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**USP Patient Safety CAPSLink™**

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**USP Patient Safety CAPSLink™**

This message has been sent to you as a service of the U.S. Pharmacopeia, Center for the Advancement of Patient Safety (CAPS). USP is a not-for-profit, non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. CAPS is a component of USP's Patient Safety public health program. The USP Center for the Advancement of Patient Safety was created to encourage medication error reporting, conduct data analysis and research, develop educational programs, and propose standards, recommendations, and guidelines that ultimately improve the safety and quality of patient care.

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**Examining Medication Errors in Emergency Departments**

Emergency departments in U.S. hospitals have to a great extent become our nation's front door for patient access to health care by providing unscheduled care for a wide variety of people. The levels of care range from life-threatening

conditions to problems that could be more appropriately treated in a primary care setting. The 2007 National Hospital Ambulatory Medical Care Summary (NHAMCS) that examined 2005 emergency department data estimated that approximately 115 million patients are seen annually in emergency departments (EDs) in the United States, which equates to 39.6 visits per 100 persons or an average of 219 ED visits every minute.<sup>1</sup> Nationwide, ED visits increased by 20 % between 1995-2005, while the number of actual emergency rooms across the country decreased by 14%.<sup>1</sup> The report also documented that approximately 12% of all ED visits resulted in a hospital admission; in addition procedures were performed during 47.3% of all visits, and medications were prescribed at 76.7% of ED visits.<sup>1</sup> Increasingly, EDs are coming under great scrutiny with pressure to provide care for more patients, resulting in severe crowding and frequent ambulance diversions to other facilities. With the volume of ED visits increasing, patient waiting times are certain to increase, which in the long term could negatively impact the quality of care provided.<sup>2</sup> Although in any given year most people do not use an ED, some subgroups, such as the elderly and the poor, have higher utilization rates than others, as evidenced in a study published in the *Annals of Emergency Medicine* in 2007, which documented a 34% increase in ED visits for patients between the ages of 65 and 74 for the period 1993-2003.<sup>3</sup> If this current trend continues, ED visits for this older age group will more than double by 2013.<sup>3</sup>

### **Medication Issues in the Emergency Department**

It is estimated that 5% of all patients seen in an emergency department experience an adverse event, with 70% of those being preventable.<sup>4, 5</sup> The 2005 NHAMCS emergency department summary also documented that medications were provided, prescribed, or continued in 76.7% of ED visits, resulting in 204.9 million drug mentions.<sup>1</sup> There was an average of approximately 2.0 drug documentations per ED visit. For visits with at least one drug documentation, the average was 2.5 drugs prescribed, administered or dispensed per visit and three or more drugs were provided, prescribed, or continued at 29.3% of visits.<sup>1</sup> The leading therapeutic drug subclasses prescribed were narcotic analgesics, nonsteroidal anti-inflammatory drugs and non-narcotic analgesics. The generic drugs most often given in the ED were ibuprofen, promethazine, and ketorolac and most often prescribed or dispensed at ED discharge were ibuprofen, acetaminophen and hydrocodone, and acetaminophen alone.<sup>1</sup> Narcotic drugs represented approximately one-half of all pain relievers prescribed; however, this varied by both patient age and ethnicity.<sup>6</sup> Medication management in the emergency department remains a serious challenge with numerous opportunities for well-defined patient safety improvement initiatives focused on the goal of preventing harmful medication errors and adverse events.

### **MEDMARX Data for Medication Errors Over Five Years in EDs**

During the period from January 1, 2002 through December 31, 2006, a total of 29,801 medication errors associated with emergency departments were reported

to USP's MEDMARX<sup>®</sup> program. 34% of the errors were intercepted before reaching the patient (Category B, Table 1) which is lower than the historical MEDMARX average of (40.4%) for the same reporting period. Conversely, a larger percentage (49.9%) of the errors did reach the patient (Categories C and D) and a larger percentage (3.0 %) resulted in harm or death (Categories E-I). This proportion of harm is greater than twice the percentage of harm seen for all errors reported to MEDMARX for the corresponding reporting period (1.4%). This suggests that errors involving medications prescribed, administered and dispensed in emergency departments are more likely to result in patient harm as compared to medication errors in general and, thus, medication use processes in the ED should be closely monitored and managed to reduce and prevent harmful errors.

