

NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications

Version 1.0

March 2014



This paper provides the healthcare industry, in particular the pharmacy sector, with historical and background information on the patient risks associated with the dosing of liquid medications and recommendations to mitigate those risks through best practices in prescription orders, prescription labeling, and the provision of dosing devices.

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Executive Summary

The purpose of this white paper is to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for error when patients and caregivers take and administer these medications. To accomplish this, the white paper advocates harmonizing prescribing, transcribing, labeling, dispensing, and administering these medications in the community setting with standards used in hospital and other healthcare settings, recommendations for over-the-counter (OTC) medications, and international standards of expressing volumetric measurement.

The audience for this white paper are all stakeholders who: dispense oral liquid prescription medication; review, revise, or generate prescription container labels; develop, produce, deploy, or use pharmacy system software, prescribing software, or drug information content; design or manufacture drug dosing devices; or educate healthcare professionals, patients, and caregivers on the appropriate use of these medications.

In September 2012, NCPDP hosted a stakeholder meeting involving 27 participants representing a wide range of perspectives to discuss the possibility of improving the standardization and consistency of dosing designations used on prescription container labels of oral liquid medications. This stakeholder meeting was catalyzed by the PROTECT Initiative, a public-private partnership, which has as one of its objectives to reduce the likelihood of patient and caregiver errors by standardizing dose designations of oral liquid medications. Based on the success of NCPDP's previous efforts to promote patient safety through improving prescription container labels, this effort was assigned to a task group of the NCPDP Professional Pharmacy Services Work Group (WG10).

Dosing errors involving oral liquid medications administered by patients and caregivers in home settings have been a source of concern for many years. Of particular concern are medication errors involving young children, as they may be more susceptible to harm from measurement errors and overdoses. To administer most oral liquid medications, a patient or caregiver must rely on the container label dosing designation to guide him/her in measuring out the proper dose with a dosing device. This additional step introduces numerous opportunities for error with each administration of an oral liquid medication.

Error-prone dosing designations contribute to medication errors and patient harm. The use of both multiple volumetric units (e.g., teaspoons, tablespoons, droppersful) and multiple abbreviations for the same volumetric units (e.g., mL, cc, mls; tsp, TSP, t) increase the likelihood of dosing errors by healthcare professionals, patients, and caregivers. One of the most common dosing errors is a patient or caregiver confusing teaspoons and tablespoons, resulting in three-fold dosing errors. In addition, the use of teaspoons and tablespoons as units of measure on labels may encourage the public to believe they can use non-calibrated household spoons for dosing medications. The omission of leading zeros for decimal amounts less than one and the use of unnecessary trailing zeros after whole number or decimal amounts can lead to potentially more serious ten-fold dosing errors by patients or caregivers. Further,

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assuming a patient or caregiver does use a calibrated dosing device, there is another opportunity for administration error if the numeric graduations and units of measure on the device do not correspond to the amounts and units of the container label dosing designation. Finally, the combination of multiple volumetric units and automation in some retail pharmacy computer systems may facilitate dosing designation misinterpretations by healthcare professionals when translating a prescription to a dosing designation on a container label.

This white paper outlines a concise set of recommendations and guidance that can be applied to the practices, systems and procedures for processing electronic prescriptions, printing prescription container labels, encouraging the use of appropriate dosing devices for oral liquid medications, and educating healthcare professionals, patients, and caregivers.

NCPDP Recommendations for Standardizing the Dosing Designation on Prescription Container Labels for Oral Liquid Medications	
1	Milliliter (mL) should be the standard unit of measure used on prescription container labels for oral liquid medications.
2	Dose amounts should always use leading zeros before the decimal point for amounts less than one and should not use trailing zeros after a decimal point on prescription container labels for oral liquid medications.
3	Dosing devices with numeric graduations and units that correspond to the container labeling should be made easily and universally available such as including a device each time oral liquid prescription medications are dispensed.

The NCPDP Task Group Call to Action maps out roles for many stakeholders, but particularly relies on local and corporate pharmacy leadership to:

- Adopt the recommendations in this white paper
- Communicate these recommendations as preferences or policies to all pharmacy staff
- Measure the performance of your organization in achieving these recommendations and stress accountability across your organization for adhering to them Explore innovative patient-centered communication and education initiatives that encourage pharmacist-to-patient education at point of dispensing
- Facilitate communication by stakeholders outside the community pharmacy system, including prescribers, with a role in patient and healthcare professional education on using standardized dosing designations for prescribed oral liquid medications.

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A stakeholder map identifies all the relevant stakeholders who need to play a role in adopting, communicating, adhering, and educating. The map outlines a call to action and identifies some of the challenges and opportunities for each stakeholder group.

Adoption of this white paper's recommendations will standardize dosing designations for prescription container labels of oral liquid medications in the community setting with standards used in hospital and other healthcare facilities, recommendations for OTC medications, and international standards of volumetric measurement.

NCPDP calls on all the relevant stakeholders to support efforts to adopt, implement, and adhere to the recommendations in this white paper, and to educate healthcare professionals, patients, and caregivers on how to accurately measure and administer oral liquid medications.

1. Audience

The audience for this white paper includes all stakeholders who:

- Dispense oral liquid prescription medication
- Review, revise, or generate prescription container labels
- Develop, produce, deploy, or use pharmacy system software
- Develop, produce, deploy, or use prescribing software
- Develop, produce, deploy, or use drug information content
- Design or manufacture drug dosing devices
- Educate healthcare professionals, patients, and other caregivers on the appropriate administration of prescribed oral liquid medications

2. Purpose, Goals, and Key Recommendations

The purpose of this white paper is to provide recommendations and guidance for standardizing dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies.

The immediate goals of the recommendations are to:

- (1) Reduce variability in dosing designations on prescription container labels of oral liquid medications dispensed from community pharmacies by harmonizing the dosing designations with standards used in hospital and other healthcare facilities, recommendations for over-the-counter (OTC) medications, and international standards of volumetric measurement.
- (2) Facilitate proper administration by patients and caregivers of oral liquid medications dispensed from community pharmacies.

The ultimate goal of the recommendations is to improve patient safety and patient outcomes by decreasing the potential for overdoses, underdoses, and other errors when patients and caregivers measure and administer oral liquid prescription medications dispensed from community pharmacies.

To meet these goals, NCPDP outlines below a set of recommendations and guidance that can be applied to the practices, systems, and procedures for processing prescriptions, printing prescription container labels, encouraging the use of appropriate dosing devices for oral liquid medications, and educating healthcare professionals, patients, and caregivers.

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RECOMMENDATIONS	
1	<p>Milliliter (mL) should be the standard unit of measure used on prescription container labels of oral liquid medications.</p> <ul style="list-style-type: none"> • Metric units should be used whenever possible. Non-metric and non-volumetric units of measure should be avoided. • When the prescription Sig contains dosing designations in mL, mL dosing instructions should be used on the prescription container label. • When the prescription Sig contains dosing instructions in non-volumetric units (e.g., mg) or non-standard volumetric units (e.g., dropperful), convert the dosing instructions to mL, and use mL dosing instructions on the prescription container label. • The standard abbreviation “mL” should be used on the prescription container label. Other abbreviations for milliliter (e.g., cc, mls) should be avoided. If use of mixed case is not possible (e.g., because of legacy software limitations), lowercase (“ml”) or uppercase (“ML”) may be used while changes to the preferred “mL” can be implemented. • Mnemonics, Sig codes, or any defaults used in computer systems to print prescription labels should produce dosing designations using mL.
2	<p>Dose amounts should always use leading zeros before a decimal point for amounts less than one and should not use trailing zeros after a decimal point on prescription container labels of oral liquid medications.</p> <ul style="list-style-type: none"> • The dose designation on a prescription container label should be “0.5” mL, NOT “.5” mL. • The dose designation on a prescription container label should be “5” mL, NOT “5.0” mL. Do not use trailing zeros in the hundredths, or thousandths position (e.g., “2.5” mL NOT “2.50” mL or “2.500” mL) either. • Place adequate space between the dose and unit of measure (e.g., “5 mL” NOT “5mL”).
3	<p>Dosing devices with numeric graduations and units that correspond to the container labeling should be made easily and universally available such as including a device each time oral liquid prescription medications are dispensed.</p> <ul style="list-style-type: none"> • The standard abbreviation “mL” should be used on the dosing device to correspond to the prescription container label. • Leading zeros before a decimal point should always be used on dosing devices and trailing zeros after a decimal point should never be used on dosing devices to correspond to the prescription container label.

3. Background

3.1 Why an NCPDP White Paper?

In September 2012, NCPDP hosted a stakeholder meeting involving 27 participants representing a wide range of perspectives¹ to discuss the possibility of improving the standardization and consistency of dosing designations (i.e., the amount to be given and the unit of measure to use) on prescription container labels of oral liquid medications. This stakeholder meeting was catalyzed by the PROTECT Initiative,² a public-private partnership, which has as one of its objectives to reduce the likelihood of healthcare professional, patient, and caregiver errors by standardizing dosing designations used for oral liquid medications.

NCPDP has previously played a key role in efforts to clarify information on the labels of prescription drugs. An NCPDP white paper on improving prescription container labels for medications containing acetaminophen³ has, along with subsequent implementation efforts by partner organizations, helped lead to the use of “acetaminophen” instead of the more confusing acronym “APAP” on the labels of hundreds of prescription products. NCPDP also has led the way in promoting a universal medication schedule (UMS) for use on prescription medication labels, with a white paper recommending the removal of arcane notations, such as BID, or confusing instructions, such as “twice daily,” and substituting plain language instructions, such as “take 1 tablet in the morning.”⁴

Based on the success of these previous NCPDP efforts to promote patient safety through improving prescription container labels, NCPDP determined that best practices also could be developed to decrease the variability of dosing designations used for oral liquid medications. This effort was assigned to a task group of the NCPDP Professional Pharmacy Services Work Group (WG10).

3.2 How Does Standardizing Dosing Designations on Prescription Container Labels of Oral Liquid Medications Dispensed from Community Pharmacies Relate to Efforts in Other Settings?

While healthcare professionals measure and administer medications within healthcare facilities, it is up to patients or caregivers to accurately measure and administer liquid medications outside of healthcare facilities. When patients or caregivers administer liquid medications, the dosing

¹ Participants included electronic drug database publishers, chain pharmacies, mail order pharmacies, drug distributors, community pharmacy system software vendors, drug manufacturers (McNeil Healthcare), government (Food and Drug Administration [FDA] and Centers for Disease Control and Prevention [CDC]), and non-governmental organizations (Institute for Safe Medication Practices [ISMP], National Association of Boards of Pharmacy [NABP], National Association of Chain Drug Stores [NACDS], and United States Pharmacopeial Convention [USP])

² Centers for Disease Control and Prevention. The PROTECT Initiative: Advancing Children’s Medication Safety. http://www.cdc.gov/medicationsafety/protect/protect_Initiative.html (accessed November 29, 2013).

