for complete spelling of all active ingredients as in Section 6.1 of this document; and the recommendation for the warning label as in Section 6.2 of this document.

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7. Stakeholder Call to Action: Adopt, Implement, Adhere, Communicate, and Educate

The NCPDP Acetaminophen Best Practices Task Group call to action remains first and foremost directed to all pharmacy system stakeholders, as they can continue to drive the changes required to implement best practices in pharmacy systems as described in this white paper. This section therefore outlines a call to action to all pharmacy system stakeholders, including national drug databases publishers, commercial and proprietary pharmacy system software companies, warning label companies and pharmacies, to further explore implementation of innovative patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point-of-dispensing, utilizing their state of the art clinical decision-support module systems.

Changing consumer and patient behaviors to encourage appropriate use of acetaminophen-containing medicines warrants a concerted effort of stakeholders to optimize communication with and education of healthcare professionals, consumers, and patients. As a first step, this white paper will be syndicated to all stakeholders who currently play a critical role in educating healthcare professionals, consumers and patients on the appropriate use of medicines.

All stakeholders are encouraged to enter into a dialogue to find synergies in utilizing existing programs and to collaborate on future initiatives.
### 7.1 Pharmacy System Stakeholder Map: Call to Action, Challenges, and Opportunities

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Call to Action</th>
<th>Challenges and Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Drug Database</td>
<td>1. Include the complete spelling of acetaminophen and all other active</td>
<td>Complete spelling of acetaminophen and all other active ingredients</td>
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<tr>
<td>Publishers</td>
<td>ingredients for acetaminophen containing combination medicines.</td>
<td>• Changes implemented by national drug database publishers regarding complete spelling</td>
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<tr>
<td></td>
<td>2. Eliminate “APAP” and abbreviations or truncated versions of acetaminophen</td>
<td>of acetaminophen and all other active ingredients in acetaminophen-containing combination</td>
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<td></td>
<td>from product names in the data files of all acetaminophen-containing</td>
<td>medicines require a coordinated effort with pharmacy system software companies to overcome any</td>
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<tr>
<td></td>
<td>medicines. (Section 6.1)</td>
<td>existing challenges with field lengths designated for drug names.</td>
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<td></td>
<td>3. Provide data to support the printing of acetaminophen and all other</td>
<td>Implement 1 standard acetaminophen warning label</td>
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<tr>
<td></td>
<td>active ingredients in addition to the brand or branded generic name of the</td>
<td>• Opportunity to collaborate with the warning label companies and pharmacy system software</td>
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<tr>
<td></td>
<td>medicine on the prescription labels.</td>
<td>companies to establish industry standard.</td>
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<td></td>
<td>4. Adopt 1 standard warning label for all acetaminophen-containing prescription</td>
<td>• Explore opportunities to harmonize and standardize warning labels for other active ingredients</td>
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<tr>
<td></td>
<td>medicines, utilizing the concepts presented in this white paper. (Section 6.2)</td>
<td>to improve patient understanding of all warning labels provided on the same prescription</td>
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<tr>
<td></td>
<td>• Standardize prioritization of print sequence for the new standard</td>
<td>container label of all acetaminophen-containing medicines, in collaboration with both pharmacy</td>
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<tr>
<td></td>
<td>acetaminophen warning label to print among the top 3 pharmacy warning labels.</td>
<td>system software and warning label companies.</td>
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<tr>
<td></td>
<td>• Delete all warning labels containing similar key messages from warning</td>
<td>Education and communication with healthcare professionals and patients</td>
</tr>
<tr>
<td></td>
<td>label data files to prevent duplication of key messages on prescription</td>
<td>• Collaborate with both pharmacy system and other stakeholders to find synergies and seek</td>
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<tr>
<td></td>
<td>labels.</td>
<td>innovative solutions to improve patient education and communication at point-of-dispensing and</td>
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<tr>
<td></td>
<td>5. Provide publisher specific guidance for customers on name/ingredient/warning</td>
<td>point-of-use.</td>
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<tr>
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<td>label databases and to support adherence to recommendations.</td>
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</table>
## Stakeholders

### Pharmacy System Software Companies

### Call to Action

1. Complete spelling of acetaminophen and other active ingredients.
   - Eliminate “APAP” and abbreviations or truncated versions for acetaminophen spelling from data files of all acetaminophen-containing medicines.
   - When a brand or branded generic is dispensed, acetaminophen should be completely spelled in addition to the brand or branded generic name on prescription container labels. (Section 6.1.1)
   - Review the “name” field options for labeling to ensure sufficient length of the field to allow complete spelling of acetaminophen and all other active ingredients on prescription labels for all acetaminophen-containing medicines as described in Section 6.1.
   - Review the appropriate choice of data options from national drug database publisher in order to provide the full spelling of acetaminophen and other active ingredients.
   - Review any manual drug name creation or national drug database publisher overrides which either truncate or abbreviate acetaminophen or other active ingredients.
   - Assist customers with updating any available custom drug name fields.

2. Provide company-specific guidance to customers on name/ingredient/warning label databases to support adherence to recommendations.

3. Adopt a standard warning label for all acetaminophen-containing prescription medicines with prioritization of print among the top 3 pharmacy warning labels. (Section 6.2)
   - Delete all warning labels containing similar key messages from warning label data files, to prevent duplication of key messages on prescription labels.

### Challenges and Opportunities

Complete spelling of acetaminophen and other active ingredients

- Collaborate with national drug database publishers on the timing of system change for complete spelling of all active ingredients in order to overcome any existing spacing challenges of drug name fields.

**Implement 1 standard acetaminophen warning label**

Opportunity to collaborate with the warning label companies and national drug database publishers to:

- Adopt 1 standard acetaminophen warning label aligned with the FDA approved warnings for OTC Drug Facts labels.
- Develop the new standard warning label in a patient-centered manner, applying plain language and health literacy principles.
- Standardize print sequence for these labels to ensure printing of acetaminophen warning labels within the top 3 of warning labels.
- Explore opportunities to harmonize and standardize warning labels for other active ingredients to improve patient understanding of all warning labels provided on same prescription container label of all acetaminophen-containing medicines, in collaboration with both national drug database publishers and warning label companies.

**Education and communication between healthcare professionals and patients**

- Collaborate with both national drug database publishers, pharmacy software companies and other stakeholders to find synergies and seek innovative solutions to improve patient education and communication at point-of-dispensing and point-of-use.
### Stakeholders and Call to Action

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Call to Action</th>
<th>Challenges and Opportunities</th>
</tr>
</thead>
</table>
| **Pharmacy Warning Label Companies** | 1. Adopt content for new standard acetaminophen-ingredient warning label and ensure warning label is developed in a patient-centered manner, utilizing appropriate and optimized font size.  
2. Delete all warning labels containing similar key messages from warning label data files to prevent duplication of key messages on prescription labels. | **Implement 1 standard warning label**  
Opportunity to collaborate with the warning label companies and national drug database publishers to:  
- Develop an industry standard warning label for acetaminophen-containing prescription medicines, in collaboration with colleagues.  
- Consider including 1 standardized acetaminophen-ingredient icon across industry to further help patient recognition of acetaminophen as active ingredient.  
- Explore opportunities to harmonize and standardize warning labels for other active ingredients to improve patient understanding of all warning labels provided on the prescription container of acetaminophen-containing medicines, in collaboration with both national drug database publishers and pharmacy system software companies. |
| **Pharmacy** | 1. Adopt the proposed labeling changes for all acetaminophen-containing medicines dispensed in pharmacy.  
2. Collaborate with pharmacy system software company(ies) to incorporate the labeling changes recommended in this white paper.  
3. Optimize pharmacist-patient counseling, communication and education at point-of-dispensing and point-of-use.  
   - Alert pharmacy staff of importance of pointing out acetaminophen in addition to opioids and other active ingredients. | **Education and communication with healthcare professionals and patients**  
- Seek synergies and innovative solutions to improve patient education and communication at point-of-dispensing and point-of-use through collaboration with both pharmacy system, as well as other stakeholders. |
7.2 Improved Communication and Education

7.2.1 NCPDP Recommendation: Pharmacy Communication and Education about Acetaminophen-Containing Medicines

NCPDP calls for pharmacies and pharmacy staff members to explore patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point-of-dispensing and point-of-use about the safe and appropriate use of prescription and OTC acetaminophen-containing medicines.