**Table 1: Severity of Errors in the Emergency Department**

Error Category <sup>a</sup>	n	% <sup>b</sup>
<b>Potential Errors</b>		
A	3,860	13.0
<b>Intercepted Errors</b>		
B	10,164	34.1
<b>Nonharmful Errors</b>		
C	11,647	39.1
D	3,230	10.8
<b>Harmful / Fatal Errors</b>		
E-I	900	3.0
<b>Total</b>	<b>29,801</b>	

a. For complete definition of error categories see <http://www.nccmerp.org/>

b. Based on 29,801 records reported to MEDMARX during the period 01/02-12/06.

### **Origination Node (Phase)**

A majority of the errors associated with emergency departments occurred during the administering node (phase) of the medication-use process (39.7%). This is approximately 10% higher than the MEDMARX (30.2%) historical data for the same reporting period. Following the administering node were prescribing (30.7%), transcribing and documenting (19%), and dispensing (9.3%). Errors originating during monitoring activities made up 1% of the total, while those occurring during drug procurement totaled less than 1%. These data suggest that the administration and prescribing of medications in emergency departments present a rich opportunity for focused improvement strategies.

### **Products Involved**

The product group most associated with emergency department errors was heparin which included heparin, heparin sodium in dextrose and heparin sodium in sodium chloride (Table 2). These three products combined accounted for almost 4% of all reported errors. Closely behind in frequency were acetaminophen and insulin at 2.9%. Drug product errors documented in

emergency departments that caused patient harm included heparin (n=51, 6.0%) hydromorphone (n=27, 3.2%), and diltiazem (n=25, 2.9%). This proportion of harmful errors was higher when compared to MEDMARX overall for the same reporting period (Table 3). This suggests that high risk medications like heparin, insulin, and others should be a specific area of focus in the ED as relates to appropriate and safe drug therapy and the prevention of harmful errors.

**Table 2. Products most Associated with Emergency Department Errors<sup>a</sup>**

Drug Product	n	%
Heparin <sup>b</sup>	1,227	4.0
Acetaminophen	869	2.9
Insulin <sup>b</sup>	868	2.9
Ceftriaxone	806	2.6
Morphine <sup>b</sup>	799	2.6
Ibuprofen	773	2.5
Azithromycin	632	2.1
Potassium Chloride <sup>b</sup>	581	1.9
Levofloxacin	564	1.9
Promethazine	550	1.9

a. Based on 26,641 records with 30,416 selections reported to MEDMARX 01/02-12/06

b. Includes all products and dosage forms.

**Table 3. Products Causing Harm in Emergency Departments<sup>a</sup>**

Product	n	% <sup>c</sup>	MEDMARX Overall %
Insulin <sup>b</sup>	66	7.8	11
Heparin <sup>b</sup>	51	6.0	3.9
Morphine <sup>b</sup>	35	4.1	5.2
Hydromorphone	27	3.2	2.8
Diltiazem	25	2.9	1.3
Fentanyl	17	2.0	2.5
Potassium Chloride	15	1.8	2.5
Dopamine	12	1.4	1.1
Enoxaparin	11	1.3	1.8
Warfarin	9	1.1	2.9

a. Based on a total of 845 records with 229 selections reported to MEDMARX during the period 01/02–12/06. A total of 229 distinct products were involved with harmful outcomes (Categories E-I).

b. Includes all products and dosage forms.

c. Percentages rounded.

## Types of Error

*Prescribing error* was the most frequently reported type of error (33.8%) indicating that more than 1/3 of all patients experienced a problem related to a medication they were prescribed. This is 13.3% higher than MEDMARX overall for the same reporting period. The second most frequently reported type was *Improper dose/quantity* (21.2%) followed by *Omission error* (13.9%) (see Table 4). Both *Improper dose/quantity* and *Omission error* types reported from emergency departments were lower than the same types of errors as documented in MEDMARX overall for the same reporting period, based on the data documented for *Prescribing*, *Improper dose/quantity* and *Omission error* types.