³ National Council for Prescription Drug Programs, Inc. NCPDP Recommendations for Improved Prescription Container Labels for Medicines Containing Acetaminophen Version 1.1. <http://www.ncdp.org/Whitepaper.aspx> (accessed November 29, 2013).

⁴ National Council for Prescription Drug Programs, Inc. Universal Medication Schedule White Paper. <http://www.ncdp.org/Whitepaper.aspx> (accessed October 24, 2013).

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designations on the medication container labels and consistency with accompanying dosing devices are particularly important because container labels often provide the only instructions they use when administering medications.

For many decades, the American Society of Health-System Pharmacists (ASHP) and other practice organizations (e.g., American Health Care Association (AHCA), American Pharmacists Association (APhA)) have recommended the use of metric units and metrically marked dosing devices for the measurement and administration of oral liquid medications.^{5,6,7,8,9} Confusion and resultant medication errors (e.g., unit conversions) from multiple systems of measure was the principal rationale for the recommended use of metric units in these settings. In fact, in some studies, the majority of dosing errors were associated with administration of wrong doses of liquid medications.

The Joint Commission also has required the facilities it accredits (e.g., hospitals, nursing and rehabilitation centers) to standardize dosing designations in order to reduce medication administration errors in inpatient healthcare facilities.¹⁰ Other organizations, including the Institute for Safe Medication Practices (ISMP)¹¹ and the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP), have supported using the same or similar recommendations in all healthcare settings.

Since 2011, to reduce medication administration errors when using over-the-counter (OTC) oral liquid medication outside of healthcare facilities, a Consumer Healthcare Products Association (CHPA) guideline¹² and the Food and Drug Administration (FDA) Voluntary Guidance for Industry¹³ have provided details for standardization and consistency in medication dosing designations for OTC product labels and dosing devices.

A recent study of the most commonly used pediatric OTC liquid medications demonstrated that just two years after these voluntary standards were finalized, 91% of dosing directions and 62%

⁵ American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. *Am J Hosp Pharm.* 1971; 28:110-2.

⁶ American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. *Pharmaceutical services in the long-term care facility.* 7th edition, second printing. Washington, DC: 1975.

⁷ Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. *Am J Hosp Pharm.* 1964; 21:66-7.

⁸ Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. *Am J Hosp Pharm.* 1970; 27:802-14.

⁹ American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf. (accessed October 24, 2013).

¹⁰ The Joint Commission. Facts about the Official "Do Not Use" List. http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf. (accessed October 24, 2013).

¹¹ Institute for Safe Medication Practices. ISMP's list of error-prone abbreviations, symbols, and dose designations. <http://www.ismp.org/Tools/errorproneabbreviations.pdf>. (accessed November 06, 2013).

¹² Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age. http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx (accessed October 24, 2013).

¹³ U.S. Food and Drug Administration. Guidance for Industry: Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products. <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf> (accessed November 29, 2013).

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of dosing devices adhered to all top-tier recommendations, suggesting that voluntary initiatives can promote adherence to safety recommendations.¹⁴ Similar or higher adoption rates are the goal for prescription oral liquid medications.

In 2013, FDA released draft guidance for industry on safety considerations for commercial container labels and carton labeling design to minimize medication errors. This guidance includes details for standardization and consistency of dosing designations for commercial container and carton labeling of prescription drug and biological products but does not specifically address containers or cartons dispensed from the community pharmacies.¹⁵ While some medications are dispensed from community pharmacies in the original carton or container, many, if not most, are dispensed from community pharmacies in other containers filled by the pharmacy with only the prescribed amount. In addition, even when medications are dispensed in the original container or carton, labels created in the community pharmacy with dosing directions that are ordered for the specific patient are added and may differ in units of measure and other dosing instructions.

Because more and more community prescriptions are ordered by electronic transmission of prescriptions from the prescriber to the community pharmacy (e-prescribing), in 2013, the American Academy of Pediatrics (AAP) issued a policy statement outlining safe practices for e-prescribing which also includes details for standardization and consistency in medication dosing designations transmitted to community pharmacies.¹⁶

This white paper draws on these existing standards and medication safety research to provide recommendations for portraying dosing designations on the prescription container label of oral liquid medications dispensed from community pharmacies that align with recommendations for inpatient settings and other healthcare facilities, for OTC medications, for the original container and carton labeling, and for e-prescribing.

4. Rationale for Key Recommendations

4.1 Recommendation 1: Milliliter (mL) Should be the Standard Unit of Measure Used on Prescription Container Labels of Oral Liquid Medications

4.1.1 The Need to Measure Oral liquid Medication Volumes Makes Accurate Use More Challenging than for Solid Medications

¹⁴ Budnitz DS, Lovegrove MC, Rose KO. Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications. *Pediatrics*, online early release, January 6, 2014

<http://pediatrics.aappublications.org/content/early/2014/01/01/peds.2013-2362> (accessed January 15, 2014)

¹⁵ DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) (April 2013). Page 12 – Leading and Terminal Zeros, Decimals, and Commas.

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf> (accessed January 15, 2014).

¹⁶ AAP Policy Statement - Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management, *Pediatrics* 2013;131:824–826, April 1, 2013.

<http://pediatrics.aappublications.org/content/131/4/824.full.pdf> (accessed January 15, 2014).

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Using oral liquid prescription medications is more complicated than using solid medication dosage forms. Unlike oral solid dosage forms, most liquid medications are not “pre-packaged” in unit-of-use containers or dosing units. Oral liquid medications typically must be measured by a patient or caregiver at every administration. This additional step requires further manipulation of the product and introduces opportunities for error.

Healthcare professionals often rely on liquid formulations when prescribing medications for young children. Because of their small body mass, young children may be more susceptible to harm from measurement errors and overdoses. In any given week in the United States, 20% of children younger than 12 years of age are taking at least one prescription medication.¹⁷ This high rate of medication use in children indicates the importance of addressing the problem of caregiver medication administration errors.

4.1.2 The Use of Multiple Volumetric Measures Contributes to Oral Liquid Medication Dosing Errors

While essentially all solid dosage form medications have been measured in metric units (e.g., mg for milligrams) for decades, dosing designations for oral liquid medications still use, and patients and caregivers are still instructed to administer medications using,¹⁸ a variety of U.S. customary or household units (teaspoons, tablespoons), non-standard units (droppersful), apothecary units (drams), and metric units (milliliters, mL). The use of non-standard metric abbreviations or terminology unfamiliar to parents and other caregivers, such as cubic centimeters (cc), creates an additional potential source of confusion. The cc abbreviation also is associated with other errors of misinterpretation.

The use of multiple volumetric measures increases the likelihood of multi-fold dosing errors by patients, caregivers, and healthcare professionals. For example, a hurried prescriber or pharmacist who switches mL and teaspoon may mistakenly prescribe or dispense a 5-fold overdose or underdose. A caregiver who confuses teaspoon and tablespoon can accidentally administer a 3-fold overdose or underdose.

During pharmacy dispensing, numerous cases have been reported of errors involving multiple volumetric measures, most frequently due to a physician’s prescription being changed from an mL dose to a teaspoon dose.¹⁹ The design of some community pharmacy computer systems may facilitate confusion involving multiple volumetric measures. For efficiency, some systems may default to a dose expressed in teaspoon amounts in the directions when oral liquids are selected. (Some prescribing systems may default to teaspoons as well.) If this happens when an mL dose is intended, pharmacists and pharmacy technicians may not remember to change the instructions for the container label back to mL when teaspoons automatically appear.

¹⁷ Vernacchio L, Kelly JP, Kaufman DW, Mitchell AA. [Medication use among children <12 years of age in the United States: results from the Slone Survey](#). Pediatrics. 2009 Aug;124(2):446-54.

¹⁸ Sobhani S, Christopherson J, Ambrose PJ, Corelli RL. Accuracy of oral liquid measuring devices: comparison of dosing cup and oral dosing syringe. Ann Pharmacother. 2008;42:46-52.

¹⁹ Seifert SA, Jacobitz K. [Pharmacy prescription dispensing errors reported to a regional poison control center](#). J Toxicol Clin Toxicol. 2002;40(7):919-23.

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Distractions and confirmation bias will inevitably contribute to pharmacy personnel and prescribers forgetting to change the dosing designations from these error-prone default settings.

The ISMP reports over 50 serious cases in which confusion with units of measure has led to errors, primarily attributed to transcription/dispensing errors.

Example: A pharmacist accidentally put on a child's prescription container label that the child should be given 3.5 teaspoons of an antibiotic instead of the 3.5 mL that the doctor had ordered, resulting in administration of a 5-fold overdose for 3 days.²⁰

Example: A pharmacist typed out instructions on the prescription container label as "take 4 cc (4/5 teaspoon) three times a day." The parents of the child did not understand the term "cc" and mistook the slash mark to mean 4.5 teaspoons. The child was given 4.5 teaspoons three times daily, almost five times more than intended.²¹

When oral liquid medications are administered in home settings, volumetric measure confusion by parents and other caregivers has been a source of concern for the ISMP and the FDA for many years.^{22,23} Over 10,000 calls made to U.S. poison control centers annually are attributed to confusion around units of measurement, with approximately three quarters involving children 12 years of age or younger.^{24,25,26,27,28,29}

²⁰ Institute for Safe Medication Practices. Another TEAspoon—mL mix-up. *ISMP Med Saf Alert Acute Care*. 2011;16(19):3.

²¹ Institute for Safe Medication Practices. Misunderstood abbreviations. *ISMP Med Saf Alert Com/Amb Care*. 2005 Aug;4(8):2.

²² Institute for Safe Medication Practices. Another TEAspoon—mL mix-up. *ISMP Med Saf Alert Acute Care*. 2011;16(19):3.

²³ Food and Drug Administration. Information for Healthcare Professionals: Long-Acting Hydrocodone-Containing Cough Product.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126196.htm> (accessed October 24, 2013).

²⁴ Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Heard SE. 2006 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS). *Clin Toxicol (Phila)*. 2007 Dec;45(8):815-917.

²⁵ Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Heard SE; American Association of Poison Control Centers. 2007 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 25th Annual Report. *Clin Toxicol (Phila)*. 2008 Dec;46(10):927-1057.

²⁶ Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2008 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 26th Annual Report. *Clin Toxicol (Phila)*. 2009 Dec;47(10):911-1084.

