REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (A-19)
The Impact of Pharmacy Benefit Managers on Patients and Physicians
(Reference Committee A)

EXECUTIVE SUMMARY

At the 2018 Annual Meeting, the House of Delegates adopted Policy D-120.933, "Pharmacy Benefit Managers Impact on Patients." The Board of Trustees assigned the following provisions of the policy to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting:

> Our American Medical Association (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; and (2) examine issues with PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts.

PBMs no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity with utilization management tools. The Council believes that PBMs' role managing drug benefits now resembles the typical role of insurers, and they should be treated as such by regulators. Overall, regulators must better understand and control the costs to patients and the systems that are resulting from PBM practices. As such, the Council recommends that PBMs be actively regulated under state departments of insurance. To implement this new policy, the Council believes that our AMA should develop model state legislation addressing state regulation of PBMs. On the federal level, the Council believes that PBMs, like health plans, should be subject to federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.

The Council recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders – but not patients. The Council is concerned that the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor manufacturers currently have an incentive to lower list prices. As such, the Council questions whether rebates that are being negotiated by PBMs are resulting in any true savings. The disclosure of rebate and discount information, financial incentive information, and pharmacy and therapeutics (P&T) committee information would constitute critical steps toward improved transparency. The Council also believes that manufacturer rebates and pharmacy price concessions should be applied to drug prices at the point-of-sale. This policy, which also applies directly to DIR fees, would add much needed transparency and ensure that beneficiaries benefit from discounts, and dispensing physicians and practice-based pharmacies have more clarity regarding their true reimbursement rates.

In order to maintain cost transparency for patients and keep patients stable on their medications, the Council also recommends the reaffirmation of policies addressing mid-year formulary changes and utilization management requirements. These practices employed by PBMs can undermine the ability of patients to have timely access to the medically necessary treatment that they need.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-A-19

Subject: The Impact of Pharmacy Benefit Managers on Patients and Physicians

Presented by: James G. Hinsdale, MD, Chair

Referred to: Reference Committee A
(John Montgomery, MD, MPH, Chair)

At the 2018 Annual Meeting, the House of Delegates adopted Policy D-120.933, "Pharmacy Benefit Managers Impact on Patients." The Board of Trustees assigned the following provisions of the policy to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting:

> Our American Medical Association (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; and (2) examine issues with PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts.

This report provides background on PBM operations and market conditions, outlines issues of concern for patients and physicians with respect to PBM operations; and presents policy recommendations.

BACKGROUND: PHARMACY BENEFIT MANAGER OPERATIONS AND MARKET CONDITIONS

PBMs represent payers, including health insurers and self-insured employers, to negotiate discounts on the prices of prescription drugs and rebates based on volume of sales with pharmaceutical companies. In turn, payers determine which drugs to cover and how much patients pay. The role of PBMs as "middlemen" among payers, pharmaceutical companies and pharmacies goes beyond the negotiation of drug prices on behalf of their clients. PBMs are more frequently fully administering the drug benefit of their clients, creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. They also create networks of pharmacies and negotiate reductions in dispensing fees.

In general, PBMs have three primary revenue sources:

1. Fees from payers for claims administration and drug dispensing;

2. A percentage of the savings secured from rebates and discounts negotiated from pharmaceutical companies; and

3. Fees and savings associated with maintaining pharmacy networks.

The PBM market is highly concentrated: three PBMs – Express Scripts, CVS Caremark and OptumRx – control more than 70 percent of the market.[1] These three PBMs, by representing so many covered lives, have substantial bargaining power in their negotiations with drug manufacturers. Complicating the market concentration is the trend toward PBMs merging with health insurers, and how that could impact pharmacy networks available to patients. CVS-Aetna announced their proposed merger in December of 2017. The US Department of Justice (DOJ) has approved the CVS-Aetna merger, contingent on a federal court approving a settlement in which Aetna has agreed to divest its Medicare Part D prescription drug plan business. At the time this report was written, a federal court is reviewing that settlement. Cigna-Express Scripts announced their intention to combine in March of 2018. The Cigna-Express Scripts merger has been approved and is being consummated. Pertaining to PBM operations, the health insurers in these instances are trying to merge with the entity that is providing them with PBM and pharmacy services. Concerns have been raised by the AMA and others that the CVS-Aetna merger could substantially lessen competition in PBM services, health insurance, retail pharmacy, Medicare Part D, and specialty pharmacy.[2]