**Table 4. Types of Medication Errors for Emergency Departments<sup>a</sup>**

Error Type	n	%	MEDMARX Overall % <sup>b</sup>
Prescribing error	9,849	33.8	20.5
Improper dose/quantity	6,175	21.2	24.1
Omission error	4,043	13.9	23.2
Unauthorized/wrong drug	3,914	13.4	12.6
Wrong patient	1,482	5.1	5.0
Extra dose	1,362	4.7	5.7
Wrong time	1,361	4.7	6.9
Drug prepared incorrectly	980	3.4	3.5
Wrong route	782	2.7	1.6
Wrong administration technique	781	2.7	1.5

a. Based on 29,166 records documenting 31,766 selections reported to MEDMARX for the period 01/02-12/06.

b. Based on 1,037,928 records reported to MEDMARX for the period 01/01/02-12/31/06.

## Error Causes

Performance deficit (36.1%) was the most frequently reported cause of all emergency department medication errors (Table 5). When combined with errors caused by procedures or protocols not followed (21.8%) this accounted for more than two-thirds of all ED reported errors, which can be attributed to causes related to human factors issues. These documented causes should serve as a reminder to facilities to ensure that policies and procedures are in place in addition to implementing procedures to monitor adherence by staff in following such procedures. Rounding out the top five causes of ED reported medication errors were the lack of documentation, ineffective communications and knowledge deficit. Because of the busy, hectic and demanding environment in emergency departments, complete documentation is often lacking and communications diminished. Verbal orders are commonplace in emergency rooms, resulting from the need to provide a rapid assessment of the patient and immediate care. Also worth noting is the frequency of errors associated with automated dispensing devices and inaccurate and omitted transcriptions. Automated dispensing

devices have been implemented in many healthcare facility EDs and other patient care areas where there is either an absence of comprehensive 24-hour pharmacy services or where pharmacy resources for dispensing medications to patients seen in the ED are lacking. This supports the dispensing node (phase) as being lower than usual in overall MEDMARX data. That data also suggest that transcription-related causes are higher due to the fast pace of the ED environment, during which time information may not be recorded at all or recorded clearly.

**Table 5. Common Causes of Errors in Emergency Departments<sup>a</sup>**

Error Cause	n	%
Performance deficit	10,562	36.1
Procedure/protocol not followed	6,355	21.8
Documentation	5,594	19.1
Communication	3,853	13.2
Knowledge deficit	3,202	11.0
Transcription inaccurate/omitted	1,699	5.8
Written order	1,573	5.4
Calculation error	1,310	4.5
Abbreviations	1,235	4.2
Verbal orders	1,225	4.2
Computerized prescriber order entry	1,172	4.0
Computer entry	1,168	4.0
Dispensing device involved	1,092	3.7
Contraindicated, drug allergy	1,039	3.6
System safeguard(s)	859	2.9
Monitoring inadequate/lacking	798	2.7

a.

Based on 51,287 records reported to MEDMARX during the period 01/02-12/06

### Case Examples<sup>a</sup>

1. A 54-year-old patient received vitamin K (10 mg) IV Push in the Emergency Department, after which time she became unresponsive. A code was called and cardio-respiratory resuscitation was attempted. Despite aggressive resuscitation efforts the patient expired. Initially the episode was thought to be an adverse medication reaction rather than an error; however, after further analysis and a medical literature search it was realized that the administration of vitamin K IV Push was in error. A root cause analysis of the error revealed that the ED staff was unaware that vitamin K was dangerous at the rate/dose ordered (IV Push 10mg), and that it should have been given PO or via a slow IV infusion. It was also determined that there was inadequate communications between the resident physician, RN, and attending physician. Actions taken to prevent recurrence of this error included the addition of vitamin K to the institution's list of high risk medications; all vials of the medication removed from all patient care areas and

all storage and distribution entirely from the pharmacy. The facility's medical information system (pharmacy module software) was modified to include prescriber computer ordering revisions that eliminated the option of vitamin K IV or IV push and only allowing for vitamin K to be ordered IV piggyback (to be prepared in pharmacy) in addition to orally (PO), subcutaneously (SQ) and intramuscularly (IM).