²⁷ Bronstein AC, Spyker DA, Cantilena LR Jr, Green JL, Rumack BH, Giffin SL. 2009 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 27th Annual Report. *Clin Toxicol (Phila)*. 2010 Dec;48(10):979-1178.

²⁸ Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2010 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 28th Annual Report. *Clin Toxicol (Phila)*. 2011 Dec;49(10):910-941.

²⁹ Bronstein AC, Spyker DA, Cantilena LR Jr, Green J, Rumack BH, Dart RC. 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 29th Annual Report. *Clin Toxicol (Phila)*. 2012 Dec;50(10):911-1164.

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Errors attributed to confusion around units of measure have been associated with sometimes severe adverse events in young children.³⁰

4.1.3 Parents Measure Liquids More Accurately Using mL

Although prescribers and pharmacists may assume that parents and other caregivers cannot administer liquid medications accurately using mL, a recent study indicates this is a false assumption. The study showed that parents who reported their dose in mL were not only more likely to use a standardized dosing device, but also were half as likely to make a dosing error.³¹

4.1.4 Milliliter Has Been Endorsed as the Standard Unit of Measure for Oral Liquid Medications by Many Professional and Patient Safety Organizations

The Joint Commission requires the facilities it accredits (e.g., hospitals and nursing and rehabilitation centers) to standardize dosing designations in order to reduce medication administration errors within inpatient healthcare facilities and has suggested that organizations avoid apothecary units (e.g., dram) and non-standard abbreviations (e.g., do not use cc; mL is preferred).³² Based on reports of errors and patient harm, ISMP,³³ NCC-MERP, ASHP,^{34,35,36} and others also have issued or endorsed recommendations to only use metric units (mL) in all settings (Appendix A).

The United States Pharmacopeial Convention (USP) adopted the use of metric units as a standard over thirty years ago. More recently, USP has published standards stating that prescriptions for medications should be written to state the quantity and/or strength of the medication in metric units unless otherwise indicated in an individual monograph. The USP also states that if an amount of a medication is prescribed by any other system of measure, only the

³⁰ Tzimenatos L, Bond GR; Pediatric Therapeutic Error Study Group. Severe injury or death in young children from therapeutic errors: a summary of 238 cases from the American Association of Poison Control Centers. *Clin Toxicol (Phila)*. 2009 Apr;47(4):348-54.

³¹ Yin HS, Dreyer BP, Ugboaja DC, Sanchez DC, Paul IM, Moreira HA, Rodriguez L, Mendelsohn AL. Unit of Measurement Used and Parent Medication Dosing Errors. *Pediatrics*, published online July 14, 2014. <http://pediatrics.aappublications.org/content/early/2014/07/09/peds.2014-0395.abstract> (accessed August 14, 2014).

³² The Joint Commission. The Joint Commission Official "Do Not Use" List, 2009. http://www.jointcommission.org/assets/1/18/dnu_list.pdf (accessed January 21, 2014).

³³ Institute for Safe Medication Practices. ISMP Statement on Use of Metric Measurements to Prevent Errors with Oral Liquids. <http://www.ismp.org/pressroom/PR20110808.pdf> (accessed October 24, 2013).

³⁴ American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf (accessed October 24, 2013).

³⁵ American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. *Am J Hosp Pharm*. 1971; 28:110-2.

³⁶ American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. *Pharmaceutical services in the long-term care facility*. 7th edition, second printing. Washington, DC: 1975.

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metric equivalent amount should be dispensed and labeled accordingly.³⁷

Unfortunately, changes made in the volumetric units during community pharmacy dispensing may decrease the use of mL on container labeling. In a study of liquid medications dispensed to children 12 years of age or younger from 4 community pharmacies, 68% of prescription instructions were written using milliliters; 24% used teaspoons; and 7% used other units. When the corresponding container labels were examined, 62% used milliliters and 29% used teaspoons, suggesting that at least 5% of prescriptions were switched from milliliters to teaspoons.³⁸

4.2 Recommendation 2: Dose Amounts Should Always Use Leading Zeros Before a Decimal Point and Should Not Use Trailing Zeros After a Decimal Point on Prescription Container Labels of Oral Liquid Medication

4.2.1 How Amounts are Expressed Can Cause Significant Overdoses

Error-prone methods of expressing doses have contributed to medication errors and patient harm.^{39,40,41,42,43} The inclusion of a decimal point and trailing zero for whole number doses (e.g., 5.0 instead of 5) and the failure to include a zero before the decimal point for doses less than a whole unit (e.g., .5 instead of 0.5) have resulted in 10-fold dosing errors. Such errors can be fatal.⁴⁴

Example: A 9-month-old girl tragically died following a 10-fold overdose of morphine. The baby's physician wrote an order, without the use of a leading zero, for morphine ".5

³⁷ The USP-NF adopted the use of metric units as a standard as expressed in the International System of Units (SI) as established and revised by the *Conférence générale des poids et mesures* over 30 years ago. The convention includes milliliter (mL) as a standard metric unit. The convention has been incorporated into standards for prescribing and dispensing that state that compendial articles (drug/drug product) must be written to state the quantity and/or strength desired in metric units. Additionally, "teaspoon," a definition for a measuring device that is currently published in the USP-NF has been expressed in metric units as a standard since 1995 and United States Pharmacopeial Convention. General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 9 – Prescribing and Dispensing, USP 36 – NF 31 edition May 1, 2013.

³⁸ Shah, Rita; Blustein, Leona; Kuffner, Edward; Davis, Lisa. Communicating Doses of Pediatric Liquid Medicines to Parents/Caregivers: A Comparison of Written Dosing Directions on Prescriptions with Labels Applied by Dispensed Pharmacy. *JPeds*, 2013. [http://www.jpeds.com/article/S0022-3476\(13\)01393-0/abstract](http://www.jpeds.com/article/S0022-3476(13)01393-0/abstract) (accessed December 23, 2013).

³⁹ The Joint Commission. Facts about the Official "Do Not Use" List.

http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf. (accessed October 24, 2013).

⁴⁰ Institute for Safe Medication Practices. ISMP's list of error-prone abbreviations, symbols, and dose designations. <http://www.ismp.org/Tools/errorproneabbreviations.pdf>. (accessed November 06, 2013).

⁴¹ U.S. Food and Drug Administration. Medication Errors.

<http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm> (accessed November 12, 2013).

⁴² Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. *Am J Hosp Pharm*. 1964; 21:66-7.

⁴³ Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. *Am J Hosp Pharm*. 1970; 27:802-14.

⁴⁴ Gaunt MJ, Cohen MR. Error-prone abbreviations and dose expressions. In: Cohen MR, ed. Medication errors. 2nd ed. Washington (DC): American Pharmacists Association; 2007:165.

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mg.” However, the decimal point was missed and the order misinterpreted. Two 5 mg doses were administered to the baby.⁴⁵

4.2.2 Existing Healthcare Standards Suggest Dose Designations Always Use Leading Zeros and Never Use Trailing Zeros

The Joint Commission’s Information Management Standard IM.02.02.01 requires accredited organizations to adhere to the Joint Commission’s official “Do Not Use” list. This list dictates that when the amount of medication is a whole number, the amount should never be designated with a trailing zero (e.g., express as 5 not 5.0). If the amount of medication is less than 1, the amount should always include a leading zero (e.g., express as 0.5 not .5).⁴⁶ The USP has published similar standards when expressing the active ingredients of drug products.⁴⁷

In addition, the ISMP, FDA, ASHP, NCC-MERP, and others (Appendix B) have issued statements or endorsed recommendations to use leading zeros and avoid trailing zeros in dose designations in all settings.^{48,49,50}

4.3 Recommendation 3: Dosing Devices With Numeric Graduations and Units That Correspond to the Container Labeling Should be Made Easily and Universally Available Such as Including a Device Each Time Oral Liquid Prescription Medications are Dispensed

4.3.1 How Dosing Designations Are Represented on Dosing Devices Contributes to Medication Administration Errors

Non-metric units of measure presented, alone or in combination, on dosing devices also have contributed to errors. Inclusion of units such as drams, minims, fluid ounces, cc, TSP (teaspoon), TBSP (tablespoon), and DSSP (dessertspoon) have caused mistakes when healthcare professionals, patients, and caregivers confuse the unit of measure on a measuring device with the unit of measure specified on a prescription container label or other set of instructions.

⁴⁵ Institute for Safe Medication Practices. Please don’t sleep through this wake-up call. *ISMP Med Saf Alert Acute Care*. 2001;6(9):1. Available from Internet: <http://www.ismp.org/Newsletters/acute/20010502.asp> (accessed November 06, 2013).

⁴⁶ The Joint Commission. Facts about the Official “Do Not Use” List.

http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf (accessed October 24, 2013).

⁴⁷ United States Pharmacopeial Convention General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 10 - Preservation, Packaging, Storage, and Nomenclature, from USP 36 – NF 31 edition May 1, 2013.

⁴⁸ Institute for Safe Medication Practices. ISMP’s list of error-prone abbreviations, symbols, and dose designations. <http://www.ismp.org/Tools/errorproneabbreviations.pdf>. (accessed November 06, 2013).

⁴⁹ Institute for Safe Medication Practices. ISMP and FDA campaign to eliminate the use of error-prone abbreviations. 2006. <http://www.ismp.org/tools/abbreviations/>. (accessed November 06, 2013).

⁵⁰ American Society of Health-System Pharmacists. Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. www.ashp.org/s_ashp/docs/files/BP07/MedMis_End_NCCMERP.pdf (accessed October 24, 2013).

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Example: A nurse administered five drams of acetaminophen concentrate liquid (100 mg/mL) instead of 5 mL. As a result, the patient received 18.45 mL or 1.845 g of acetaminophen, almost four times the intended amount (Figure 1).⁵¹



Figure 1. Dose cup used to measure liquid acetaminophen (Image courtesy of the ISMP)

4.3.2 Use of Household Spoons or Other Utensils Can Cause Administration Errors

Household teaspoons and tablespoons have proven to be inaccurate and error-prone when used by patients and caregivers as medication measuring tools since volumes in these household devices are not standardized. Although some kitchen measuring sets include a volumetric measure along with the household measure, these too cannot be relied on to provide accurate dosing.

In addition, the use of teaspoons or tablespoons in dosing designations on prescription container labels may encourage patients and caregivers to believe that using household spoons or other kitchen utensils is advisable if a pharmacy-provided dosing device is not available.⁵² Dispensing dosing devices with numeric graduations and units (mL) that correspond with the container labeling can reinforce use of a calibrated dosing device rather than household spoons or kitchen utensils.

