

HOSPICE PHARMACY INSIGHTS

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Prepared by:
David Bougher
Senior VP of Regulatory Affairs

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REGULATORY CENTER

ADDENDUM OF ELECTION OF BENEFITS STATEMENTS

SOME FINAL (?) DETAILS

The addendum should be titled “Patient Notification of Hospice Non-Covered Items, Services and Drugs.” According to Medicare (CMS) filling out this addendum with the patient/representative will only take “10 minutes.” However, the addendum must include the following list of 8 items, including “a written clinical explanation” supporting the determination that certain care is unrelated.

The addendum must contain:

- Name of the hospice
- Beneficiary’s name and hospice medical record identifier
- Identification of the beneficiary’s terminal illness and related conditions
- A list of the beneficiary’s current diagnoses/conditions present on hospice admission (or upon plan of care update, as applicable) and the associated items, services, and drugs, not covered by the hospice because they have been determined by the hospice to be unrelated to the terminal illness and related conditions
- A written clinical explanation, in language the beneficiary and his or her representative can understand, as to why the identified conditions, items, services, and drugs are considered unrelated to the terminal illness and related conditions and not needed for pain or symptom management
- References to any relevant clinical practice, policy, or coverage guidelines
- Information on the following domains:
 - Purpose of Addendum
 - Right to Immediate Advocacy
 - Name and signature of Medicare hospice beneficiary (or a representative) and date signed, along with a statement that signing this addendum (or its updates) is the only acknowledgment of receipt of the addendum (or its updates) and not necessarily the beneficiary’s agreement with the hospice’s determinations

CMS has expanded on the timeframes from the proposed rule, moving the initial completion of the addendum to within 5 days of the time of election and 72 hours if the request comes during any other time when a beneficiary is in the hospice benefit.



FOR YOUR CONSIDERATION DRUG SHORTAGES: AN UPDATE

IN 2018

the FDA launched a new task force to examine U.S. drug shortages, determine the root causes of the shortages, and recommend long-term solutions to address the problem. The task force commissioned a team of FDA economists and scientists to analyze data on 163 drugs that experienced shortages between 2013 and 2017. Many of these drugs were older (median of 35 years since first approved), 109 had generic competitors, 103 were sterile injectables.

Reasons for the shortages:

- 63% of the drugs' shortages stemmed from the supply disruptions tied to product quality or manufacturing issues.
- 18% stemmed from unknown reasons.
- 12% stemmed from unanticipated increases in demand.
- 5% occurred after natural disasters.
- 3% stemmed from product discontinuations.

According to the task force the root causes of the shortages were (1) a lack of incentives for manufacturers to produce less profitable treatments, (2) logistical and regulatory barriers that slow the recovery from production disruption and (3) the market's failure to reward manufacturers quality systems that prioritize continuous improvements and early detection of supply chain issues.

The task force's recommendations centered around improving the quality of the manufacturing systems and financial incentives for drug manufacturers to increase the production of low profitability drugs.

Critics of the task force point out that all of the recommendations are "voluntary" and don't involve any government action therefore are not strong enough to produce any change in the market.

It appears that, if manufacturers don't change their approach, we will continue to see shortages due to: "just in time" inventory, no stockpile, no margin of safety and any disruption causes a shortage.

<https://www.advisory.com/daily-briefing/2019/10/31/drug-shortage>



In case **YOU WERE WONDERING**

WHAT DO EXPIRATION DATES ON MEDICATIONS ACTUALLY MEAN?

Expiration dates on prescription and over the counter (OTC) medications have been required of manufacturers by the FDA since 1979. The expiration date is usually between 12 and 60 months where the drugs full potency and safety are guaranteed. At the present time there is no incentive in the regulations for manufacturers to lengthen that date of expiration.