2. A child (age 3) was left unattended in an Emergency Department treatment room with his mother. An ENT resident brought a cup containing approximately 1cc of Phenol 89%, which was being used to treat the mother and placed it on the counter, within reach of the child, who then picked up the cup and placed it to his lips pouring it down his chest. Approximately ½ mL spilled on the child causing irritation to the lips, chin, and chest areas resulting in redness on the face and mouth. The areas were flushed and the child was transported to a local Children's Hospital Emergency Department for further evaluation and treatment. The patient's respiratory status was stable and the child was observed and subsequently released with no long term sequelae. Detailed analysis of the error documented that the ENT resident had bypassed the pharmacy in obtaining the phenol from the ENT clinic. A formal in-service for all ED staff, otolaryngology residents, fellows, and clinical faculty was conducted to review the event and educate all physician staff. Additionally, a presentation and discussion on Systems-Based Medicine: Patient Safety Issues was provided. In working with the ENT clinic, the pharmacy became aware of a commercially available unit-dose phenol product specifically for use in the myringotomy procedure, which was procured for both ED and ENT with a requirement that the distribution of all phenol products for use within the facility originate from the pharmacy.

3. A 37-year-old patient was seen in the Emergency Department (ED) for the diagnosis and treatment of polycystic kidney disease with a documented contraindication to non-steroidal anti-inflammatory drugs (NSAIDs). The patient was given 2 doses of Toradol<sup>®</sup> (ketorolac tromethamine) on the first ED visit and returned approximately 14 hours later complaining of fluid retention. After evaluation, the patient was admitted and experienced a prolonged hospitalization that was required to resolve the renal insufficiency that resulted from the preventable adverse drug event. The ED staff questioned the patient about drug allergies, but not "contraindications." Staff did not look at information that was available in front of them, only took patient's word - in short: did not perform medication reconciliation. Another problem identified was that the automated dispensing device (ADD) only displayed the last allergy entered into the main computer medication record, not all allergies and contraindications. Therefore, the ADD alert messaging was changed to contain "no" allergy information and to automatically refer providers to the hard copy medical record. Medication reconciliation was mandated to be completed on every patient with every ED visit and processes were put in place to monitor compliance.

### **Recommendations to Prevent Emergency Department Medication Errors:**

- Consider assigning a pharmacist to the ED.<sup>7</sup>
- Implement CPOE for all medications prescribed in the ED.
- Perform medication reconciliation on all ED patients.<sup>8</sup>

- Document all drug allergies and contraindications and ensure ED staff has access to complete patient medication information.
- Implement automated dispensing device (ADD) technology in ED and ensure interface with facility medical information system with pharmacy review of all medication orders.
- Check for look-alike/sound-alike drugs stored in the ED and make certain they are separated to prevent confusion and possible error.
- Implement double check procedures for all high alert medications stocked in the ED by two separate personnel prior to administration and/or dispensing.
- Require double check procedures for all high-alert medications that are stocked in the ED (to include storage in automated dispensing cabinets), which will be double checked at the pharmacy prior to being released for issue and/or restock to the ED.
- Educate ED staff on high-alert medications.
- Educate ED staff on safe medication administration techniques.
- Monitor ED staff to ensure compliance with all medication-related policies and procedures.

a. Case reports reflect actual error descriptions but may have been modified for clarity.

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## 1. USP Offers Educational Programs on Revised Chapter <797>

USP will conduct educational Webinars and Workshops on General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. The sessions will provide practitioners with a variety of tools to facilitate implementation of the revised standard by June 2008. Learning exercises will include developing a gap analysis, creating implementation time lines, and establishing standard operating procedures. Webinar participants will receive a free copy of the new *Guidebook to Pharmaceutical Compounds*. Pharmacy continuing education credits (ACPE) will be provided for all Workshop sessions.

### <797> Webinar Series 2008 (90 minutes each)

**Dates-** Mar. 6, Mar.13, Apr. 3, May 1, May 15, Jun. 5

**Topics-** Chapter <797> revisions, microbial contamination, sterilization methods, disinfectant cleaning, garbing, media fill testing, hazardous drugs, environmental monitoring controls, facility design, radiopharmaceuticals, and specialty CSPs.

