To: AmeriHealth Caritas Next and First Choice Next Providers

Date: May 9, 2023

Subject: **Akorn Issues Voluntary Nationwide Recall of Various Human and Animal Drug Products Within Expiry Due to Company Shutdown**

On May 4th, the U.S. Food and Drug Administration published that Akorn Operating Company LLC which had filed Chapter 7 bankruptcy on February 23, 2023, is removing several products from the market due to the discontinuation of the Quality program which would result in the company's inability to assure that products meet the identity, strength, quality, and purity characteristics. The company has ceased and shutdown all operations and terminated all its employees of all domestic US Sites. The Akorn Trustee is initiating a voluntary recall of various within-expiry human and animal products as a result of the closures and discontinuation of the Quality activities of these marketed products. (Refer to Attachment I and II*). The discontinuation of the Quality program means the company will not be able to support or guarantee that the products will meet all intended specifications through the labeled shelf life of the product. Further distribution or use of any remaining product on the market should cease immediately.

Risk Statement: The discontinuation of the Quality program would result in the company's inability to assure that products meet the identity, strength, quality, and purity characteristics that they are purported or represented to possess which render the products adulterated. While specific risks to patients, from use of these adulterated products, cannot always be identified or assessed, it is also not possible to rule out patient risks resulting from the use of such products. Akorn has not received any reports of adverse events related to this recall.

The affected products are listed in Attachment I (human drugs) and II (animal drugs) of this release. **Only products listed in the attachments are affected by the recall. Products not included in the press are continuing to be monitored under a Quality Program and will remain on the market.** The products were distributed nationwide to Wholesalers, Retailers, Manufacturers, Medical Facilities, and Repackagers and via the Internet to Consumers.

Consumers with questions regarding this recall can contact Akorn at (800) 932-5676 during normal business hours (8am – 5pm CDT) Monday – Friday. A qualified medical professional will return your call within one business day. Consumers should contact their physician, their healthcare provider or

veterinarian if they, or animals in their care, have experienced any problems that may be related to taking or using these drug products.

* Only products listed in the attachments are affected by the recall. Products not included in the press are continuing to be monitored under a Quality Program and will remain on the market.

Attachment I - List of Human Products (PDF - 231KB)

Attachment II – List of Veterinary Products (PDF - 220KB)

Please see the link below for more details.
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/update-akorn-issues-voluntary-nationwide-recall-various-human-and-animal-drug-products-within-expiry