4.3.3 Guidelines for Over-the-Counter Medications Already Recommend that Milliliter (mL) Should be the Standard Unit of Measure Used for Oral Liquid Medication Dosing Devices

Voluntary guidelines from CHPA and FDA suggest that dosing devices should always accompany OTC oral liquid medications, and these devices should include the units and numeric doses as described in the dosing directions.^{53,54} CHPA further recommends that mL be the preferred unit of measure in dosing directions.⁵⁵ Other organizations, such as the American

⁵¹ Institute for Safe Medication Practices. Archaic liquid measure a factor in medication errors. *ISMP Med Saf Alert Com/Amb.* 2012;11(7):1-2.

⁵² Dewalt DA. Ensuring Safe and Effective Use of Medication and Health Care: Perfecting the Dismount. *JAMA.* 2010; 304(23):2641-2642.

⁵³ Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age. http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx. Accessed October 24, 2013.

⁵⁴ Food and Drug Administration. Nonprescription Cough and Cold Medicine Use in Children – Full Version. <http://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm078927.htm>. Accessed October 24, 2013.

⁵⁵ Consumer Healthcare Products Association. Guideline Volumetric Measures for Dosing of Over-the-Counter Liquid Oral Drug Products for Children ≤12 Years of Age.

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Pharmacists Association (APhA), also recommend that standardized dosing devices be included with all liquid medications, while ISMP specifies that dosing devices should allow parents and other caregivers to measure liquid medications in mL (Appendix C).

5. Regulation Overview

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

- Examples of federal statutes and regulations concerning prescription labels include:
 - Food, Drug and Cosmetic (FD&C) Act⁵⁶ – “Exemptions and consideration for certain drugs, devices, and biological products”
 - Controlled Substances Act – Labeling and Packaging⁵⁷ which includes “Statement of required warning”⁵⁸ and “Labeling of substances and filling of prescriptions”⁵⁹
- 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)⁶⁰ identify critical and important information for patients that must appear, as well as additional information that may appear, on all prescription labels.

As previously mentioned, oral liquid medications may be prescribed in a variety of units of measure. Although federal and state laws mandate the required elements of prescription container labels, including directions for use, it is allowable for pharmacists to use their professional judgment to determine the appropriate units of measure, such as mL, to include on the prescription container label to ensure that oral liquid medications are dosed accurately.

A review of state labeling requirements indicates that there are no existing laws or regulations that expressly prohibit a pharmacist from changing the unit of measure or notation of decimal amounts to be used on a prescription label.⁶¹

Most states provide for labels to contain “directions for use,” and therefore by interpretation, would allow pharmacists to use mL as the unit of measure. Certainly, in instances where the prescriber has indicated the dosage in mL, pharmacists should be encouraged to prepare the prescription label according to the prescription, and should not arbitrarily change it to teaspoons or any other measure. NABP endorses the use of mL and supports pharmacists in exercising professional judgment to select mL as the preferred unit of measure.

http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx. Accessed October 24, 2013.

⁵⁶ 21 United States Code (USC) §353 (b) (2)

⁵⁷ 21 USC §825 (c)

⁵⁸ 21 CFR §290.5

⁵⁹ 21 CFR §1306.24

⁶⁰ NABP. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*NABP Model Act*), August 2012. <http://www.nabp.net/publications/model-act/> (accessed December 11, 2013).

⁶¹ NABP LAW® Search results of state labeling requirements conducted 4/17/13

6. Stakeholder Challenges and Opportunities

Variations in how a liquid medication is ordered, transcribed and transmitted, and then interpreted, entered and printed provide opportunities for errors in what appears on the prescription container labels of oral liquid prescription medications. Mitigation of these errors requires consistent use of mL as the standard unit of measure and the use of leading zeros and avoidance of trailing zeros in dose designations by all the stakeholders who play a role in prescribing or providing patient instructions on the prescription container label. This consistency needs to extend to any oral instructions given to the patient at the time of prescribing and dispensing.

Even when the prescription container label utilizes mL as the standard unit of measure and standard notation of decimal amounts in dosing designations, a dosing device with numeric graduations and units that correspond to the container labeling should be made available and its use explained to the patient or caregiver so that the dose can be correctly interpreted and measured. Otherwise, if the patient or caregiver does not understand how to use the measuring device, he or she may resort to the use of the familiar and available household teaspoon or tablespoon. Because the volumes of these household utensils are not standardized, they have proven to be inaccurate and error-prone when used as medication measuring tools. Even sets of kitchen measuring spoons are not designed to accurately deliver oral doses of medications.

6.1. Pharmacy System Software Companies

Pharmacy system software can automate and speed outpatient medication dispensing. Pharmacy system software also can help standardize dosing units of measure and notation of amounts that display and print on container labels, but current software systems may have limitations.

6.1.1 Assessment of Input and Output of Standard Dosing Designations

Pharmacy systems may need to make modifications to Sig or directions components to be able to use mL as the standard unit of measure for oral liquid prescription medications, instead of teaspoon, tablespoon, cc, dram, and others, and to express dose amounts, per the white paper recommendations. For a pharmacy system to output the recommended standardized dosing designations, consideration must be given to the inputs into the pharmacy system. A key first step is to confirm the pharmacy system can accept, and is in fact receiving, dose designation information input as recommended from: drug databases, prescribing system software (particularly in the case of true e-prescribing), directly input data from the user, and other data input sources (e.g. payer claim responses, other interfaces such as eMAR/HL7 data sources.)

Because pharmacy systems also may output data to other systems, the impact of changing pharmacy systems to output recommended standardized dosing designations also should be assessed. For example, some pharmacy software systems may be unable to fully support mixed case character sets in text strings, including drug descriptions and units of measure. These legacy limitations may require all UPPER CASE drug descriptions when displaying information on a computer monitor, printing on prescription labels and in patient education

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materials, and other situations. Furthermore, systems may not be able to programmatically convert internal use of UPPER CASE characters to lower case or mixed case immediately prior to transmitting data to a third party via NCPDP SCRIPT⁶² transactions, continuity of care documentation, or electronic medical records and health information exchange. Typically, systems that have this type of limitation may be able to receive lower case or mixed case text, but once received, these are converted automatically to upper case so that the internal applications can properly process the data, and the data may not be able to be converted back

While lower case “ml” is not optimal or recommended due to the potential confusion between the lower case letter “l” and the number one (“1”) in some printer and display fonts, “ml” still is preferable to the use of teaspoon, tablespoon, cc, dram, liquid ounce, oz, pint, etc. Therefore, although ISMP, USP, this white paper, and others recommend that milliliter be represented in mixed case (i.e., “mL”), some systems currently have no option other than to represent milliliter in upper case, or “ML”, and some may only be able to represent milliliter in all lower case, or “ml”. These limiting situations currently may affect systems’ programmatic testing, error testing, and compliance reporting. However, NCPDP recommends that the pharmacy system industry respond to these challenges by working to resolve these limitations to enable universal use of mL as the standard unit of measure and dosing and move as expeditiously as possible toward explicitly mandating mixed case support in future interface standards.

6.1.2 Enhancing Systems for Standardizing Dosing Designations

After it is confirmed that pharmacy systems can receive standardized dosing designation inputs, it still is likely that not all dosing information will be input as recommended. Appropriate decimal notation for amounts and mL as the unit of measure can be input manually by users by utilizing a “free form Sig” in combination with standard system Sig codes. However, manual data input by pharmacy system users takes more time and requires workflow changes, and asks for 100% compliance by users.

Pharmacy systems can facilitate standardized dosing designations by removing non-standard designations from the “Sig File” and setting default values to standardized dose designations.

Use of the NCPDP Structured and Codified Sig⁶³ within SCRIPT in conjunction with the recommendations in this white paper for standardizing dosing designations for oral liquid medication could further reduce ambiguity of the instructions.

Until widespread adoption of Structured and Codified Sig is achieved, implementation of enhanced pharmacy system logic can help standardize (“edit” or “scrub”) inputs by users.

⁶² The SCRIPT is an NCPDP standard developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities for new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, electronic prior authorization and other transactions.

⁶³ The Structured and Codified Sig Format is intended to facilitate communication between prescribers and pharmacists, improve the efficiency of the prescribing and dispensing activities, and help reduce the opportunity for errors. It provides standardization of the portion of an electronic prescription containing the directions for use, using existing, accepted electronic transmission standards. The structured and codified is available in NCPDP SCRIPT Standard 10.4 and above.

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Enhanced system logic may be designed to automatically express the Sig in desired “mL” units when oral liquids are selected. When a user inputs “.5,” enhanced system logic can ‘auto-correct’ and store/output the data as “0.5”. When a user inputs “ML”, enhanced system logic can ‘auto-correct’ and store/output the data as “mL”.

6.2 Electronic Drug Database Publishers

Pharmacy system software must reference accurate and timely drug databases to safely dispense medications as well as efficiently process medication claims. For claims processing, the NCPDP Billing Unit Standard contains mL as one of three billing units. Use of “mL” is indicated when a product is measured by its liquid volume, including liquid non-injectable products of 1 mL or greater.⁶⁴ For safe and accurate medication dispensing, drug database publishers often offer dosing-related modules, such as structured Sig strings, Sig building tools, and dose screening databases. These dosing-related modules also can be used by payers and pharmacy benefit managers (PBMs) to process drug claims, but when embedded into workflow applications for use by prescribers, pharmacists, nurses, and other healthcare professionals, they can help ensure medications are dispensed in appropriate doses and labeled with appropriate dosing designations.

Drug database modules and tools such as structured Sig strings, Sig builders, and dose screening, should consistently represent liquid volumes in metric units and use the metric designation “mL” as a unit of measure for liquids where appropriate. In 2009, ISMP issued a call to action for healthcare professionals, prescribing software companies, and pharmacy system software companies in an effort to eliminate the use of non-metric measurements, such as “teaspoon” and “tablespoon,” or associated variations like “tsp,” to prevent medication errors in prescription instructions.^{65,66} As supported by ISMP case reports, the disparity between the actual volume measured by using a household teaspoon or tablespoon as well as the possible confusion between the two easily can lead to incorrect dosing, with potentially serious consequences, especially in the pediatric population. In support of the ISMP initiative, drug database publishers reviewed their clinical database offerings to make sure that no non-metric measurements were included and metric units were used in dose screening databases and Sig databases.

Pharmacy system software companies that use drug database publishers’ flat file data in their software are encouraged to adopt “mL” for use in structured Sig strings, just as “mL” is used in Application Programming Interfaces (APIs) units for alert messages. To support the limitations noted in 6.1.1 as well as multiple end-user needs that are beyond the scope of this white paper, the drug database publishers may also offer their customers fields that use all upper case and/or all lower case text strings, in addition to the preferred mixed-case text strings, but should encourage migration as soon as feasible to the preferred mixed-case representation.