OPERATIONS OF PHARMACY BENEFIT MANAGERS: ISSUES OF CONCERN FOR PATIENTS AND PHYSICIANS

Insufficient Regulation

While most states have laws that regulate various aspects of PBM operations, such laws are rather limited in nature, and do not necessarily reflect the roles that PBMs have assumed in fully administering the drug benefit of their clients. State laws that regulate aspects of PBM operations generally fall into the following categories:

- Requiring a PBM to register with or be licensed by the state, in order to conduct business in the state;
- Specifying pharmacy audit procedures by PBMs, including outlining audit appeals mechanisms, audit notification requirements, how frequently audits can occur and what can be audited;
- Outlining conflict of interest provisions with respect to pharmacy and therapeutics (P&T) committees and other areas;
- Requiring transparency in the development and utilization of maximum allowable cost (MAC) lists, which list the maximum amount a PBM will pay for drugs;
- Prohibiting "gag clauses" in PBM-pharmacy contracts;
- Enacting "anti co-pay clawback" provisions that aim to prevent patient co-payments from exceeding the full cost of the drug;
- Imposing a fiduciary duty on a PBM to the entity with which it contracts; and
- Imposing a performance duty on a PBM, which requires a PBM to operate in good faith with the entity with which it contracts.

On the federal level, the function PBMs have assumed in administering the drug benefit of their clients raise the issue of if, and to what extent, PBMs are currently subject to federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity. Concerns have been raised that clarity is needed in this regard, as while they are not a health plan, they are operating very much like one pertaining to drug benefits.

AMA Policy and Advocacy Regarding Regulation

Policy D-185.995 puts PBMs on the same footing as public and private sector payers, by stating that our AMA will (1) advocate our policies related to health plan coverage of prescription drugs to PBMs, as well as to public and private sector payers; and (2) advocate for the enactment of legislation consistent with AMA policies related to health plan coverage of prescription drugs. Accordingly, the multitude of AMA policies addressing formulary requirements and transparency, utilization management, mental health parity and other issues are applicable to PBMs in addition to health plans.

Policy H-125.986 provides significant guidance with respect to federal regulation of PBM operations. The policy: 1) encourages the Federal Trade Commission (FTC) and the Food and Drug Administration (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; 2) states that certain actions/activities by PBMs and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients; 3) 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 4) encourages the FTC and FDA to monitor PBMs' policies for potential conflicts of interest and anti-trust violations, and to take appropriate enforcement actions should those policies advantage pharmacies in which the PBM holds an economic interest.

In its comments in response to the *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint)* in July of 2018, the AMA outlined its support for regulating PBMs, stating that the benefit management of PBMs now resembles the typical role of insurers, and they should be treated as such by regulators. Also in July, the AMA submitted a letter in support of the efforts of the National Council of Insurance Legislators (NCOIL) in developing a draft state model act to require licensure of PBMs in the state and allow for oversight by the department of insurance or other equivalent regulatory agency. Additionally, the AMA has advocated for the National Association of Insurance Commissioners (NAIC) to include in its pharmacy benefit model legislation the regulation of PBM activities.

Lack of Transparency

The Council recognizes that the ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. The opaque nature of PBM negotiations of drug prices has raised questions whether the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor drug manufacturers currently have an incentive to lower list prices. In addition, there is a lack of transparency regarding what percent of the savings associated with rebates are passed through to patients or payers. The degree to which savings are passed on to payers and patients impacts health plan premiums as well as cost-sharing requirements.

Concerns have also been raised by physicians and their patients pertaining to transparency in formularies, prescription drug cost-sharing requirements, and utilization management requirements. This lack of transparency makes it exceedingly difficult for physicians to determine what treatments are preferred by a particular payer at the point-of-care, what level of cost-sharing their patients will face, and whether medications are subject to any step therapy or other utilization

management requirements. For patients, lack of transparency in their drug coverage may lead to delays in necessary medication treatment, as well as being unaware of their formulary and cost-sharing responsibilities, which can lead to an inability to afford the medications they need. Such lack of transparency is exacerbated when formularies are changed mid-year, which can have negative effects on patients and can have a major impact on health care costs. Actions of PBMs to remove a medication from a patient's formulary during the middle of the plan year and replace it with another medication that is not effective for the patient – or which the patient has previously tried and not done well on – could result in potential trips to the emergency room and/or hospitalizations, increased out-of-pocket costs if the patient is responsible for paying for the drug, and potential physician and patient resources spent on appeals and alternative solutions.

AMA Policy and Advocacy regarding Transparency

The AMA has been highly engaged in efforts to promote the transparency of PBM practices and operations, resulting from the adoption of Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs and health insurance companies. Addressing mid-year formulary changes specifically, Policy H-125.979 states that drugs may not be removed from the formulary nor moved to a higher cost tier within a patient's health plan policy term. To expose the opaque process that pharmaceutical companies, PBMs, and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency, the AMA launched a grassroots campaign and website, TruthinRx.org, in 2016. At the time this report was written, more than 338,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency, with the campaign also generating more than one million messages sent to Congress demanding drug price transparency.

