RESOLUTION 45-16

Title: Pharmacy Benefit Managers and Compounded Medications

Introduced by: Domenic Federico, MD, for the Kent County Delegation

Original Author: David E. Hammond, MD

Referred to: Reference Committee A

House Action: **REFER**

Whereas, compounding pharmacies tailor and customize prescriptions in order to meet patients' needs for medications that are not commercially available, and

Whereas, many of these patients have problems with mass-produced medications including allergic reactions, inability to swallow pills, or a need for a different dosage or formulation than is available on the commercial market, and

Whereas, compounding pharmacies must have federal certification as a result of the Drug Quality and Security Act enacted in 2013, and

Whereas, compliance with this Act by compounding pharmacies requires acceptable manufacturing practices, proper labeling including directions for use, inspections of these pharmacies by the U.S. Food and Drug Administration (FDA) on a regular basis, and FDA approval prior to marketing compounding medications, and

Whereas, pharmacy benefit managers (PBMs) are hired by employers to manage their employee prescription drug coverage, and

Whereas, PBMs control the drug benefits of 210 million Americans of which 28 million are Medicare Part D patients, and

Whereas, the four largest PBMs in the U.S. are Express Scripts, CVS Caremark, Optum Rx (owned by United Healthcare), and Prime Therapeutics, and

Whereas, at the heart of the conflict between PBMs and compounding pharmacies is the fact that PBMs have used their position and power as health plan administrators to boycott compounding pharmacies by eliminating coverage for compounding ingredients, cutting off health network access, and devising various "gate keeper tactics" using unreasonable administrative mandates designed to deny prescriptions from being filled, and

Whereas, their intent is to cause a significant decline and potential elimination of independent compounding pharmacies from the health plan market, and

Whereas, PBMs have a conflict of interest in their gatekeeper role as they own a financial stake in a mail order business that competes with compounding pharmacies that use the U.S. Postal Service, UPS, and other delivery systems; thereby, representing a violation of Sherman Act anti-trust laws, and

Whereas, PBMs maintain that spending on compound medications has increased exponentially, and

Whereas, their solution to address these rising costs is to target and block thousands of ingredients used by compounding pharmacies that they claim are greatly inflated but provide no added clinical benefit, and

Whereas, one needs to question whether PBMs are qualified to evaluate clinical benefit or is it just part of their financial agenda in the $270 billion drug market, and

Whereas, PBMs have sent letters to patients and pharmacies containing inaccurate and misleading information about the safety and efficacy of compound medications. These letters to patients inform them there has been an unspecified change in their compound medication benefit plan although PBMs lack the authority to alter the terms of patient health care plans. These documents serve to cover up the financially driven scheme of PBMs to cut their compound spending by 95 percent, and

Whereas, this scheme has resulted in denial of care to thousands of patients as PBMs continue to issue unlawful blanket denials of compounded medications, and

Whereas, PBMs have engaged in retroactive audits of compounding pharmacies to claim back reimbursements for compounded scripts already filled citing the lack of FDA approval of the medications, and

Whereas, they have removed compounding pharmacies from provider networks by terminating agreements without just cause and often without knowledge of these compounding pharmacies, and

Whereas, PBMs have also threatened some physicians with accusations of fraud or abuse if they prescribe compounded medications, and

Whereas, as a result of their anti-competitive conduct, PBMs have continued to “line their pockets” financially at the expense of the most vulnerable patients in America; therefore be it

RESOLVED: That Michigan Delegation to the American Medical Association (AMA) ask our AMA to support federal regulation, consistent with existing anti-trust laws, that require pharmacy benefit managers to establish drug reimbursement plans for compounded medication based on medical need rather than financial concerns.

WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE