WHEREAS, Compounding pharmacies tailor and customize prescriptions 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 largest PBMs in the U.S. include Express Scripts, CVS Caremark, OptumRx, Argus, EnvisionRx, ProCareRX, 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; 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 our American Medical Association amend policy H-125.986 by addition as follows:

Pharmaceutical Benefits Management Companies H-125.986
Our AMA: (1) encourages physicians to report to the Food and Drug Administration’s (FDA) MedWatch reporting program any instances of adverse consequences (including therapeutic failures and adverse drug reactions) that have resulted from the switching of therapeutic alternates;

(2) encourages the Federal Trade Commission (FTC) and the FDA to continue monitoring the relationships between pharmaceutical manufacturers and PBMs, especially with regard to manufacturers’ influences on PBM drug formularies and drug product switching programs, and to take enforcement actions as appropriate;

(3) pursues congressional action to end the inappropriate and unethical use of confidential patient information by pharmacy benefits management companies;

(4) states that certain actions/activities by pharmacy benefit managers and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients;
(5) encourages physicians to routinely review their patient's treatment regimens for appropriateness to ensure that they are based on sound science and represent safe and cost-effective medical care; and

(6) supports Congressional action to ensure that reimbursement policies established by PBMs are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medications, and encourages the FTC and FDA to monitor PBMs' policies for potential conflicts of interests and anti-trust violations, and to take appropriate enforcement actions should those policies advantage pharmacies in which the PBM holds an economic interest. (Modify Current HOD Policy)

Fiscal Note: Not yet determined

Received: 05/02/18

RELEVANT AMA POLICY

Pharmaceutical Benefits Management Companies H-125.986
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(3) pursues Congressional action to end the inappropriate and unethical use of confidential patient information by pharmacy benefits management companies;
(4) states that certain actions/activities by pharmacy benefit managers and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients; and
(5) encourages physicians to routinely review their patient's treatment regimens for appropriateness to ensure that they are based on sound science and represent safe and cost-effective medical care.
Citation: BOT Rep. 9, I-97; Appended: Res. 224, I-98; Appended: Res. 529, A-02; Reaffirmed: Res. 533; A-03; Reaffirmation I-08; Reaffirmation A-10; Reaffirmed: Alt. Res. 806, I-17;