PBM transparency has also been a key theme highlighted in federal advocacy efforts related to drug pricing. In its comments in response to the proposed rule *Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-Of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* in April 2019, the AMA supported applying manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale, and requiring PBMs to disclose a wide range of information, including additional information about their fee arrangements. In its statement for the record to the US House of Representatives Committee on Oversight and Reform on examining the actions of drug companies in raising prescription drug prices in January 2019, the AMA supported requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices; requiring increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections; and prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons. These concerns were echoed in the comments of the AMA submitted in response to *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint)* in July 2018.

In addition, in August 2018, the AMA submitted a letter in support of S 2554, the "Patient Right to Know Drug Prices Act," which has since become law. The law prohibits health insurers and PBMs from using "gag clauses" that prevent pharmacists from sharing with patients the lower cost options when patients are purchasing medically necessary medication. In addition, the law will ensure that the FTC will have the necessary authorities to combat anti-competitive pay-for-delay

settlement agreements between manufacturers of biological reference products and follow-on biologicals.

In March 2019, the AMA submitted a letter that supported HR 1781, the Payment Commission Data Act of 2019. If enacted into law, the bill would provide access to essential data that the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) need to evaluate the practices of various entities within the pharmaceutical supply chain that are either not readily available or not available at all for independent analysis, including drug pricing and rebate data. In its letter, the AMA noted that the lack of independent, data driven, third-party analysis of drug pricing and rebate data continues to hamstring additional efforts needed to combat anti-competitive business practices that undermine affordability and harm patients.

Concerning state-level advocacy, the AMA developed model state legislation entitled, "An Act to Increase Drug Cost Transparency and Protect Patients from Surprise Drug Cost Increases during the Plan Year" (AMA Model Act), which addresses the issues of stabilized formularies and cost transparency. In particular, the AMA Model Act requires PBMs operating in the state to disclose any discounts or other financial consideration they received that affect the price and cost-sharing of covered medicines placed on a formulary. In addition, the AMA has model state legislation that prohibits clawbacks and standard gag clauses in pharmacy-PBM contracts.

PBM Clawbacks and Direct and Indirect Remuneration Fees

DIR is a term used by the Centers for Medicare & Medicaid Services (CMS) to refer to compensation Medicare Part D plan sponsors or their PBMs receive after the point-of-sale, including rebates provided by drug manufacturers and concessions paid by pharmacies. Concessions paid by pharmacies – which can include dispensing physicians and practice-based pharmacies – can comprise of network participation fees and reimbursement reconciliations. Such additional compensation after the point-of-sale, therefore, changes the final cost of drugs for payers, or the prices paid to pharmacies for drugs. In Part D, DIR impacts Medicare payments to Part D plans. However, DIR fees or similar fee mechanisms are being used in the commercial marketplace as well.

The concern raised in Policy D-120.933, was directed not toward the role of DIR in capturing rebates from pharmaceutical companies, but the impact of DIR fees on pharmacies. The Council recognizes that such fees have negatively impacted some physicians who conduct in-office dispensing and/or have practice-based pharmacies. If DIR fees are not collected from pharmacies on a real-time basis, but rather after transactions take place, pharmacies and affected physician specialties have raised concerns that there exists a lack of clarity regarding their true reimbursement rates. In addition, such entities have cited a need for additional transparency regarding how DIRs are determined and calculated.

In November 2018, the Centers for Medicare & Medicaid Services issued a proposed rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," that contains potential policy recommendations that would respond to the concerns raised in Resolution 225-A-18 concerning the impact of DIR fees on pharmacies. The proposed rule considers having DIR fees be accounted for and applied at the point-of-sale, which impacts the predictability of pharmacy reimbursement rates as well as patient cost-sharing.[3]

AMA Policy and Advocacy regarding Clawbacks and DIR Fees

Policy H-110.991 states that our AMA will disseminate model state legislation to promote increased drug price and cost transparency and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and PBMs that bar pharmacists from telling consumers about less-expensive options for purchasing their medication. Accordingly, in January 2019, the AMA submitted comments in response to the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. In its comments, the AMA supported the proposed changes to the definition of "negotiated price" and other related changes that were outlined to ensure reduction in cost burden by beneficiaries at the point-of-sale for Part D prescription drugs, increased transparency, and enhanced competition among Part D plan sponsors. Further, the AMA noted that "when all pharmacy price concessions are not reflected in the price of a drug at the point-of-sale, beneficiaries do not benefit through a reduction in the amount that they must pay in cost-sharing and pay a larger share of the actual cost of a drug."