#### To Register for the Webinars

Visit [www.intellor.com/usp/797webinars](http://www.intellor.com/usp/797webinars)

### <797> Workshops 2008 (2 day program)

**Dates-** Mar. 31– Apr.1, Apr.17–18, May 22–23

**Topics-** Facility design, media fill testing, isolator types, clean rooms, implementation timelines, aseptic gap analysis, CSP microbial contamination, sterilization methods, developing SOPs, training employees and more.

#### To Register for the Workshops

Call (301) 230-6304, or email: [www.usp.org/goto/797resources](http://www.usp.org/goto/797resources)

## 2. MEDMARX<sup>®</sup> Enhanced through USP / Quantros Partnership

Early in December 2007, USP announced the formation of a strategic alliance with Quantros, a health care information technology management company that will enhance MEDMARX<sup>®</sup>, USP's adverse drug event reporting program. This partnership will provide USP and all subscribers of MEDMARX access to increased data sets from more U.S. hospitals and health systems related to the identification and prevention of medication errors and adverse drug events. MEDMARX database currently draws from more than 400 hospitals and healthcare systems and is the largest medication error database in the world. Under this agreement, Quantros will manage all operational aspects of

MEDMARX, including marketing, sales, and client / customer service support. USP will focus its efforts on MEDMARX data analysis; research, standards-setting, and dissemination of safe practices that will help practitioners prevent errors. The USP/Quantros partnership takes effect Jan. 1, 2008. For full story [click here](#)

### **3. ISMP Discusses Error Potential with Investigational Drugs**

In a recent Institute of Safe Medication Practices (ISMP) Newsletter, concern was expressed about the routine practices used to name, label, package, and store investigational drugs that could potentially cause serious patient safety issues. As an example, as reported to ISMP by a pharmacist, in a Bristol-Myers Squibb investigational study comparing apixiban and enoxaparin, the packaging of the enoxaparin and placebo syringes raised concern. The plain-looking syringes are labeled with an identification number, while the syringe labels did not include lot numbers or expiration dates. The most predominant feature on the syringes is the company name. Although the syringes are provided in a labeled carton, once the syringes are removed from the box, the carton label containing important information is lost. This could lead to a patient assigned to the study in receiving medication from the wrong syringe once the products are sent to a patient care. For additional information, [Click here:](#)

Reports submitted to USP on investigational drugs will be analyzed in a future issue of CAPSLink.

### **4. FDA Issues Stronger Public Advisory on Fentanyl Patches**

The FDA recently issued a public health advisory to alert patients, caregivers, and healthcare professionals on important information on the safe use of the fentanyl transdermal system, marketed as Duragesic<sup>®</sup> and other generics. Despite issuing an advisory in July 2005 that emphasized the safe use of the fentanyl patch, the FDA continues to receive reports of death and life-threatening adverse effects in patients who use the fentanyl patch. The reports document that doctors have inappropriately prescribed the fentanyl patch to patients for acute pain following surgery, for headaches, occasional or mild pain, and other indications for which the fentanyl patch should not be prescribed. Further, the reports indicate that patients continue to incorrectly use the patch by replacing it more often than directed in the instructions, resulting in significantly harmful toxic levels of fentanyl in the blood. The FDA has requested that all manufacturers of fentanyl patches update information and to develop a Medication Guide for patients. The FDA also recently published information on a voluntary recall of certain fentanyl transdermal patches that may have a cut along one side of the drug reservoir within the patch, which could result in the release of fentanyl thus potentially exposing patients and caregivers to fentanyl gel on the skin. Complete FDA Press Releases are available [here](#) and [here](#)

### **5. PDE5 Inhibitor Information for Healthcare Professionals**

The FDA has approved labeling changes for erectile dysfunction (ED) drugs in the class that includes Cialis, Levitra, and Viagra, to display more prominently the potential risk of sudden hearing loss, and to guide consumers on what to do if they experience sudden problems with their hearing. Additionally, the FDA will

require the same changes in labeling for the drug Revatio, also a member of this drug class known as phosphodiesterase type 5 (PDE5) inhibitors; which is indicated in the treatment of pulmonary arterial hypertension (PAH). The FDA asked manufacturers of these drugs to revise product labeling after a very small number of patients taking the PDE5 inhibitors reported sudden hearing loss, sometimes accompanied by ringing in the ears and dizziness. Patients taking Cialis, Levitra, or Viagra who experience sudden hearing loss should immediately stop taking the drug and seek prompt medical attention. Those using Revatio should continue taking their medication but should contact their health care provider for further evaluation. For additional information [click here](#) or [here](#)

