SUBJECT: Extension of the Shelf Life Extension Program (SLEP) by the FDA

SUBMITTED BY: Richard Boyd, OMS-II, PharmD, RPh

REFERRED TO:

- WHEREAS, the healthcare system faces a multitude of medication shortages and high
 medication prices; and
- 3 WHEREAS, the FDA's Shelf Life Extension Program (SLEP) has 34 years of data
- supporting the extension of shelf life for over 122 medications by an average of 5.5
 years; and
- 6 WHEREAS, the FDA's program cost \$3.1 million annually to save the federal
- 7 government \$2.1 billion annually in medications that do not need discarded; and
- 8 WHEREAS, all hospital and retail pharmacies are held to the same environmental
- 9 control standards for the storage of medications that the federal government is
- 10 subjected to; and
- 11 WHEREAS, a significant increase in the availability of medications would occur if FDA
- expanded the SLEP program to all civilian hospital and retail pharmacies; and
- 13 WHEREAS, the safe extension of expiration dating on medications would result in a
- significant annual cost savings to the US healthcare system; now, therefore be it
- 15 RESOLVED, that the Ohio Osteopathic Association petition the US Food and Drug
- Administration (FDA) and the Congress of the United States for the expansion of the
- 17 Shelf Life Extension Program to all civilian hospital and retail pharmacies

ACTION TAKEN: _____

DATE: _____

References:

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Cantrell, F. Lee, et al. "Epinephrine Concentrations in EpiPens After the Expiration Date." Annals of Internal Medicine, vol. 166, no. 12, 20 June 2017.

Cantrell, Lee, et al. "Stability of Active Ingredients in Long-Expired Prescription Medications." Archives of Internal Medicine, vol. 172, no. 21, 26 November 2012.

Commissioner, Office of the. "Expiration Dating Extension." U.S. Food and Drug Administration, FDA, 8 Aug. 2020, <u>www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension</u>.

Diven, Dayna G., et al. "Extending Shelf Life Just Makes Sense." Mayo Clinic Proceedings, vol. 90, no. 11, 1 November 2015, pp. 1471-1474.

Lyon, Robbe C., et al. "Stability Profiles of Drug Products Extended Beyond Labeled Expiration Dates." Journal of Pharmaceutical Sciences, vol. 95, 7 July 2006, pp. 1549–1560.