

# *Hospital Pharmacist Monthly*

From D Ross Consulting, Inc.  
938 Calle Del Pacifico, Glendale, CA 91208 – 818.500.8262 - [www.HospitalPharmacistMonthly.com](http://www.HospitalPharmacistMonthly.com)

---

Volume 3, Number 11

November 2011

Welcome to the current issue of *Hospital Pharmacist Monthly*.

- **“CMS – Revised Appendix A, Interpretive Guidelines for Hospitals”** ([https://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter12\\_05.pdf](https://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter12_05.pdf) ). This is a very welcome change to the Standards of Participation. CMS has issued revised interpretive guidelines to 42 CFR 482.23(c) concerning medication administration – specifically the “30-minute rule”. Following the recommendations of ISMP, CMS will no longer require all medications to be administered within a 30-minute window on either side of the scheduled time. The interpretive guidelines are revised to include a lengthy discussion on “Timing of Medication Administration”. The requirements are that the hospital defines in policies and procedures the timing of medication administration and that this be based on both the nature of the medication and its clinical application. At a minimum the policies must address: medications not eligible for scheduled dosing times (stat, one-time, first time or loading doses, prn doses and investigational drugs); medications eligible for scheduled dosing times (meds prescribed on a repeated cycle of frequency); administration of eligible medications outside of their scheduled dosing times and windows; and evaluation of medication administration timing policies, including adherence to them. Time-critical medications are those for which an early or late administration of greater than 30 minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological. Examples of time-critical scheduled medications may include, but are not limited to: antibiotics, anticoagulants, insulin, anticonvulsants, immunosuppressive agents, pain medication, medications prescribed for administration within a specified period of time of the medication order, medications that must be administered apart from other medications for optimal effect or medications prescribed more frequently than every 4 hours. For non-critical scheduled medications greater flexibility in the timing of administration is permissible. Medications prescribed for daily, weekly or monthly administration may be administered within 2 hours before or after the scheduled time for a window of 4 hours and medications prescribed more frequently than daily but not more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time for a window not to exceed 2 hours.
  - **HPM Recommendation – This is great news. Make sure you revise your policy to conform to the guidelines as outlined in this transmittal. Remember that your policy needs to meet the regulatory requirements and your practice has to match your policy.**
- An article titled **“Medication Errors: A Year in Review”** (*Pharmacy Practice News – Special Edition. 2011 – link*) was discussed. The authors review the alerts provided in the ISMP Medication Safety Alert! Newsletter for 2010. We have discussed many of these alerts in previous editions of HPM, but it is still beneficial to scan the document and make sure that you have taken steps to address the ISMP recommendations as they apply to your facility. The nice part about this article is that the alerts are broken out into categories according to the phase in the medication use process. The categories include: Labeling, Packaging and Nomenclature; Order Communication; Drug Information, Patient Information, Staff Education and Patient Education; and Medical Devices and other discussion items. One particular area of errors discussed is the safe use of insulin. A link to a tool to self assess the safety risk of insulin in your facility was provided and we recommend that you download (<http://patientsafetyauthority.org/educationaltools/patientsafetytools/insulin/pages/homes.aspx>).
  - **HPM Recommendation – Review the article and each error discussed and assess whether or not you have addressed in your organization. We particularly liked the self-assessment for the safe use of insulin and the link to this document is provided.**