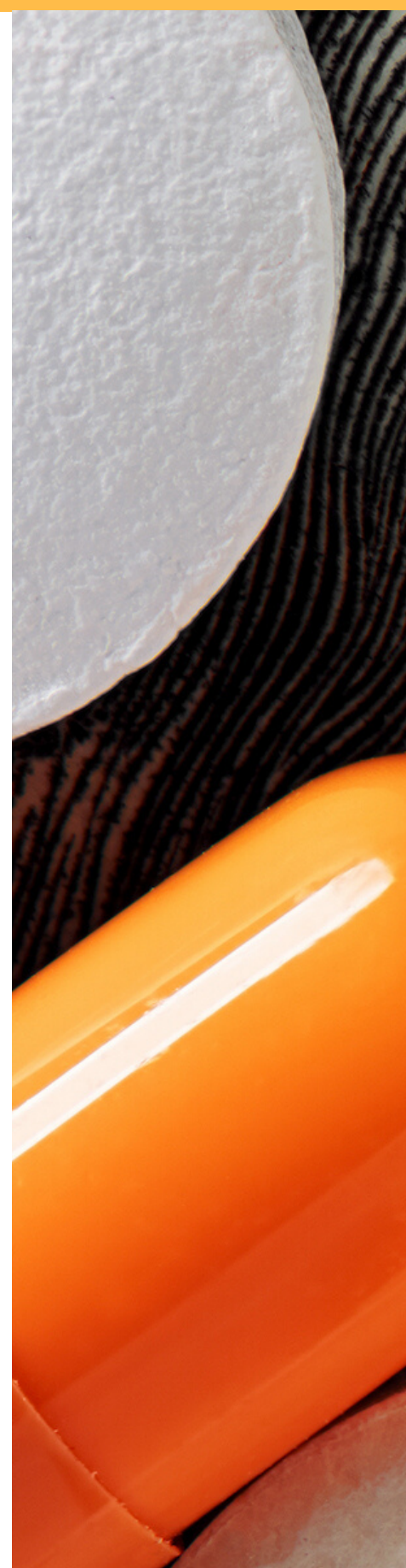
The FDA has a program, The Shelf Life Extension Program (SLEP) that analyzed the potency of 122 common medications to check the long-term stability of federal drug stockpiles. They found that the average extension of potency and stability was 5 years.

There have been other studies, one of note, that analyzed drugs between 28 and 40 years beyond their expiration dates. The majority (86%) were found to have maintained 90% potency. Keep in mind that these drugs were found in their original, unopened containers.

According to the author, he would respond to a patient who was concerned about an expired medication that if it was a pill or capsule it could be safely used...in a pinch. However, if it was a liquid, solution or suspension especially if they are cloudy, discolored or have precipitated he would recommend discarding.

For more details on this subject check out the article cited below.

***Are Drug Expiration Dates a Myth? Douglas S. Paauw, MD; Medscape
5/5/20***



Updated March 2020

DRUG SHORTAGE LIST

• Atropine (Inj/Ophth)	2/21/20
• Bisacodyl (Supps)	2/28/20
• Carbidopa/Levodopa (ER Tablets)	1/17/20
• Cipro (Inj/Ophth/Solution)	12/9/19
• Dexamethasone (Inj)	2/18/19
• Diazepam (Inj)	12/23/19
• Doxycycline Hyclate (Inj)	1/29/20
• Enoxaparin (Inj)	2/18/20
• Erythromycin (Inj/Ophth)	2/10/20
• Famotidine (Inj/Tabs)	2/20/20
• Fentanyl (Inj)	2/18/20
• Fluticasone/Salmeterol (Inhale)	1/10/20
• Furosemide (Inj/Oral)	1/27/20
• Haloperidol (Tablets)	1/14/20
• Heparin (Inj)	1/17/20
• Hydromorphone (Inj)	2/12/20
• Ketamine (Inj)	1/28/20
• Ketorolac (Inj)	2/4/20
• Levetiracetam (Inj/Tablets)	2/25/20
• Lorazepam (Inj/Oral)	2/14/20
• Losartan (Tabs)	2/25/20
• Methadone (Inj)	2/19/20
• Metronidazole (Inj)	1/30/20
• Midazolam (Inj)	2/24/20
• Morphine (Inj/PCA vials/IR/tabs)	2/20/20
• Nitrofurantoin (Suspension)	1/29/20
• Nystatin (Suspensions)	12/9/19
• Octreotide (Inj)	1/19/20
• Ondansetron (HCL (Inj)	1/30/20
• Prednisone (Tablets)	2/25/20
• Prochlorperazine (Tablets)	1/15/20
• Promethazine (Inj)	2/12/20
• Ranitidine (Inj)	2/28/20
• Scopolamine (Transdermal)	11/20/19
• Temazepam (Capsules)	2/18/20
• Tramadol (Tablets)	2/12/20
• Valsartan (Tablets)	1/29/20
• Vancomycin HCL (Inj)	1/27/20
• Venlafaxine HCL (Tablets ER)	2/18/20
• IVBags/Solutions (various)	2/18/20