## **6. Patients Unable to Tell Doctors Medications They are Taking**

Newly published research in a study from Northwestern University's Feinberg School of Medicine has found that nearly 50 percent of patients taking antihypertensive drugs in three community health centers were unable to accurately name a single one of their medications listed in their medical chart. That number climbed to 65 percent for patients with low health literacy. The study was published in the November issue of the Journal of General Internal Medicine, and looked at 119 patients, average age 55; from community health centers in Grand Rapids, Michigan. Although the study focused on low-income patients, other patients likely have similar trouble recalling the names and dosages of all their medications, particularly those who take a lot of different drugs and the elderly, who may have cognitive limitations. Additional information on the study is available at: [http://www.eurekalert.org/pub\\_releases/2007-10/nu-pcr101107.php#](http://www.eurekalert.org/pub_releases/2007-10/nu-pcr101107.php#)

## **7. FDA Evaluates New Data on Risks of Anemia Drugs**

The FDA is reviewing new data from two studies that provide further evidence of the risks of anemia drugs known as erythropoiesis-stimulating agents, or ESAs. The studies show that patients with breast or advanced cervical cancers who received ESAs to treat anemia caused by chemotherapy died sooner or had more rapid tumor growth than similar patients who did not receive the anemia drug. FDA will examine this new data and revisit the risks and benefits of using ESAs in patients with chemotherapy-induced anemia at a public advisory committee meeting in the future. FDA Press Release available at: <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01769.html>

## **8. Children Under 2 should not be given OTC Cough and Cold Products**

On January 17, 2008, the FDA issued a Public Health Advisory for parents and caregivers, recommending that over-the-counter (OTC) cough and cold products should not be used to treat infants and children less than 2 years of age because serious and potentially life-threatening side effects can occur from such use. The FDA also stated that these medications have not been shown to be safe or effective in children under 2. A wide variety of rare, serious adverse events have been reported associated with cough and cold products, which include death, convulsions, rapid heart rates, and decreased levels of consciousness. The advisory does not include the FDA's final recommendations about use of OTC cough and cold medicines in children ages 2 to 11 years. The agency's review of data for 2-to-11-year-olds continues with additional recommendations on this age group expected in the future. The FDA recommends that anyone with questions

contact a physician, pharmacist or other health care professional to discuss how to treat a child with a cough or cold. Additional information on the FDA's Public Health Advisory available at:

[http://www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm)

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### USP Medication Error Reporting Programs:



**MEDMARX**<sup>®</sup>—USP's comprehensive, Internet-accessible, anonymous medication errors reporting program, and quality improvement tool. The program facilitates productive and efficient documentation, tracking, trending, and prevention of medication errors.



**Medication Errors Reporting (MER) Program**—presented in cooperation with the Institute for Safe Medication Practices, this nationwide program makes it possible for health professionals to report medication errors confidentially and anonymously to USP.

### Other USP patient safety resources:

- [MEDMARX Annual Data Summary reports](#)—provides readers with a wealth of information on reported error events including patterns in the types, causes, and level of harm associated with medication errors.
- [Understanding and Preventing Medication Errors: A Resource for Healthcare Practitioners](#)—a CD toolkit with practical guidelines, forms, and templates to help healthcare facilities improve error-reduction initiatives.
- [Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success](#)—a book in which hospitals share stories about how they reduced medication errors and promoted safer patient care.
- Medication Safety Pocket Reference—a pocket-sized reference booklet containing listings of similar drug names and dangerous abbreviations that could cause medication errors. Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for item #3227702.
- Similar Drug Names Poster—a wall poster for easy reference listing look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. Posters are packaged in quantities of 1 (item # 3728251) 10 (item # 3728252) and 50 (item # 3728253). Contact [custsvc@usp.org](mailto:custsvc@usp.org) and ask for the appropriate item number.

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