⁶⁴ National Council for Prescription Drug Programs, Inc. NCPDP Billing Unit Standard Fact Sheet. Publication July 2013. https://www.ncpdp.org/pdf/BUS_fact_sheet.pdf (accessed January 22, 2014).

⁶⁵ Institute for Safe Medication Practices. A teaspoon of medicine? ISMP Med Saf Alert Com/Amb Care. 2009;8(5):1-2. http://www.ismp.org/Newsletters/ambulatory/archives/200905_1.asp (accessed January 22, 2014).

⁶⁶ Institute for Safe Medication Practices. ISMP calls for elimination of “teaspoonful” and other non-metric measurements to prevent errors. <http://www.ismp.org/pressroom/PR20090603.pdf> (accessed January 22, 2014).

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All drug database publishers should be encouraged to re-review drug databases, modules, and tools for use of the standardized dosing designations for oral liquid medication recommended in this white paper. Pharmacy system software companies that use drug database publishers' flat file data in their software can then adopt "mL" for use in structured Sig strings, just as "mL" is used in Application Programming Interfaces (APIs) units for alert messages. To support the limitations noted in 6.1.1 as well as multiple end-user needs that are beyond the scope of this white paper, the drug database publishers may also offer their customers fields that use all upper case and/or all lower case text strings, in addition to the preferred mixed-case text strings, but should encourage migration as soon as feasible to the preferred mixed-case representation.

6.3 Prescribing Software Companies (including electronic health record (EHR) with prescribing applications)

Electronic transmission of prescriptions from the prescriber to the community pharmacy affords numerous benefits to prescribers, pharmacies, and patients. The goal of e-prescribing is to have an electronic prescription arrive at the pharmacy with complete and clear instructions, eliminating the need for the pharmacy staff to interpret a prescriber's handwritten instructions and prevent transcribing errors. It has been shown to improve quality and safety by decreasing dispensing errors associated with handwritten prescriptions.

Unfortunately, some segments of the industry may not have recognized the benefits, or may not have embraced e-prescribing because of training, implementation, or software issues. To help address some of these concerns, a task group of the NCPDP e-Prescribing & Related Transactions Work Group (WG11), has produced a best practice guide for the SCRIPT standard. The implementation guide is intended for prescribing software companies, physicians, and pharmacists to assist them in the proper use of fields within the SCRIPT standard. The guide includes suggestions on the use of mL as the standard unit of measure (instead of teaspoon) as recommended by the AAP to improve pediatric medication safety.

E-prescribing can provide the additional benefit of encouraging standardized dosing designations at the point of prescribing. By incorporating standard dosing designations (units using mL and amounts using decimals and zeros appropriately), e-prescribing software may be designed so that non-metric and non-volumetric units are never presented to the prescriber in any of the structured selection menus of Sig builders, drug description menus, or quantity qualifiers. In addition, the prescriber technology vendors could even implement natural language processing and clinical decision support modules to alert their users if inappropriate values are selected.

The complete guidance may be viewed in the current ["NCPDP SCRIPT Implementation Recommendations."](#)⁶⁷

⁶⁷ NCPDP SCRIPT Implementation Recommendations,

<http://www.ncdp.org/members/stds-102508/SCRIPT.Implementation.Recommendations.V1.22.pdf>

(accessed December 17, 2013)

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(accessed

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6.4 Pharmacy Leadership

NCPDP encourages community pharmacy leadership to adopt and implement the recommendations of this white paper in their pharmacies. The rationale and research cited in this white paper provide the basis for enhancing patient safety and positive medical outcomes through the use of mL as the standard unit of measure for oral liquid medications.

Nonetheless, NCPDP recognizes that the adoption and implementation of these recommendations pose a number of challenges and opportunities for the community pharmacy in the areas of pharmacy computer systems, workflow, support of pharmacy staff and patient education, and consistency across products and care settings.

6.4.1 Pharmacy System Software

Pharmacy leadership needs to make a commitment to make appropriate programming changes and create policies and procedures that will support these recommendations. There are always challenges to system changes, but such change is possible and the corporate leadership of several pharmacy chains has decided to support the use of the mL, and has started by encouraging their pharmacists to migrate prescription directions from teaspoon and tablespoon to mL units (e.g., 5 mL and 15 mL, respectively, or decimal fractions therein) and to provide appropriately marked (mL) dosing devices with all oral liquid prescription medications.

6.4.2 Workflow

Flagging of prescription receipts and sale procedures are considerations that may require changes in the workflow to allow for dispensing of calibrated dosing devices. Prescription data entry and selection of the proper Sig/direction codes for patient label directions reside in the workflow procedure and should not impede productivity and process efficiency.

6.4.3 Support of Pharmacy Staff and Patient Education

One significant way pharmacy leadership can support this initiative is to inform, educate, and empower pharmacy staff by:

- Establishing policies and procedures that support the recommended dose designations for all oral liquid medications dispensed in pharmacies and convey the preferences or policies to all the staff
- Providing pharmacies with adequate numbers of appropriately calibrated and marked dosing devices for distribution at dispensing of oral liquid prescription medication
- Sharing the expectation that staff should:
 - Provide appropriate dosing devices with oral liquid prescription medication
 - Explain to patients how to use the device to measure oral liquid medication
 - Ensure patients and caregivers understand the use of the device before leaving the pharmacy

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- Providing ready access to this white paper (Web site link or printed copies) or other documentation of the:
 - Three white paper recommendations (See Section 2)
 - Dangers of improper dosing measurement and administration of oral liquid medications, especially in children and infants, and the rationale for the recommendations (See Section 4)
 - NABP endorsement of the use of mL and support of pharmacists exercising professional judgment to select mL as the preferred unit of measure (See Section 5)
 - USP endorsement and support of mL as the standard unit of measure for oral liquid medications (See Appendix A)
 - Other documents and resources from professional, patient safety, and standard setting organizations, and government agencies, consistent with the white paper recommendations (See Appendices A-C)
 - Call to Action for pharmacy staff in this white paper (See Section 7.1, Stakeholder Map)

Pharmacy leaders are encouraged to support pharmacist-patient counseling, communication, and education at point-of-dispensing. Community pharmacies can provide brochures or other patient-centered printed information to patients and caregivers and can emphasize these patient safety measures are being implemented to ensure proper dosing and patient safety.

6.4.4 Consistency Across Care Settings and Products

In the acute care inpatient setting and other healthcare facilities, mL is the standard oral liquid unit of measure and the use of leading zeros and avoidance of trailing zeros in dose designations is a requirement for certification by The Joint Commission. Responding to FDA and industry recommendations, OTC manufacturers are moving to the use of mL for the standard unit of measure and standard notation of decimal amounts on package labels and dosing devices packaged with oral liquid OTC medications.⁶⁸ Implementing the dose designation recommendations in this white paper will harmonize the labeling and administration of oral liquid prescription medications in the community setting with the standards used in inpatient settings and other healthcare settings, as well as the standards used for OTC medications. This standardization should decrease patient, caregiver, and health professional confusion, and therefore improve patient safety.

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

The NCPDP Task Group Call to Action maps out roles for many stakeholders, but particularly relies on local and corporate community pharmacy leadership to:

⁶⁸ Budnitz DS, Lovegrove MC, Rose KO. Adherence to Label and Device Recommendations for Over-the-Counter Pediatric Liquid Medications. *Pediatrics*, online early release, <http://pediatrics.aappublications.org/content/early/2014/01/01/peds.2013-2362> (accessed January 6, 2014).
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- Adopt and implement the recommendations in this white paper
- Communicate these as preferences or policies to all pharmacy staff
- Measure the performance of your organization in achieving these recommendations and stress accountability across your organization adhering to them
- Explore implementation of innovative patient-centered communication and education solutions that target and encourage pharmacist-to-patient conversations and education at point of dispensing
- Facilitate communication by stakeholders outside the community pharmacy system, including prescribers, with a role in patient and healthcare professional education on using standardized dosing designations for prescribed oral liquid medications.

The following [“Stakeholder Map”](#) identifies all the relevant stakeholders, listed alphabetically, who need to play a role in adopting, communicating, adhering, and educating. The map outlines a call to action and identifies some of the associated challenges and opportunities for each stakeholder group.

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7.1 Stakeholder Map: Call to Action, Challenges, and Opportunities

Stakeholder(s)	Call to Action	Challenges and Opportunities
Certification Organizations – Professional and Systems	<ul style="list-style-type: none"> • Incorporate the white paper dose designation recommendations for oral liquid prescription medication into criteria for professional certification • Incorporate the white paper dose designation recommendations for oral liquid prescription medications into updates, inspections, and testing of pharmacy system software, drug databases, and prescribing software 	<ul style="list-style-type: none"> • Provide education for healthcare professionals involved in dispensing medication, prescribing medication, and instructing patients and caregivers to administer medication • Provide education for system developers and designers
Dosing Device Manufacturers	Manufacture calibrated dosing devices for the pharmacy customer that have dose designations as recommended in this white paper	Call for and participate in discussion about the standardization of devices, such as elimination of extraneous markings and leading and trailing zeros

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Stakeholder(s)	Call to Action	Challenges and Opportunities
<p>Electronic Drug Database Publishers</p>	<ul style="list-style-type: none"> • Review drug databases, modules, and tools for use of the standardized dosing designations for oral liquid medication. If not already used, update dosing designations to use mL as the standard unit of measure and to use leading zeros and to avoid the use of trailing zeros for oral liquid prescription medication • Provide electronic referential drug information products using metric units (such as “mL”) in lieu of non-metric units (such as “teaspoon”) • Provide quantity qualifier mappings between proprietary internal codes and NCPDP codes so that technology vendors can send accurate codes in all outbound messages • Encourage technology vendors to only use non-metric and non-generic codes while communicating prescription quantity values • Offer customers fields that use the preferred mixed case text strings rather than only upper case and/or all lower case text strings 	<ul style="list-style-type: none"> • Provide consistency for all healthcare professionals in both inpatient and outpatient practice settings, eliminate confusion, and deliver a safer patient experience • A coordinated effort with pharmacy system software companies is required to overcome any existing challenges with field lengths designated for drug names

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Stakeholder(s)	Call to Action	Challenges and Opportunities
Government Agencies	<ul style="list-style-type: none"> • Incorporate dosing designations that use mL as the standard unit of measure and use leading zeros and avoid the use of trailing zeros for oral liquid prescription medication into standards and guidances • Collaborate with standards setting organizations and device manufacturers to develop standards for dosing devices for oral liquid prescription medications aligned with existing guidelines and guidances for OTC medications 	<ul style="list-style-type: none"> • Provide guidance to healthcare organizations and professionals to support the transition to mL as the standard unit of measure for oral liquid prescription medications • Drive elimination of units of measure that are already in use through a widespread coordinated effort to overcome any existing challenges • Provide a coordinated announcement and/or distribution mechanism that will effectively communicate to all relevant stakeholders
National Association of Boards of Pharmacy and State Boards of Pharmacy	<ul style="list-style-type: none"> • Reiterate supportive stance for the use of mL as the standard unit of measure for oral liquid prescription medications • Find opportunities to incorporate metric recommendations into Model Act • Provide an announcement and/or distribution mechanism that will effectively communicate to the state board of pharmacies and pharmacists 	

