MEMO:

Date: March 26, 2020

To: Licensees, Registrants, Regulatory & Government Affairs and Colleagues in Healthcare

From: Nicki Chopski

Re: Rule 704 Medication Limitations addition, FDA and DEA updates

The Board of Pharmacy remains open during the extreme emergency declaration. The COVID FAQ on our website is updated daily as information evolves. Phone lines are open, though we are experiencing high call volumes. You may receive a faster response through use of info@bop.idaho.gov as it is monitored continually.

The Board conducted an emergency meeting this morning and promulgated additional language to the existing temporary rule 704. The rule is effective immediately. District Health Departments have verified patients can receive a copy of their test results through their provider.

Rule 704. Medication Limitations.

01. No prescription for chloroquine or hydroxychloroquine may be dispensed unless all of the following apply:
   a. The prescription bears a written diagnosis from the prescriber consistent with the evidence for its use;
   b. The prescription is limited to no more than a fourteen (14) day supply; and
   c. No refills may be permitted unless a new prescription is furnished.
   d. The provisions of subsections b and c do not apply if the patient was previously established on the medication prior to the effective date of this rule.

02. No prescription for oral azithromycin may be dispensed unless all of the following apply:
   a. The prescription bears a written diagnosis from the prescriber consistent with the evidence for its use;
   b. The prescription is limited to no more than a five (5) day supply; and
   c. No refills may be permitted
   d. The provisions of subsections b and c do not apply if the patient was previously established on the medication prior to the effective date of this rule. (3/26/2020)
FDA News - The FDA’s Intergovernmental Affairs (IGA) team would like to bring your attention to the following announcement concerning hydroxychloroquine.

The FDA added hydroxychloroquine sulfate to category 1 under the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act. The FDA does not intend to object to registered outsourcing facilities using hydroxychloroquine (or chloroquine phosphate, which was already on category 1), to compound human drugs provided the drugs meet other conditions and requirements in the FD&C Act. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The FDA is placing hydroxychloroquine sulfate on category 1 after it reviewed the nomination and determined there was sufficient information for the agency to evaluate the substance for outsourcing facilities to use in compounding. When FDA categorized hydroxychloroquine sulfate it did not change its approach, but we prioritized this substance due to the COVID-19 pandemic. There are currently no FDA approved therapeutics or drugs to treat, cure or prevent COVID-19; however, there are FDA-approved treatments that may help ease the symptoms of COVID-19. Additionally, state-licensed pharmacies and federal facilities that compound drugs under section 503A of the FD&C Act may compound drugs using hydroxychloroquine sulfate or chloroquine phosphate bulk drug substances because they are components of an FDA-approved drug, provide other requirements in the Act are met.

In addition, there is a significant surge in demand of chloroquine/hydroxychloroquine and FDA is doing everything possible to work with manufacturers to increase production. We are working with manufacturers to assess their supplies and are actively evaluating market demand for patients dependent on it for treatment of malaria, lupus and rheumatoid arthritis. But please know this is a fluctuating and dynamic situation we are actively engaged on.

Currently the manufacturers still have supply and are increasing production and we are working on that with them -now it’s a matter of continuing to meet demand and also making sure there is not a shortage for rheumatologic patients.

Please know that FDA will continue to do all we can to work with the firms to increase supplies to meet the ongoing demand and prevent shortages.

FDA encourages State Pharmacy Boards to consider policies to protect supply for patients who have existing prescriptions for these drugs that are non-COVID-19 related for conditions such as Lupus, Arthritis, Sjogren’s Syndrome, and other autoimmune disorders.

For general FDA-related inquiries, please feel free to contact FDA’s IGA staff at IGA@fda.hhs.gov.

DEA News - Dear Registrant,

Effective March 23, 2020, the DEA Call Center has temporarily suspended phone operations due to COVID-19 health epidemic. Assistance will only be available through DEA.Registration.Help@usdoj.gov. We will respond to your emails as quickly as possible.

Please register your e-mail address using the below link to obtain up to date information concerning DEA’s response to the COVID-19 health emergency.

https://public.govdelivery.com/accounts/USDOJDEADCD/subscriber/new

Please continue to direct all policy questions concerning COVID-19 to the Policy email box at Natural.Disaster@usdoj.gov