7.2.2 Stakeholder Response to the Recommendation

National educational initiatives have arisen or have multiplied their efforts to provide education for the public and support for healthcare professional efforts to educate their patients on the safe use of acetaminophen. Messaging for all of these programs encourage and provide tools for the public to read their medicine labels and take action to make sure they do not take multiple medicines with acetaminophen simultaneously.

These educational efforts and coalitions are organized, well-positioned and poised to communicate to the public the importance of comparing medicine labels to avoid harm, as well as other messaging that becomes essential to increase patient safety. Full implementation of this white paper’s recommendations will trigger an escalation in those efforts.

7.2.3 Guidance for Pharmacy Stakeholders

This white paper offers guidance to facilitate pharmacies and pharmacy staff members’ efforts to educate their patients about the safe and appropriate use of prescription and OTC acetaminophen-containing medicines.

Public education materials that can assist the healthcare professional in educating patients can be obtained in most cases at no cost or can be downloaded for use in counseling patients or for distribution. A variety of types and formats are available, and some also come in Spanish.

See Section 10, Appendix D for a list and links for online educational resources. The appendix is grouped into materials for healthcare professional education and materials healthcare professionals can use to educate consumers and patients.

- “Know Your Dose” campaign, organized by the Acetaminophen Awareness Coalition, a collaboration between consumer, healthcare professional and health organizations. Printed copies can be ordered at no cost on the website.
- “Using Acetaminophen and Nonsteroidal Anti-inflammatory Drugs Safely,” the US Food and Drug Administration acetaminophen education initiative. It provides materials for adult consumers and parents in a wide variety of media. Printed copies can be obtained at no cost, or downloaded from the website. Many are available in Spanish.
- Other medication education groups, such as the National Council for Patient Information and Education, have developed acetaminophen online materials that target specific groups, including teen influencers, college students, seniors and caregivers.
8. Conclusions

Even though rare in the context of its widespread use, liver injury from acetaminophen overdose remains a serious public health problem. In particular, there has been a disproportionate increase in liver injury in recent years as a result of misuse of acetaminophen-containing prescription medicines.

Efforts by stakeholders to conduct regulatory and educational initiatives to decrease harm caused by accidental overdoses from acetaminophen-containing medicines are ongoing. While these efforts are essential and important ways to impact patient safety, these efforts alone are not enough to improve patient safety. Other non-regulatory, voluntary, parallel efforts are needed to potentiate the effect of those efforts.

Over the past year, the pharmacy system industry’s voluntary responses to the NCPDP white paper have provided significant improvement to prescription container labels for acetaminophen-containing medicines.

However, continuing these efforts to implement the NCPDP recommendations needs to remain a priority for all stakeholders identified in the white paper. Consistency across OTC and prescription container labels is a critical first step to enable consumers and patients to identify and compare ingredients and take the necessary steps to improve their appropriate and safe use of acetaminophen.

The pharmacy system stakeholders are well positioned to play a critical role in supporting and driving development of patient-centered prescription container labels and implementing sustainable change and improvement. Additional steps needed are:

- NCPDP will continue to explore dissemination strategies designed to engage all stakeholders identified as audiences for this white paper.
- NCPDP will continue to encourage syndication among all stakeholders who currently play a critical role in educating healthcare professionals, consumers and patients on appropriate use of medicines.
- NCPDP will encourage stakeholders to harmonize efforts to optimize healthcare professional, consumer and patient communication. All pharmacy system stakeholders, including national drug databases publishers, commercial and proprietary system software companies, and warning label companies will be encouraged to further explore implementation of innovative patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point-of-dispensing and point-of-use, utilizing their state of the art clinical decision-support module systems.
9. References

21 CFR §201 Subpart B labeling requirements for prescription drugs and/or insulin

21 CFR §201.326 Over-the-counter drug products containing internal analgesic/antipyretic active ingredients; required warnings and other labeling

21 CFR §201.57 (c)(1) Specific requirements on content and format of labeling for human prescription drug and biological products described in 201.56(b)(1)

21 CFR §201.61 Statement of identity

21 CFR §201.66(c)(2) and (3) Format and content requirements for over-the-counter (OTC) drug product labeling

21 CFR §290.5 Drugs; statement of required warning

21 CFR §299.4 Established names for drugs

21 USC §353 (b)(2) Exemptions and consideration for certain drugs, devices, and biological products (b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