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Stakeholder(s)	Call to Action	Challenges and Opportunities
<p>Pharmacists and Pharmacy Technicians</p>	<ul style="list-style-type: none"> • Use professional judgment to determine the most appropriate units of measure, and most appropriate notation of decimal amounts to include in the dose designation of the prescription container label of oral liquid medications to facilitate accurate dosing • Use mL as the standard unit of measure whenever possible on prescription container labels. Avoid other abbreviations (cc, ml, ML) and the spelled-out term millimeters <ul style="list-style-type: none"> ○ When the prescription Sig contains dosing designations in mL, mL dosing instructions should be used on the prescription container label ○ When the prescription Sig contains dosing instructions in non-volumetric units (e.g., mg) or non-standard volumetric units (e.g., dropperful), convert the dosing instructions to mL, and use mL dosing instructions on the prescription container label • Always use leading zeros before a decimal point, and never use trailing zeros after a decimal point on prescription container labels for oral liquid medications <ul style="list-style-type: none"> ○ Do not use trailing zeros in the hundredths, or thousandths position (e.g., “2.5” mL not “2.50” mL or “2.500” mL) ○ Place adequate space between the dose and unit of measure (e.g., “10 mL” NOT “10mL”) 	<ul style="list-style-type: none"> • Communicating with healthcare professionals and educating and counseling patients and caregivers takes additional time • Seek synergies and innovative solutions to improve patient education and communication at point-of-dispensing through collaboration with pharmacy system as well as other stakeholders • Periodically perform quality control checks by observing processes in the pharmacy to ensure adherence to the standardized work practices

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Stakeholder(s)	Call to Action	Challenges and Opportunities
	<ul style="list-style-type: none"> • When dispensing an oral liquid medication, include a dosing device with numeric graduations and units that correspond to the container labeling, or tell patients or caregivers where an appropriate device can be obtained. • Ensure verbal patient counseling, communication and education at point-of-dispensing that use dosing designations that are consistent with the prescription container label and the dosing device • Educate patients or caregivers on how to use dosing devices correctly and ensure they have access to an appropriate dosing device before they leave the pharmacy • Educate other pharmacy staff regarding importance of using mL as the unit of measurement for all oral liquid medications 	

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Stakeholder(s)	Call to Action	Challenges and Opportunities
<p>Pharmacy Leadership - Local and Corporate</p>	<ul style="list-style-type: none"> • Commit to adopting and implementing dose designations recommendations for prescription container labels for oral liquid medications dispensed from their pharmacies <ul style="list-style-type: none"> ○ Make appropriate computer system programming changes that will support the dose designation recommendations ○ Make required changes in the workflow to allow for dispensing of calibrated dosing devices ○ Establish policies and procedures that support the recommended dose designations for all oral liquid medications dispensed in pharmacy ○ Convey the preferences or policies to all the staff ○ Provide pharmacies with adequate numbers of dosing devices that correspond with numeric graduations and dose designations on container labels for distribution at the dispensing of oral liquids ○ Share expectations with staff that they should distribute dosing devices with oral liquid prescription medication, explain to customers how to use the device, and ensure customers understand the use of the device before leaving the pharmacy • Inform pharmacy staff where they can access this white paper readily (Web site or printed copies) or other documentation of the white paper's recommendations and the rationale for them; the 	<ul style="list-style-type: none"> • Seek synergies and innovative solutions to improve patient education and communication at point-of-dispensing through collaboration with both pharmacy systems, as well as other stakeholders (such as local prescribers) • Test and update pharmacy system software to ensure it incorporates the recommendations in this white paper • Educate staff regarding the importance of standardizing to use of mL as the unit of measure, the use of leading zeros, and the avoidance of trailing zeros for oral liquid prescription medications • Periodically perform quality control checks by observing processes in the pharmacy to ensure adherence to the standardized work practices

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Stakeholder(s)	Call to Action	Challenges and Opportunities
	<p>dangers of improper dosing; the NABP endorsement and support of pharmacists exercising professional judgment in selecting mL as the preferred unit of measure; USP's endorsement and support; other documentation and resources from professional, patient safety and standards setting organizations, and from government agencies, that are consistent with the white paper recommendations; and this white paper's call to action for pharmacy staff</p> <ul style="list-style-type: none"> • Collaborate with pharmacy system software companies to incorporate the recommended labeling changes • Optimize pharmacist-patient counseling, communication and education at point-of-dispensing 	

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Stakeholder(s)	Call to Action	Challenges and Opportunities
Pharmacy System Software Companies	<ul style="list-style-type: none"> • Eliminate “teaspoon” and other non-metric volumetric units of measure from data files for all oral liquid medications • Modify the Sig or directions components of the systems program to be able to use mL as the standard unit of measure for oral liquid medication instead of teaspoon or other non-metric measures and to express dose amounts per the white paper recommendations <ul style="list-style-type: none"> ○ Use free text Sig in combination with standard system Sig codes ○ Automate the change as a system default in the “Sig file” • Assure that mnemonics, Sig codes, or any defaults used in computer systems to generate prescriptions and prescription labels produce directions using mL • Use “mL” in any alert messages, just as the drug database publishers Application Programing Interfaces (APIs) use “mL” units for alert messages • Address legacy limitations to representing milliliter in mixed case (mL) to enable universal use of mL as the standard unit of measure 	<ul style="list-style-type: none"> • Eliminate “teaspoon” and other non-metric volumetric units of measure from data files for all oral liquid medications • Collaborate with drug database publishers on the timing of system change for the elimination of non-metric measures for liquid oral medications • Test and update pharmacy system software to ensure it incorporates the recommendations in this white paper

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Stakeholder(s)	Call to Action	Challenges and Opportunities
<p>Prescribing Software Companies (including EHR with prescribing applications)</p>	<ul style="list-style-type: none"> • Provide default dosing designations that use mL, use leading zeros, and avoid use of trailing zeros in prescribing software • Use “mL” in dosing-related modules (such as structured Sig strings, Sig building tools, and dose screening databases) that can be embedded into workflow applications and e-prescribing whenever appropriate • Develop documentation for end users on creation of basic and complex e-prescription messages and provide training to users • Work with certification organizations to incorporate the white paper recommendations in the testing criteria • Incorporate Best Practices from the NCPDP SCRIPT Implementation Recommendations 	<p>Communicate this white paper’s recommendations to all prescribers that use your prescribing software, emphasizing the patient safety benefits</p>

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Stakeholder(s)	Call to Action	Challenges and Opportunities
Professional Organizations and Trade Associations	Incorporate or reiterate supportive stance on the white paper dose designation recommendations for oral liquid prescription medications into policy statements or statements of professional standards	<ul style="list-style-type: none"> • Provide an announcement and/or distribution mechanism that would effectively communicate to all members • Obtain organizational consensus to publish support and advocate for the elimination of non-metric volumetric units of measure and adoption of the use of mL as the default unit of measure for oral liquid medications
Standards Setting Organizations	Incorporate or reiterate supportive stance on the white paper dose designation recommendations for oral liquid prescription medications	<ul style="list-style-type: none"> • Provide an announcement and/or distribution strategy to effectively communicate to healthcare organizations and professionals • Provide guidance to healthcare organizations and professionals to support the transition to the use of mL as the standard unit of measure for oral liquid medications, the use of leading zeros, and the avoidance of the use of trailing zeros

8. Conclusions

Although metric units (e.g., mg for milligrams) have been the standard unit of measure for solid dose form medications for decades, oral liquid medications continue to be prescribed, transcribed, dispensed, measured, and administered using a variety of volumetric units, which continues to lead to confusion, dosing errors and overdosing or underdosing by healthcare professionals, patients, and caregivers. Standard dosing designations used consistently on prescriptions and container labels of oral liquid medications, as well as on the dosing devices used to measure and administer them, could help improve patient safety and patient outcomes.

The adoption of this white paper's recommendations will harmonize the transcription, labeling, dispensing, measuring, and administration of oral liquid prescription medications in the community setting with standards used in hospital and other healthcare facilities, recommendations for OTC medications, and international standards of volumetric measurement. In addition, many professional and safety organizations already promote recommendations that align with the dose designation recommendations in this white paper.

The NCPDP mL Task Group Call to Action is directed first and foremost to the local and corporate pharmacy leadership, as they can catalyze many of the changes required to implement the best practices described in this white paper.

NCPDP recognizes there are challenges for pharmacy leadership to adopt and implement the recommendations, as well as for many of the other stakeholders.

A concerted effort of all stakeholders is necessary to realize the opportunities and meet and overcome the challenges, and NCPDP calls upon all the relevant stakeholders to support efforts to adopt, implement, and adhere to the recommendations in this white paper, and to educate of healthcare professionals, patients, and caregivers on how to accurately measure and administer oral liquid medications.

All stakeholders are encouraged to consider the recommendations and call to action of this white paper and to collaborate to achieve standardized dosing designations for prescription container labels of oral liquid medications dispensed from community pharmacies.

