### HOSPICE PHARMACY INSIGHTS

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## REGULATORY CENTER COVID-19 REGULATORY UPDATES

The response to the COVID-19 pandemic by federal, state and local government agencies has attempted to stay up with the rapidity of the spread of the virus. As a result, rules and regulations are ever changing. As long as COVID-19 remains a serious issue we will provide brief regulatory updates with appropriate links to help you stay abreast of regulatory changes that impact your hospice. Because this is a monthly newsletter the information may not be as timely as you need so we suggest that you stay in close communication with your state hospice and/or national hospice organizations.

## CORONAVIRUS AID, RELIEF, & ECONOMIC SECURITY ACT (CARES ACT)

This massive bill was signed into law late last week. Aspects of this bill that are most important to hospices are the following:

- Section 3706 the use of telehealth to conduct face-to-face encounters
  - The legislation will allow face-to-face encounters for recertification for hospice care to be completed by hospice physicians and nurse practitioners using telehealth technologies during the emergency period.
  - Posted in the Federal Register 3/31/20
    - Detailed guidance on providing the hospice face-to-face encounter through telehealth.
      - Use audio and video equipment permitting two-way, real-time interactive communication between the patient (from home, or any other site permissible for receiving services under the hospice benefit) and distant site hospice physician or hospice NP.
    - Details on the ability of the hospice to provide routine home care through telehealth. Details must be:
      - Included on the plan of care.
      - Meet the requirements at § 418.56.
      - Tied to the patient specific needs as identified in the comprehensive assessment.
      - Plan of care must include a description of how the use of such technology will help to achieve the goals outlined on the plan of care.
  - \$100 billion Public Health and Social Services Emergency Fund the following provisions could potentially benefit hospice and palliative care providers.



## REGULATORY CENTER COVID-19 REGULATORY UPDATES (CONT.)

- Funding will be used to prevent, prepare for, and respond to coronavirus, domestically or internationally, and for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to the coronavirus.
- Funds appropriated under this program shall be available for building or construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity.

To view the entire bill (S. 3548) follow this link: <a href="https://www.congress.gov/bill/116th-congress/senate-bill/3548/text">https://www.congress.gov/bill/116th-congress/senate-bill/3548/text</a>

## CMS GUIDANCE FOR INFECTION CONTROL AND PREVENTION CONCERNING COVID-19 BY HOSPICE AGENCIES

#### **BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients and residents of healthcare facilities or homecare settings from the spread of infectious disease. This memorandum responds to questions we have received and provides important guidance for Hospice Agencies in addressing the COVID-19 outbreak and minimizing transmission to other individuals.

#### **GUIDANCE**

Hospice Agencies should regularly monitor the CDC website (see links below) for information and contact their local health department when needed (https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html). Also, hospice agencies should be monitoring the health status of patients, residents, visitors, volunteers, and staff under their care setting for signs or symptoms of COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors at the facility. For exposed staff, hospice agencies should consider frequent monitoring for potential symptoms of COVID-19 as needed throughout the day.

<u>To obtain full details you can follow this link:</u>
<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html</a>



### AN ONGOING CONCERN DRUG SHORTAGES

#### **MORE TO UNCOVER**

Researchers at the Center for Infectious Disease Research and Policy (CIDRAP) have raised concerns that the COVID-19 pandemic will lead to shortages of critically needed medications because of our dependence on drugs made in other countries. As we've noted in recent newsletters, the United States relies on foreign countries for approximately 80% of the drugs, brand and generic, we use.

CIDRAP notes that the precise risk of drug shortages is hard to assess because of "the lack of structural transparency and available supply chain data about drugs, which may be known by pharmaceutical companies, wholesalers, suppliers, and contract manufacturers, but not shared with the Food and Drug Administration or the public."

David J. Margraf, PharmD, MS, a research project specialist with the CIDRAP team, said pharmaceutical companies are required to report some supply-chain information to the FDA, but the data can be up to 6 months old and tends to be very vague. The companies "don't give a clear reason as to why there might be a shortage."

According to the researchers they have directly asked the pharmaceutical companies for details on their supply chains but none of them have been willing to share that information. Currently the FDA does not have any authority to compel discloser of this information. Pharmaceutical companies report shortages on a "voluntary basis."

As the COVID-19 pandemic evolves Wise Hospice Options will closely watch for supply chain issues. We will pass on pertinent information we learn as quickly as possible.



# FDA REQUESTS IMMEDIATE REMOVAL OF ALL RANITIDINE (ZANTAC) FROM THE MARKET (4/1/20)

The U.S. Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately.

This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by thebrand name Zantac). The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.



<u>To obtain full details you can follow this link:</u>
<a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html</a>



### DRUG SHORTAGE LIST

Albutaral (MDI)	7/2//20
Albuterol (MDI)  Attaching (Ini/Onth)	3/24/20
Atropine (Inj/Opth)	2/21/20
Dexamethasone (Inj)	3/18/20
Doxycycline Hyclate (Inj)	3/10/20
• Enoxaparin (Inj)	2/18/20
Erythromycin (Inj/Opth)	2/20/20
Famotidine (Inj/Tabs)	3/4/20
Fentanyl (Inj)	3/14/20
Furosemide (Inj/Oral)	3/2/20
• Heparin (Inj)	3/23/20
<ul> <li>Hydromorphone (Inj)</li> </ul>	3/6/20
Ketamine (Inj)	3/25/20
Ketorolac (Inj	3/23/20
<ul> <li>Levetiracetam (Inj/Tablets)</li> </ul>	3/23/20
Lorazepam (Inj/Oral)	3/14/20
• Losartan (Tabs)	3/9/20
Methadone (Inj)	2/19/20
Metronidazole (Inj)	3/16/20
Midazolam (Inj)	2/24/20
<ul> <li>Morphine (Inj/PCA vials/IR/tabs) ———</li> </ul>	3/20/20
Nitrofurantoin (Suspension)	1/29/20
Octreotide (Inj)	1/29/20
Ondansetron (HCL (Inj)	3/18/20
Pantoprazole (Inj)	3/14/20
Prednisone (Tablets)	
Prochlorperazine (Tablets)	
Promethazine (Inj)	
Ranitidine (Inj)	
Temazepam (Capsules)	
• Tramadol (Tablets)	
Valsartan (Tablets)	
Vancomycin HCL (Inj)	
Venlafaxine HCL (Tablets ER)	
• IVBags/Solutions (various)	
- IV Dags, Solutions (various)	5, 21, 20