- We reviewed the article “**Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008**” (*MMWR*. 2011; 60(43):1487-1492). The authors of this article are from the CDC. It is noted that there were 36,450 deaths due to opioids pain relievers in 2008 and that death rates increased substantially from 1999 to 2008. It is identified that there is a 5-fold difference in death rate across the United States with the highest rate being 27.0 per 100,000 population in New Mexico and the lowest rate being 5.5/100,000 in Nebraska and an average rate across the US of 11.9. The authors noted that there were sufficient opioids pain relievers prescribed in the United States in 2010 to medicate every American adult with a standard pain treatment dose of 5 mg of hydrocodone taken every 4 hours for one month. Recommendations for action to reduce both inappropriate and illegal prescribing include: insurers and prescription drug monitoring data be used to identify misuse and abuse of opioids pain relievers; third party payors could limit reimbursement in ways that reduce inappropriate prescribing; discourage efforts to obtain opioids pain relievers from multiple prescribers; and changes in state laws to focus on prescribing practices of health care providers to reduce prescription drug abuse and overdoses and still allow for safe and effective pain treatment.
  - **HPM Recommendation – Review the article and identify where your state falls and what level of opportunity exists in your area. Determine if there are any actions you can take to minimize the abuse of opioids pain relievers.**
  
- Recent announcements/alerts from the FDA were briefly discussed.
  - ✓ November 14, 2011 – “Frequently Asked Questions about the FDA Drug Approval Process” (<http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm> ). This is a brief summary of the FDA approval process that describes how drugs are brought to market in the United States. It appears to be written for non-healthcare professionals, but the information is worth review by all of us. Subject matter includes: why drugs are evaluated; what are clinical trials and how do they relate to drug approval; how long the drug approval process takes; what are the different types of drug applications; and a discussion of OTC medications and clarification that these products are not approved by the FDA.
  - ✓ November 18, 2011- “FDA Commissioner announces Avastin decision”. The FDA announced that they are revoking the agency’s approval for the breast cancer indication for Avastin (bevacizumab). This product received FDA approval for the treatment of metastatic breast cancer in 2008 under the FDA accelerated approval program. After this initial approval the manufacturer was required to perform further clinical studies and this data was submitted to the FDA. The data showed a small beneficial effect on tumor growth without providing evidence of increased life span or quality of life and this did not outweigh the risk of taking the drug. It will still remain on the market for the approved treatments of colon, lung, kidney and brain cancer.
  
- An article titled “**FDA Reviews Narrow Therapeutic Index Requirement**” was reviewed. (*Hosp Pharm*. 2011;46(11):829). The author describes that an FDA advisory committee has determined that the current bioequivalence requirements for not sufficient as they relate to drugs with a narrow therapeutic index (NTI). It is noted that the NTI is defined in Federal code as when there is less than a 2-fold difference in the median lethal dose and the median effective dose or there is less than a 2-fold difference in the minimum toxic concentration and the minimum effective concentration. In the United States a product is defined as bioequivalent if the mean ratio of area under the curve and maximum concentration fall between 80% and 125% of reference products. The advisory committee noted that these limits are too large to ensure the safe use of NTI agents and has recommended that the range be tightened to 90% to 111%. The FDA is evaluating the information presented at the advisory committee to determine if these new recommendations will be adopted.
  - **HPM Recommendation- FYI – No specific action recommended.**
  
- A recent notification from HRSA titled “**Clarification of Non-Discrimination Policy**” (<http://www.hrsa.gov/opa/Docs/PolicyReleaseNon-discrimination.pdf> ) was reviewed. Basically this notification is describing the requirement that manufacturers provide drugs at 340B prices to covered entities and if the drug is in short supply for some reason they cannot discriminate against 340B covered entities as far as availability, but must ensure that allocation procedures be in place and that

all purchasers be treated equivalently. Manufacturers must submit allocation plans to HRSA and HRSA will publish these plans on their website.