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10. Appendices

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10.1 Appendix A: Documents and Resources Consistent with the White Paper Recommendation on the Use of Milliliter (mL)

Organization	
<p>Academic Pediatric Association (APA)</p>	<p>APA Focus Volume 48, Issue 6 (December 2011). http://www.ambpeds.org/publications/newsletters/2011/newsDec2011.pdf</p> <p>APA Board Vote “to support and advocate for mL as the preferred unit for measurement of liquid medications.”</p>
<p>American Academy of Family Physicians (AAFP)</p>	<p>AAFP Policy - Preferred Unit of Measurement for Liquid Medications (September 21, 2011). http://www.aafp.org/about/policies/all/preferred-unit.html</p> <p>“The AAFP supports a standardized approach for the use of milliliters (mL) as the preferred unit of measurement for liquid medications, in order to prevent unintended medication overdoses in children. (Board Chair 1:1)”</p>
<p>American Academy of Pediatrics (AAP)</p>	<p>AAP Policy Statement - Electronic Prescribing in Pediatrics: Toward Safer and More Effective Medication Management, <i>Pediatrics</i> 2013;131:824–826, April 1, 2013. http://pediatrics.aappublications.org/content/131/4/824.full.pdf</p> <p>“Because safety for children is paramount, e-prescribing systems used for the care of children should include...metric-only labeling instructions...”</p> <p>Article in AAP News – Antidote for Medication Overdoses: Use Metric Dosing, Educate Parents, AAP News Vol. 34 No. 12 December 1, 2013; pp. 4. http://aapnews.aappublications.org/content/34/12/4.full</p> <p>“Pediatricians are encouraged to use and discuss mL-based dosing when prescribing liquid medications, and to avoid dosing in teaspoons or tablespoons.”</p> <p>Article in AAP News – Out with Teaspoons, in with Metric Units: Pediatricians urged to prescribe liquid medications in mLs only, AAP News Vol. 33 No. 3 March 1, 2012; pp. 10. http://aapnews.aappublications.org/content/33/3/10.full</p> <p>“Pediatricians are encouraged to help prevent unintentional medication overdoses by eliminating the practice of prescribing medications with volumes in teaspoons and tablespoons. Instead, metric-based dosing using milliliters (mLs) for all liquid medicine prescriptions is preferred...”</p>
<p>American Association of Poison Control Centers (AAPCC)</p>	<p>AAPCC Resolution - Standardizing Volumetric Measures for Oral Medications Intended for Use by Children (2010). “We encourage member poison centers, to the extent feasible, to join in educating the public about the value and importance of... measuring</p>

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	liquid medications using mL rather than other measuring units.”
American Medical Association (AMA)	<p>AMA Policy H-120.968 Medication (Drug) Errors in Hospitals http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-120.968.HTM “(1) Our AMA encourages individual physicians to minimize medication errors by adhering to the following guidelines when prescribing medications:... (g) Medication orders should be clear and unambiguous. Physicians should: ... (viii) and use the metric system.”</p>
American Pharmacists Association (APhA)	<p>APhA - Email Interview (October 18, 2013). “APhA supports the following National Coordinating Council for Medication Error Reporting and Prevention recommendation: “...all prescription orders be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. Units should be spelled out rather than writing “U.” The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts.”</p>
American Society of Health-System Pharmacists (ASHP)	<p>ASHP Statement Endorsing Use of Metric System for Prescriptions Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention. Medication Misadventures—Endorsed Document (1999. Reviewed and re-endorsed in 2005). http://www.ashp.org/DocLibrary/BestPractices/MedMisEndNCCMERP.aspx “All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc....The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts.”</p> <p>Many decades earlier, ASHP and other practice organizations (e.g., American Health Care Association (AHCA), American Pharmacists Association (APhA)) began recommending the use of metric units and metrically marked dosing devices for the measurement and administration of oral liquid medications.^{69,70,71,72}</p>

⁶⁹ American Society of Hospital Pharmacists. Guidelines for single unit packages of drugs. Approved by the ASHP Board of Directors December 2, 1966. Am J Hosp Pharm. 1971; 28:110-2.

⁷⁰ American Health Care Association, American Pharmaceutical Association, and American Society of Hospital Pharmacists. Pharmaceutical services in the long-term care facility. 7th edition, second printing. Washington, DC: 1975.

⁷¹ Barker KN, Heller WM. The development of a centralized unit-dose dispensing system for UMAC. Part III: An editing center for physicians' medication orders. Am J Hosp Pharm. 1964; 21:66-7.

⁷² Hynniman CE, Conrad WF, Urch WA, Parker PF. A comparison of errors under the University of Kentucky unit dose system and traditional drug distribution systems in four hospitals. Am J Hosp Pharm. 1970; 27:802-14.

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<p style="text-align: center;">Consumer Healthcare Products Association (CHPA)</p>	<p>CHPA Guideline - Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age (Adopted November 17, 2009). http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx “2. Use milliliter as the preferred unit of measure in the dosing directions...4. Use the following abbreviation and text exactly: a. Abbreviations: “mL”; Full text: “teaspoonful”...Avoid use within labeling dosing directions of the following: tablespoon, cubic centimeters, cc, dram, fluid ounce, Fl. Oz., and dropper(ful).”</p>
<p style="text-align: center;">Food and Drug Administration (FDA)</p>	<p>DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) April 2013; Page 10 – Metric Measurements. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf “The dose or expression of strength should appear in metric units of measure such as mL, mg, and mcg, rather than apothecary or household measurements (e.g., tsp for teaspoon, TBSP for tablespoon, drams, and grains) or ratios (e.g., 1:1000). Fatal errors have occurred when healthcare providers or patients miscalculated medication doses when converting from one unit of measure to another...”</p>
<p style="text-align: center;">Institute for Safe Medication Practices (ISMP)</p>	<p>ISMP Statement - Use of Metric Measurement to Prevent Errors with Oral Liquids (October 2011). http://www.ismp.org/pressroom/PR20110808.pdf “The Institute for Safe Medication Practices (ISMP) is asking prescribers, pharmacists, and other healthcare professionals, as well as pharmacy computer system and e-prescribing system vendors, to only use metric measurements in prescription directions. ISMP has taken this step after careful deliberation, in order to better protect patients from harmful errors and give providers a greater level of comfort and confidence when calculating and administering doses of medication... ISMP first reported on the confusion of teaspoonfuls and mL in its newsletter in 2000, and in 2009 issued a call for practitioners to move to sole use of the metric system for measuring over-the counter (OTC) and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults.... ISMP has received more than 50 reports of mL-teaspoonful errors alone, including cases where injuries required treatment or hospitalization.” “Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and</p>

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	<p>pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.”</p> <p>“Express doses for oral liquids using only metric weight or volume (e.g., mg or mL)—not household measures such as teaspoonfuls or tablespoonfuls, which are not an accurate volume of measure.”</p>
<p style="text-align: center;">National Association of Boards of Pharmacy (NABP)</p>	<p>NABP Model Act - Model Rules for the Practice of Pharmacy. Section 3 Pharmacy Practice, page 84 (August 2013). http://www.nabp.net/publications/model-act/</p> <p>“All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirements....The label...shall include...the strength and volume, where appropriate, expressed in the metric system whenever possible”...</p> <p>“All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall contain a label affixed to the container in which such Drug is Dispensed including...drug strength, expressed in the metric system whenever possible”...</p>
<p style="text-align: center;">National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)</p>	<p>Recommendations to Enhance Accuracy of Prescription Writing (Adopted by NCCMERP 1996, Revised 2005). http://www.nccmerp.org/council/council1996-09-04.html</p> <p>“All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. ...The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts.”</p> <p>NCCMERP is an independent body comprised of 27 national organizations: AARP, AHA, AMA, ANA, APhA, ASHP, FDA, GPhA, TJC, NABP, NCSBN, PhRMA, USP, AAPA, AGS, ASHRM, ASCP, ASMSO, APSF, DOD, DVA, IHI, ISMP, NASPA, NCPIE, NPSF, SHM. http://www.nccmerp.org/leadershipMemberOrgs.html.</p> <p>Actions/Decisions are those of the Council as a whole and may not reflect the views/positions of individual member organizations.</p>
<p style="text-align: center;">United States Pharmacopeial Convention (USP)</p>	<p>General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 9 – Prescribing and Dispensing, from USP 36 – NF 31 (Edition May 1, 2013). http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gn_usp36.pdf</p> <p>“9.10 Use of Metric Units. Prescriptions for compendial articles shall be written to state the quantity and/or strength desired in metric units unless</p>

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	otherwise indicated in the individual monograph...If an amount is prescribed by any other system of measurement, only an amount that is the metric equivalent of the prescribed amount shall be dispensed. Apothecary unit designations on labels and labeling shall not be used.”
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10.2 Appendix B: Documents and Resources Consistent with the White Paper Recommendation on the Use of Leading Zeros and Avoidance of Trailing Zeros

Organization	
<p>American Congress of Obstetricians and Gynecologists (ACOG)</p>	<p>Improving Medication Safety. Committee Opinion No. 531. American Congress of Obstetricians and Gynecologists, <i>Obstet Gynecol</i> 2012;120:406-10 (August 2012). http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Patient_Safety_and_Quality_Improvement/Improving Medications Safety</p> <p>One element of safely writing medication orders relates to the use of zeros and decimal points. The misuse of leading decimals and trailing zeros can be dangerous. The adage "always lead, never follow" can help mitigate errors, which can lead to 10-fold or 100-fold dosage errors (e.g., always write 0.1, never write 1.0).</p>
<p>American Medical Association (AMA)</p>	<p>AMA Policy H-120.968 Medication (Drug) Errors in Hospitals http://www.ama-assn.org/resources/doc/PolicyFinder/policyfiles/HnE/H-120.968.HTM</p> <p>"(1) Our AMA encourages individual physicians to minimize medication errors by adhering to the following guidelines when prescribing medications:...(g) Medication orders should be clear and unambiguous. Physicians should: ...(v) always use a leading "0" to precede a decimal expression of less than one (e.g., 0.5 ml), but never use a terminal "0" (e.g., 5.0 ml); (vi) avoid the use of decimals when possible (e.g., prescribe 500 mg instead of 0.5 g)..."</p>
<p>American Pharmacists Association (APhA)</p>	<p>APhA - Email Interview (October 18, 2013).</p> <p>"APhA supports the following National Coordinating Council for Medication Error Reporting and Prevention recommendation: ...a leading zero always precedes a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal. Ten-fold errors in drug strength and dosage have occurred with decimals due to the use of a trailing zero or the absence of a leading zero."</p>
<p>American Society of Health-System Pharmacists (ASHP)</p>	<p>ASHP Guidelines on Preventing Medication Errors in Hospitals American Journal of Hospital Pharmacy 1993;50 (2):305-314 (1993). http://www.ashp.org/DocLibrary/BestPractices/MedMisGdlHosp.aspx</p> <p>"5 e. Always use a leading zero before a decimal expression of less than one (e.g., 0.5 mL). Conversely, a terminal zero should never be used (e.g., 5.0 mL), since failure to see the decimal could result in a 10-fold overdose. When possible, avoid the use of decimals (e.g., prescribe 500 mg instead of 0.5 g)."</p>