21 USC §825 (c) Labeling and packaging

21 CFR §1306.24 Labeling of substances and filing of prescriptions


10. Appendices
### 10.1 Appendix A: Survey of Current Acetaminophen Warning Labels

<table>
<thead>
<tr>
<th>Label</th>
<th>Warning Label Company</th>
<th>Warning Label: Full Text</th>
<th>Key Messages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>This medicine contains ACETAMINOPHEN. Taking more than recommended may cause liver problems. Ask your doctor before taking other products containing ACETAMINOPHEN.</td>
<td>Content, Overdose, Liver warning, Concomitant use</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>This medicine contains ACETAMINOPHEN. Taking more ACETAMINOPHEN than recommended may cause serious liver problems.</td>
<td>Content, Overdose, Liver warning</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>This medicine contains ACETAMINOPHEN. Taking more ACETAMINOPHEN (PARACETAMOL) than recommended may cause serious liver problems.</td>
<td>Content, Overdose, Liver warning</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>This medicine contains ACETAMINOPHEN. Taking more than 4000 mg of Acetaminophen per day may cause serious liver problems.</td>
<td>Content, Overdose, Liver warning</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>Do not take ACETAMINOPHEN containing products at the same time without first checking with your doctor. Check all medicine labels carefully.</td>
<td>Concomitant use</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>Do not take other ACETAMINOPHEN containing products at the same time without first checking with your doctor. Check all medicine labels carefully.</td>
<td>Concomitant use</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>Do not take other ACETAMINOPHEN (PARACETAMOL) containing products at the same time without first checking with your doctor. Check all medicine labels carefully.</td>
<td>Concomitant use</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>Do not take aspirin or acetaminophen without checking with your doctor or pharmacist.</td>
<td>Other</td>
</tr>
</tbody>
</table>
10.2 Appendix B: Sample Acetaminophen Drug Facts Label Excerpt

Over-the-Counter Drug Facts Label

Selected Sections for Acetaminophen Single Ingredient Over-the-Counter Medicine Labeled for Adult Use Only

Reference Sections 5.1.2 and 5.1.3 of this White Paper for written description of Drug Facts label regulations.

Note that acetaminophen is completely spelled out in “Active ingredient” section of the Drug Facts label, as recommended for the prescription label in Section 6.1 of this White Paper. Note the “Warnings” section of the Drug Facts label contains the 4 elements recommended and described for the prescription pharmacy warning label in Section 6.2 of this White Paper.
10.3 Appendix C: Sample Acetaminophen Prescription Container Label

Adopt one standard warning label for all acetaminophen-containing prescription medicines.
Standardize prioritization of print sequence to print among the top three pharmacy warning labels.

Always completely spell “acetaminophen” and all other active ingredients on the prescription label.
No abbreviation, acronym or truncated version of any active ingredient should be permitted on a prescription label.

---

May cause drowsiness. Use care when operating a car or dangerous machines. Don’t drink alcohol when taking this medicine.

This has acetaminophen. Don’t take with other medicines that have acetaminophen (prescription or nonprescription). Too much can cause liver damage. Questions? Ask your doctor or pharmacist.

Taking more of this medicine than recommended may cause serious breathing problems.

John Smith
1234 Winding Street
Fort Washington, PA, 12345

Brandname
hydrocodone/acetaminophen
X mg / XXX mg

Take 1 tablet by mouth every 4-6 hours as needed for pain

Orig: 10/31/2011
Date Filled: 10/31/2011
Discard after: 10/31/2012
This is a white, oval-shaped tablet with no imprint

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THE DRUG TO ANY PERSON OTHER THAN THE PATIENT FOR WHOM IT WAS PRESCRIBED.

Pharmacy Phone: (809) 555-5562
Rx # A123456
Prescriber: Dr. Johnson

---

58 The information presented here is not intended to support or imply standard formatting or language to be used on a prescription label.

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National Council for Prescription Drug Programs, Inc.
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Version 1.1
January 2013
10.4 Appendix D: Online Educational Resources

This appendix supplements Section 9, References, to provide additional acetaminophen educational websites for the reference and education of healthcare professionals.

The public educational websites are provided to facilitate the efforts of healthcare professionals to educate their patients. Most of the materials can be obtained at no cost or can be downloaded and printed; some materials are also available in Spanish.