- **HPM Recommendation– Useful information that you may need to share with pharmaceutical manufacturers when they attempt to short you (or claim drug shortage) for 340B priced product, but there are no restrictions on purchasing the same product at non-340B pricing.**
  
- **“TJC Compliance Challenges – Q&A with Darryl Rich, Surveyor, The Joint Commission”** (*Pham Purch & Products. 2011; November:4-7*) was discussed. There are no changes in the medication management standards in 2012 and no changes in the medication related NPSGs either. The standards that had the most findings in 2011 (YTD) were medication storage, medication orders, pharmacist review, medication preparation and medication labeling (in descending order). Key issues in medication storage include storing medications as listed in the manufacturer package insert – for example, lorazepam injection is labeled for refrigerator storage and you cannot store in a non-refrigerated area unless you have documentation of stability from the manufacturer. We noted that Hospira will provide such a letter, but Baxter will not. With regards to pharmacist review problems identified include duplicate therapy – multiple prn anti-emetic orders without a clear definition of when each one is to be used and failure to have clear orders for titration of medications (e.g. starting dose, incremental dose). It was noted that there has been improvement in appropriate labeling in the OR. Finally, Dr. Rich described a new resource available to hospitals accredited by TJC. There is a leading practice database on the TJC intranet site (your facility TJC coordinator can help you gain access). You can find examples of best practices on this website.
  - **HPM Recommendation – Review this article and make sure that you are addressing the issues that are most often cited during TJC surveys. Check out the leading practice database if you are TJC accredited.**
  
- There was a discussion on the drug shortage crisis and multiple recent articles on the subject were reviewed.

**“White House addresses drug shortages”** (*Am J Health-Syst Pharm. 2011;68:2204-2206*). On October 31<sup>st</sup> the Obama administration released an executive order requiring the FDA to use “all appropriate administrative tools” and legal authorities to ensure that drug manufacturers notify the agency of any manufacturing discontinuances that may lead to drug shortages. It applies to drugs that are life supporting or life sustaining or that prevent debilitating disease. The current law requires the same, but only applies sole source medically necessary drugs. The executive order also requires the FDA to inform the Department of Justice information they collect on hoarding or price gouging by secondary wholesalers or others in the supply chain. An ASHP spokesperson noted that the executive order reflects actions that the FDA has already been taking, but at least serves notice to drug manufacturers that the White House is watching. It is also noted that the executive order does not give the FDA new funding to increase their capacity to alleviate drug shortages.

**“A Review of FDA’s Approach to Medical Product Shortages”** ([www.fda.gov/DrugShortageReport](http://www.fda.gov/DrugShortageReport)) This report, which was released the same day that the Obama executive order was announced, provides background information on the drug shortage crisis, describes the FDA activities related to preventing drug shortages and then provides review and discussion of key issues. The FDA notes that the number of shortages tripled from 2005 (61) to 2010 (178) and that sterile injectable products accounted for 80% of the shortages in 2010-2011. They indicate that the primary reasons for the shortages reported to the FDA are: problems with manufacturing (43%); delays in manufacturing or shipping (15%); and active pharmaceutical ingredient shortages (10%). The FDA notes that they prevented 38 drug shortages in 2010 and 99 to date in 2011. The actions taken to prevent shortages include: Expediting review of new manufacturing sites, new suppliers and specification changes (71%); exercising regulatory flexibility and discretion (20%); and asking other firms to increase production (7%). A few of the reasons as to why drug shortages have been occurring with injectable products so frequently are: the top three generic injectable manufacturers hold 71% of the market volume; most sterile injectable products have one manufacturer that produces at least 90% of the drug; and “Just in time” manufacturing and inventorying practices leave little margin for error.

**“Drug Shortages – A Critical Challenge for the Generic-Drug Market”** (*N Engl J Med.* – ePub <http://www.nejm.org/doi/full/10.1056/NEJMp1112633>). This author describes the gravity of the drug shortage situation, especially how it applies to generic chemotherapy agents. It is noted that the generic market for chemotherapy agents has consolidated to four manufacturers (Teva, Bedford, APP Pharmaceuticals and Hospira) and that they have experienced both increased demand and production problems which have contributed to the shortage. It is also noted that these products are generally sold for very little profit so are produced as inexpensively as possible using older and less efficient facilities. It is also noted that these manufacturers maintain limited inventories to minimize carrying costs. The author believes that another contributing factor to the drug shortage is the Medicare legislation which sets the reimbursement rate for injectable generics at 6% above the average sales price (ASP). The author concludes that these limits affect the price and result in little profit for manufacturers. We were unclear on how the reimbursement price impacts the price that manufacturers choose to sell their products.