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	<p>ASHP Endorsed Document: Recommendations from the National Coordinating Council for Medication Error Reporting and Prevention - Recommendations to Correct Error-Prone Aspects of Prescription Writing (Adopted by NCCMERP 1996, revised 2005). http://www.ashp.org/DocLibrary/BestPractices/MedMisEndNCCMERP.aspx "Endorsed by ASHP Board of Directors, 1999. Endorsement reviewed by ASHP and found to still be appropriate, 2005." Please also see NCCMERP entry below.</p>
<p>Consumer Healthcare Products Association (CHPA)</p>	<p>Guideline Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age (Adopted November 17, 2009). http://www.chpa.org/VoluntaryCodes_VolumetricMeasurePediatricLiquid.s.aspx "6. Use a format and style for expressing fractions that is consistent with the type of measure unit. For metric units, use a decimal; if <1 mL volume, use decimal with a leading zero (e.g., 0.5)."</p>
<p>Food and Drug Administration (FDA)</p>	<p>FDA Guidance to Industry, Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products, Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) Final as of May 2011. Page 4 – Recommendations. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf "Any decimals or fractions included on dosage delivery devices should be listed as clearly as possible. <ul style="list-style-type: none"> • Use leading zeroes before decimal points ("0.4" not ".4") to help avoid IO-fold dosing errors." DRAFT FDA Guidance for Industry – Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, Draft Guidance issued by US HHS FDA Center for Drug Evaluation and Research (CDER) (April 2013). Page 12 – Leading and Terminal Zeros, Decimals, and Commas. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm349009.pdf "9. <i>Leading and Terminal Zeros, Decimals, and Commas</i> Numbers containing decimal points in the declaration of strength can lead to tenfold dosing errors when the decimal point goes unseen (e.g., 4.0 mg is seen as 40 mg, or .4 mg is read as 4 mg). To minimize such errors, the quantity of active ingredient in the statement of strength should be presented in whole numbers, and not with a decimal point that is followed by a terminal zero (e.g., 4 mg, not 4.0 mg). Conversely, decimal</p>

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	<p>numbers smaller than one should always be preceded by a zero (e.g., 0.4 mg, not .4 mg). This serves to enhance the visibility of the decimal point.”</p> <p>See also: FDA/ISMP Campaign to Eliminate Use of Error Prone Abbreviations on Medical Errors page http://www.fda.gov/drugs/drugsafety/medicationerrors/default.htm</p>
<p>Institute for Safe Medication Practices (ISMP)</p>	<p>ISMP’s List of Error Prone Abbreviations, Symbols, and Dose Designations http://www.ismp.org/tools/errorproneabbreviations.pdf</p> <p>“Trailing zero after decimal point (e.g., 1.0 mg) – Intended meaning 1 mg, mistaken as 10 mg if the decimal point is not seen – Correction: Do not use trailing zeroes for doses expressed in whole numbers”</p> <p>“Naked” decimal point (e.g., .5mg) – Intended meaning 0.5 mg, mistaken as 5 mg if the decimal point is not seen – Correction: Use zero before a decimal point when the dose is less than a whole unit”</p> <p>Principles Of Designing A Medication Label For Community And Mail Order Pharmacy Prescription Packages (2010). http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp</p> <p>“Avoid the use of all potentially dangerous abbreviations and dose expressions (see www.ismp.org/Tools/errorproneabbreviations.pdf) including the following:</p> <ul style="list-style-type: none"> i. Do not use trailing zeros (e.g., 5 mg, never 5.0 mg). ii. Use leading zeros for doses less than a whole number (e.g., 0.3 mg, never .3 mg)” <p>See also: ISMP and FDA Campaign to Eliminate Use of Error-Prone Abbreviations http://www.ismp.org/tools/abbreviations/</p>
<p>Joint Commission (TJC)</p>	<p>Joint Commission “Do Not Use” Abbreviations (2004). http://www.jointcommission.org/assets/1/18/Official_Do_Not_Use_List_6_111.PDF http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf</p> <p>“On Official “Do Not Use” list: Applies to all orders and all medication-related documentation that is handwritten (including free-text computer entry) or on pre-printed forms.</p> <p>Do Not Use: Trailing zero (X.0 mg)* Problem: Decimal point is missed Use instead: Write X mg</p> <p>Do Not Use: Lack of leading zero (.X mg) Problem: Decimal point is missed Use instead: Write 0.X mg”</p>
<p>National</p>	<p>Recommendations to Enhance Accuracy of Prescription Writing (Adopted by NCCMERP 1996, Revised 2005).</p>

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<p>Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)</p>	<p>http://www.nccmerp.org/council/council1996-09-04.html The Council recommends:</p> <p>“6....a leading zero always precede a decimal expression of less than one. A terminal or trailing zero should never be used after a decimal. Ten-fold errors in drug strength and dosage have occurred with decimals due to the use of a trailing zero or the absence of a leading zero.”</p> <p>NCCMERP is an independent body comprised of 27 national organizations: AARP, AHA, AMA, ANA, APhA, ASHP, FDA, GPhA, TJC, NABP, NCSBN, PhRMA, USP, AAPA, AGS, ASHRM, ASCP, ASMSO, APSF, DOD, DVA, IHI, ISMP, NASPA, NCPIE, NPSF, SHM. http://www.nccmerp.org/leadershipMemberOrgs.html.</p> <p>Actions/Decisions are those of the Council as a whole and may not reflect the views/positions of individual member organizations.</p>
<p>Pediatric Pharmacy Advocacy Group (PPAG) and ISMP</p>	<p>Guidelines for Preventing Medication Errors in Pediatrics <i>J Pediatr Pharmacol Ther</i> 2001; 6:426-42. http://www.ppag.org/attachments/files/111/Guidelines_Peds.pdf</p> <p>“Recommendations for Prescribers A leading zero should always precede decimal expressions less than one (i.e., 0.1 mg), but a trailing zero should never follow a whole number (i.e., 1.0 mg).</p> <p>Computerized Order Entry System Recommendations All decimal expressions less than one whole unit should be preceded by a leading zero (i.e., 0.1 not .1) and whole numbers should not be followed by a trailing zero (1 mg not 1.0 mg).</p> <p>Training for all healthcare professionals should ... address what not to incorporate in a prescription (e.g., certain dangerous abbreviations, leading and trailing zeros).”</p>
<p>United States Pharmacopeial Convention (USP)</p>	<p>General Notices and Requirements, Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 10 - Preservation, Packaging, Storage, and Nomenclature, from USP 36 – NF 31 (edition May 1, 2013). http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/gn_usp36.pdf</p> <p>“10.40.20. Use of Leading and Terminal Zeros. To help minimize the possibility of errors in the dispensing and administration of drugs, the quantity of active ingredient when expressed in whole numbers shall be shown without a decimal point that is followed by a terminal zero (e.g., express as 4 mg [not 4.0 mg]). The quantity of active ingredient when expressed as a decimal number smaller than 1 shall be shown with a zero preceding the decimal point (e.g., express as 0.2 mg [not .2 mg]).”</p>

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<p>World Health Organization (WHO)</p>	<p>Drug and Therapeutics Committees – A Practice Guide (2003). 5.2 Monitoring and Addressing Medication Errors http://apps.who.int/medicinedocs/en/d/Js4882e/7.2.html#Js4882e.7.2</p> <p>“Some ways of preventing medication errors, particularly in hospitals, include...use of leading zeros for values less than 1 (0.2 instead of .2) and avoidance of trailing zeros for values more than 1 (2 instead of 2.0).”</p>
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10.3 Appendix C: Documents and Resources Consistent with the White Paper Recommendation on the Use of Dosing Devices for Oral Liquid Medicines

Organization	
<p>American Academy of Pediatrics (AAP)</p>	<p>AAP Policy Statement - Inaccuracies in Administering Liquid Medication Yafe SJ, et al. <i>Pediatrics</i>. 1975; 56: 327-328.</p> <p>“The Committee on Drugs recommends that all physicians advise their community pharmacies to obtain and stock appropriate liquid administration devices, and insist on the use of such devices when prescribing liquid medications.”</p> <p>Article in AAP News – Antidote for Medication Overdoses: Use Metric Dosing, Educate Parents, AAP News Vol. 34 No. 12 December 1, 2013; pp. 4.</p> <p>http://aapnews.aappublications.org/content/34/12/4.full</p> <p>“Additional steps that pediatric health providers can take to help reduce parent dosing errors and support PROTECT Initiative recommendations include: ...parents a dosing device, such as an oral syringe, when prescribing a liquid medication.”</p> <p>Article in AAP News – Out with Teaspoons, in with Metric Units: Pediatricians urged to prescribe liquid medications in mLs only, AAP News Vol. 33 No. 3 March 1, 2012; pp. 10.</p> <p>http://aapnews.aappublications.org/content/33/3/10.full</p> <p>“Pediatricians should advocate for the use of oral syringes to prevent unintentional medication overdoses. Studies have shown that syringes are used more accurately than dosing cups.”</p> <p>“Unfortunately, household spoons are still commonly used to administer liquid medications. Therefore, pediatricians should cease prescribing liquid medications to children using teaspoon or tablespoon volumes and advocate for the use of oral syringes.”</p>
<p>American Association of Poison Control Centers (AAPCC)</p>	<p>Resolution Passed by AAPCC (2010).</p> <p>“1. We encourage member poison centers, to the extent feasible, to join in educating the public about the value and importance of a) measuring medication using product-specific measuring devices when these are available and using precise measuring spoons when a product-specific device is not available...”</p>
<p>Consumer Healthcare Products Association (CHPA)</p>	<p>Guideline Volumetric Measures for Dosing of Over-the-Counter Oral Liquid Drug Products for Children ≤ 12 years of Age (Adopted November 17, 2009).</p> <p>http://www.chpa.org/voluntarycodes_volumetricmeasurepediatricliquids.aspx</p>

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	<p>“4.2 Dosing Device Accompanying the Product A1. Provide a calibrated dosing device with all products”</p>
<p>Food and Drug Administration (FDA)</p>	<p>Guidance for Industry – Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products (May 2011). http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm188992.pdf</p> <p>“Dosage delivery devices should be included for all orally ingested OTC liquid drug products. If units of liquid measure are abbreviated on the dosage device, the abbreviation used on the device should be the same abbreviation used in the labeled dosage directions, outside packaging (carton labeling), bottle, and any accompanying written instructions.”</p>
<p>Institute for Safe Medication Practices (ISMP)</p>	<p>2014-2015 Targeted Medication Safety Best Practices for Hospitals (2014). http://www.ismp.org/Tools/BestPractices/default.asp</p> <p>“Best Practice 5: Purchase oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale.</p> <p>Oral liquid dosing devices that only display the metric scale should be used. In addition, if patients are taking an oral liquid medication after discharge, supply them with (or provide a prescription for) oral syringes, to enable them to measure oral liquid volumes in mL”.</p> <p>Statement on Use of Metric Measurement to Prevent Errors with Oral Liquids (October 2011). http://www.ismp.org/pressroom/PR20110808.pdf</p> <p>“ISMP recommends the following actions to help prevent errors:</p> <ul style="list-style-type: none"> • Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters. • Coach patients on how to use and clean measuring devices; use the ‘teach back’ approach, and ask patients or caregivers to demonstrate their understanding.”

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10.4 Appendix D: Contributors to this White Paper

Note: The organizations listed below should not be considered endorsers of this White Paper.

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