A. Acetaminophen Websites Targeted to Healthcare Professionals

- **Acetaminophen Information**, from the US Food and Drug Administration (regulatory documents, advisory committee documents, consumer education, related resources)
  
  [http://www.fda.gov/acetaminophen](http://www.fda.gov/acetaminophen)

- **FDA Safe Use Initiative – Acetaminophen Toxicity**, from the US Food and Drug Administration
  

- **NCPDP: Providing Guidance on Improved Prescription Container Labels for Acetaminophen**, held March 1, 2012. NCPDP members and non-members can access this CE webinar from the NCPDP without cost.
  
  [http://www.ncpdp.org/members/audio/03-01-12NCPDP.wmv](http://www.ncpdp.org/members/audio/03-01-12NCPDP.wmv)

B. Public Educational Websites

**Using Acetaminophen Safely**

- **Know Your Dose**, from the Acetaminophen Awareness Coalition
  
  Informational website which includes interactive OTC and prescription labels; posters; information cards and card holder; tear pads for HCPs to give when prescribing and dispensing acetaminophen-containing medicines; and DVD; some materials in Spanish
  
  [http://www.knowyourdose.org/order](http://www.knowyourdose.org/order)

- **Using Acetaminophen and Nonsteroidal Anti-inflammatory Drugs Safely**, from the US Food and Drug Administration
  
  Articles; brochures; fact sheets; audio, print and video public service announcements; internet banners and widgets; and tutorials; materials in Spanish
  
  [www.fda.gov/otcpaininfo](http://www.fda.gov/otcpaininfo)

**Acetaminophen Resources for Specific Audiences**

- **Acetaminophen Safe Use: College Resource Guide**, from the National Council for Patient Information and Education
  
  [http://www.talkaboutrx.org/acetaminophen/index.jsp](http://www.talkaboutrx.org/acetaminophen/index.jsp)
NCPDP Recommendations for Improved Prescription Container Labels
for Medicines Containing Acetaminophen

- **Acetaminophen Safe Use for Seniors and Caregivers**, from the National Council for Patient Information and Education
  
  [http://www.mustforseniors.org/acetaminophen_safeuse.jsp](http://www.mustforseniors.org/acetaminophen_safeuse.jsp)

- **Acetaminophen Safe Use for Teen Influencers**, from the National Council for Patient Information and Education
  
  [http://www.talkaboutrx.org/acetaminophen/teen-influencers-landing.jsp](http://www.talkaboutrx.org/acetaminophen/teen-influencers-landing.jsp)

- **Acetaminophen continuing pharmacy education program**, for pharmacists from the American Pharmacist Association
  

- **Proper Acetaminophen Use: Resources & Handouts**, from McNeil Consumer Healthcare
  

- **An Interdisciplinary Look at Labeling Changes for Acetaminophen and the Implications for Patient Care**, from the Geriatric Society of America
  

**Using Over-the-Counter Medicines Safely**

- **Be Med Wise**, from the National Council for Patient Information and Education
  
  [http://www.bemedwise.org](http://www.bemedwise.org)

  
  [http://www.youtube.com/watch?v=hT6Th_QfQKE](http://www.youtube.com/watch?v=hT6Th_QfQKE)

- **Medicines in My Home Program**, from the US Food and Drug Administration, a multimedia educational program to teach consumers from adolescence through adulthood how to choose over-the-counter medicines and use them safely; some materials in Spanish
  
  [http://www.fda.gov/medsinmyhome](http://www.fda.gov/medsinmyhome)

- **OTC Safety**, from the Consumer Healthcare Products Association
  
  [http://www.otcsafety.org](http://www.otcsafety.org)

**Using Prescription Medicines Safely**

- **Buying and Using Medicines Safely**, from the US Food and Drug Administration
  
  [http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm296593.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm296593.htm)
- **Talk About Prescriptions**, from the National Council for Patient Information and Education
  
  [http://talkaboutrx.org](http://talkaboutrx.org)

Manufacturers’ websites can also provide useful materials for use by healthcare professionals to use with their patients, such as

- [http://www.getreliefresponsibly.com](http://www.getreliefresponsibly.com)
- [http://www.tylenol.com](http://www.tylenol.com)

from McNeil Consumer Healthcare.
10.5 Appendix E: Contributors to Versions 1.0 and 1.1 of This White Paper
Note: the organizations listed below should not be considered endorsers of this White Paper.

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