**“FentaNYL shortage- seems like 2011 all over again!”** (*ISMP Medication Safety Alert! Newsletter.* 2011;16:2). ISMP notes that the recent shortage of injectable fentanyl reminded them of a similar situation 10 years ago. In 2001 there was a shortage of injectable fentanyl and there were several cases of adverse patient outcome reported due to errors in either prescribing or manufacturing when sufentanil was substituted for fentanyl. Amy noted that she had a physician suggest that they start switching all injectable fentanyl patients to fentanyl patches. The obvious point of this discussion is to be very careful how you manage drug shortages and that you assess the risk of any alternative solutions implemented. If you do not have a policy on how to handle drug shortages in your facility this should be done immediately.

**“The Shortage of Essential Chemotherapy Drugs in the United States”** (*N Engl J Med.* 2011;365:1653-1655). This article describes the impact that drug shortages are having on the treatment of patients with cancer and provides insight into why these shortages are occurring. This author is very blunt about the cause of the drug shortage – “The main cause of drug shortages is economic. If manufacturers don’t make enough profit, they won’t make generic drugs.” An example given is the impact of the release of levoleucovorin on the availability of leucovorin. Levoleucovorin is reported to be no more effective than leucovorin and cost 58 times more. However, the use grew rapidly after FDA approval and eighteen months later there was a shortage of leucovorin. Part of the reason for the large use of levoleucovorin is probably related to the method by which Medicare reimburses for medications – average sales price (ASP) plus 6%. If a physician can administer levoleucovorin or leucovorin and their reimbursement is based on the 6% margin over ASP, choosing the product that is 58 times more expensive results in a much nicer income. The example the author provides in the article is the use of paclitaxel. Instead of administering paclitaxel and receiving 6% of \$312, oncologists administer Abraxane and receive 6% of \$5,824. It is noted that there are fewer shortages in Europe and this may be due to the fact that the price of generic products are set at a higher level than the prices in the United States.

➤ **HPM Recommendation – Keep on top of the drug shortage issues that are pertinent to your organization. Make sure that you have a policy in place to address how drug shortages are handled in your institution.**

- An article titled **“Long-term Budgeting for Pharmacy Automation”** (*Pharm Purch & Product.* 2011;November:18-20) was reviewed. The author describes the need for pharmacy automation and the importance of developing a process for long-term budgeting to procure and install automation. It is noted that the first step in the process is the development of a long-term automation plan. This is true whether the automation is facility-wide like CPOE or BCMA, or very specific to pharmacy like a TPN compounder or carousels. The next step is building interdepartmental support and this is followed by getting administrative buy-in. The author counsels that when presenting the proposal to administration that there must be justification of how this project will provide cost savings, increase safety or provide other benefits.

➤ **HPM Recommendation: Review this article for some good recommendations on how to plan for and ultimately get approval for pharmacy automation.**

- The article **“Managing Underperformers”** (*Am J Health-Syst Pharm.* 2011;68:2123-2125) was reviewed. Underperformers are defined as employees who do not consistently exercise the necessary

job skills or who exhibit undesirable behavioral characteristics. The best way to manage underperformers is to not hire underperformers and focusing on hiring for excellence. Behavioral-based interviewing is an interviewing technique that uses a guided interview process about past performance to assist managers in making good hiring choices. This organization demonstrated a much lower rate of employees leaving the organization after about a year after they implemented behavioral-based interviewing. Setting clear performance expectations during the first six months after hire is another key factor in managing for underperformance. A structured on-boarding process with follow-up meetings with the new employee at 30, 60, 90 and 180 days is in place. These meetings allow for course correction early in the process if necessary. If underperformers exist that are past their probationary period the key to handling is recognizing the undesirable traits and effectively addressing them. A corrective-action pathway that is predicated on the just-culture algorithm is described. The written plan for performance improvement should describe the target areas for improvement, detail the necessary action steps, include timelines for resolution and clearly state the consequences for failing to meet the expectations for improved performance.

- **HPM Recommendation: This article is a good reference on how to better manage underperformers in your organization. It is recommended that the article be reviewed and the recommended processes be adopted.**
  
- **“Professional policy as a catalyst to pharmacy’s transformation”** (*Am J Health-Syst Pharm. 2011;68:2261-2264*) was reviewed. The author notes that ASHP holds a policy week each year to develop and implement policies related to the professional practice of pharmacy and notes that the fundamental purpose of the policy process is to nurture the transformation of the profession of pharmacy. It is noted that more and more pharmacy professionals recognize that dispensing and order fulfillment will not sustain the profession. Four obligations of the policy development process are provided: Devote energy to big issues whose importance is self-evident to the public; don’t get bogged down in too many little items; advocate big-issue policies assertively and in collaboration with others; and consistently and regularly inform the public about pharmacists’ contributions to patient care. It is noted that pharmacists have the capacity to understand, interpret and communicate drug information and apply it in patient care and that the pharmacist’s expertise in this area exceeds other health care professionals.
  - **HPM Recommendation: FYI – a good background article to read to better understand how ASHP policy development impacts the profession of pharmacy.**
  
- The editorial **“A major stride in the advancement of emergency medicine pharmacy”** (*Am J Health-Syst Pharm. 2011;68:2237*), the brief summary **“Overview of ASHP Guidelines on Emergency Medicine Pharmacist Services”** (*Am J Health-Syst Pharm. 2011;68:2296*) and the **“ASHP Guidelines on Emergency Medicine Pharmacist Services”** were discussed. (<http://www.ashp.org/DocLibrary/BestPractices/SpecificGdlEmergMed.aspx>) The updated guidelines for emergency medicine pharmacist (EMP) services were recently published by ASHP. The guidelines describe the level of clinical practice that characterizes EMPs as clinicians with direct patient care roles as well as educational, research and management roles. The guidelines also recommend essential and desirable pharmacist roles for the provision of patient centered care in the ED. Two topics not addressed are medication administration by pharmacists and postgraduate credentialing and certification requirements for EMPs. Specific topics discussed in the guidelines under the “Essential Direct Patient Care Roles of EMPs” include: direct patient care rounds; medication order review; medication therapy monitoring; patient care involving high-risk medications and procedures; resuscitation; medication procurement and preparation; medication information; and documentation. Other areas included are essential and desirable administrative roles of EM pharmacists.
  - **HPM Recommendation: We recommend that you download the guidelines and carefully review these ASHP recommendations for Emergency Medicine Pharmacist Services.**
  
- An article titled **“Venous Thromboembolism Prophylaxis in Hospitalized Patients: A Clinical Practice Guideline From the American College of Physicians”** (*Ann Intern Med. 2011;155:625-632*) was briefly discussed. The ACP recommends: assessment of risk for thromboembolism and bleeding in all medical (including stroke) patients for VTE; pharmacologic prophylaxis with heparin or related drug (no difference in efficacy of heparin vs. LMWH noted) for VTE in medical patients

unless the assessed risk for bleeding outweighs the likely benefits; against the use of mechanical prophylaxis with graduated compression stockings for prevention of VTE.

- **HPM Recommendation: Review this article and determine if you want to change any of your practices based on these recommendations.**

*Dan Ross, PharmD*

*Amy Gutierrez, PharmD*

Drs. Dan Ross and Amy Gutierrez do not have (nor do any of their immediate family members have) a vested interest in or affiliation with any corporate organization in the past 12 months offering financial support or grant money for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias their presentation.