Whereas, The operations of third-party companies that manage specialty pharmacy benefits are an emerging national issue with significant negative effects on patients and the practice of medicine; and

Whereas, These entities contract to manage the specialty pharmacy portion of the drug formulary, generally for self-insured entities, and manage formularies, negotiate rebates, process claims, and pay pharmacies for prescriptions, like pharmacy benefit managers (PBMs); and

Whereas, Although these entities hold themselves out to be something new and different, the only difference from traditional PBMs is that they operate solely in the specialty pharmacy formulary; and

Whereas, These third-party administrators use heavy-handed tactics with physicians and patients to force the use of preferred prescriptions, with little transparency and opaque practices; and

Whereas, These entities generally use “proprietary algorithms” to determine the treatments to which a patient will have access, and are forcing patients to change medications with no clear method to override decisions made by the algorithm-- an affront to personalized medical care and to the physician and patient relationship; and

Whereas, The practices of these third-party companies amount to the practice of medicine. As an example, a common practice is a biologic taper program, overseen by staff of the entity, in which they and not the treating physician make decisions on the dosing and frequency of medication, with no transparency about who is making treating decisions or any data behind the tapering schedule; and

Whereas, As a result of the Supreme Court decision in Rutledge v. PCMA, states can require licensing, registration, and reporting for PBMs that operate in ERISA plans. Even if these entities are contracted directly with employers to manage specialty formularies, states can require licensing, registration, and transparency reporting; and
Whereas, Interest in the practices of PBMs has increased at the federal level as well, including federal legislative hearings and a review of PBM business practices by the Federal Trade Commission; and

Whereas, Because these organizations are newer to the healthcare landscape, they are not bound to PBM-related regulations or laws; therefore be it

RESOLVED, That our American Medical Association recommend that third-party pharmacy benefit administrators that contract to manage the specialty pharmacy portion of drug formularies be included in existing pharmacy benefit manager (PBM) regulatory frameworks and statutes, and be subject to the same licensing, registration, and transparency reporting requirements (New HOD Policy); and be it further

RESOLVED, That our AMA advocate that third-party pharmacy benefit administrators be included in future PBM oversight efforts at the state and federal levels. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/13/22

RELEVANT AMA POLICY

The Impact of Pharmacy Benefit Managers on Patients and Physicians D-110.987
1. Our AMA supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. Our AMA supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. Our AMA supports efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. Our AMA supports improved transparency of PBM operations, including disclosing:
   - Utilization information;
   - Rebate and discount information;
   - Financial incentive information;
   - Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee’s formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;
   - Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
   - Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
   - Percentage of sole source contracts awarded annually.
6. Our AMA encourages increased transparency in how DIR fees are determined and calculated.
CMS Rep. 05, A-19Reaffirmed: CMS Rep. 6, I-20

Pharmacy Benefit Managers Impact on Patients D-120.933
Our AMA will: (1) gather more data on the erosion of physician-led medication therapy management in order to assess the impact pharmacy benefit manager (PBM) tactics may have on patient’s timely access to medications, patient outcomes, and the physician-patient relationship; (2) examine issues with PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts; and (3) request from PBMs, and compile, data on the top twenty-five medication precertification requests and the percent of such requests approved after physician challenge.

Res. 225, A-18

**Interference in the Practice of Medicine D-125.997**

Our AMA shall initiate action by whatever means to bring a halt to the interference in medical practice by pharmacy benefit managers and others.


**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;

(6) supports efforts 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

(7) 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 disadvantage pharmacies in which the PBM holds an economic interest.