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Announcement 468

FDA Acetaminophen Dosage Announcement

On January 13, 2011, the U.S. Food and Drug Administration (FDA) announced new measures to reduce the risk of severe liver injury associated with acetaminophen. On July 28, 2011, the maker of Tylenol®, McNeil, announced new instructions to lower the maximum daily dose from 4,000 mg to 3,000 mg.

The FDA is requiring manufacturers to limit the acetaminophen content to 325 mg per dosage unit within the next 3 years.

- Acetaminophen is often combined with opiates (e.g., codeine, oxycodone and hydrocodone), which may contain more than 325 mg acetaminophen per tablet or capsule. There is NO evidence that taking more than 325 mg of acetaminophen per dosage unit provides more pain relief.

The FDA now requires a Boxed Warning on all prescription products highlighting the potential risk for severe liver injury.

- Unintentional overdose of acetaminophen is the leading cause of acute liver failure in the U.S. occurring when patients take multiple acetaminophen-containing products (e.g., Rx pain combinations and OTC products concomitantly) or when they take frequent doses of Rx pain combinations with more than 325 mg acetaminophen per tablet or capsule. Concurrent alcohol consumption has also been identified as a causative factor.

Pharmacists are requested to notify physicians when an acetaminophen dosage can exceed 3,000 mg in any 24-hour period.

- The risk of liver injury primarily occurs when patients exceed the current maximum dose of 3,000 mg within a 24-hour period. The new guidelines will allow patients to take up to 9 dosage units per day, which is still below the 3,000-mg daily maximum.

The Nevada Medicaid Drug Utilization Review (DUR) Board requests that physicians start using currently available products containing no more than 325 mg acetaminophen per tablet or capsule.

- hydrocodone/APAP 5/325 generic for Norco®
- oxycodone/APAP 7.5/325 generic for Percocet®

For more information and quantity guidelines, please refer to [Nevada Medicaid Services Manual \(MSM\) Chapter 1200](#) on the <http://dhcfp.nv.gov> website.