Utilization Management Requirements

When PBMs administer the drug benefits of payers, they have the ability to make coverage decisions and implement utilization management requirements that interfere with patients receiving the optimal treatment selected in consultation with their physicians. At the very least, utilization management requirements can delay access to needed care; in some cases, the barriers to care imposed by prior authorization and step therapy may lead to the patient receiving less effective therapy, no treatment at all, or even potentially harmful therapies. For physician practices, utilization management requirements often involve very manual, time-consuming processes that can divert valuable and scarce physician resources away from direct patient care.

The 2018 AMA Prior Authorization Physician Survey provides insight into the impact that PBM utilization management requirements can have on patients and physician practices. In response to the survey, more than nine in 10 physicians (91 percent) responded that the prior authorization process delays patient access to necessary care, and three-quarters of physicians (75 percent) report that prior authorization can at least sometimes lead to patients abandoning a recommended course of treatment. In addition, more than nine in 10 physicians (91 percent) reported that prior authorization programs have a negative impact on patient clinical outcomes. Of significant concern, 28 percent of physicians reported that prior authorization led to a serious adverse event for a patient in their care. The survey findings also showed that every week, a medical practice completes an average of 31 prior authorization requirements per physician, which take the equivalent of nearly two business days (14.9 hours) of physician and staff time to complete. To keep up with the administrative burden, more than a third of physicians (36 percent) employ staff members who work exclusively on tasks associated with prior authorization.[4]

In addition, a US Department of Health and Human Services (HHS) Office of Inspector General (OIG) review of Medicare Advantage service denials in 2014-2016 reinforces the point that utilization management requirements can prevent patients from receiving medically necessary care. The OIG found that more than 116,800 prior authorization requests that were initially denied were eventually overturned on appeal. These overturned denials represent specific drugs/services that were medically necessary and the patient needed the treatment. The Council notes that this figure is particularly concerning because beneficiaries and providers appealed only one percent of denials.[5]

AMA Policy and Advocacy regarding Utilization Management Requirements

Policy H-320.939 supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. Policy H-285.965 outlines AMA policy objectives addressing managed care cost containment involving prescription drugs. Policy D-330.910 states that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the CMS and other appropriate organizations to resolve them. Policy H-320.958 states that our AMA will advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession.

To educate the general public about the problems associated with prior authorization and to gather stories from physicians and patients about how they have been affected by it, the AMA launched a grassroots website, FixPriorAuth.org, in July 2018. At the time that this report was written, there have been 10 million social media impressions, more than 500 patient and physician stories have been captured, and approximately 90,000 petitions have been signed.

In addition, the AMA has been very active in advocating for a reduction in both the number of physicians subjected to prior authorization and the overall volume of prior authorizations. In January 2017, the AMA and a coalition of state and specialty medical societies, national provider associations, and patient organizations developed and released a set of 21 Prior Authorization and Utilization Management Reform Principles intended to ensure that patients receive timely and medically necessary care and medications and reduce the administrative burdens. More than 100 other health care organizations have supported those principles. In January 2018, the AMA joined the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association and Medical Group Management Association in a Consensus Statement outlining a shared commitment to industry-wide improvements to prior authorization processes and patient-centered care. Additionally, the AMA has model legislation addressing prior authorization and utilization management programs that are often employed by PBMs, and works closely with many state and specialty medical societies to enact legislation each year.

Concerning federal advocacy, the AMA submitted comments in response to the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule, and raised significant concerns with the proposal to allow Part D plans to apply more prior authorization and step therapy requirements to protected class drugs. In its comments submitted in November 2018 in response to the proposed rule to modify Medicare regulations to promote program efficiency, transparency, and burden, the AMA urged CMS to reinstate its 2012 policy prohibiting Medicare Advantage plans from using step-therapy protocols for Part B physician-administered medications; and to carefully consider the care delays associated with prior authorization and the resulting impact on beneficiaries and their health and well-being when evaluating any additional prior authorization requirements for the Medicare program.

DISCUSSION

The Council recognizes that PBMs no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity with utilization management tools. The Council believes that PBMs' role managing drug benefits now resembles the typical role of insurers, and

they should be treated as such by regulators. Overall, regulators must better understand and control the costs to patients and the systems that are resulting from PBM practices. As such, the Council recommends that PBMs be actively regulated under state departments of insurance. To implement this new policy, the Council believes that our AMA should develop model state legislation addressing state regulation of PBMs. On the federal level, the Council believes that PBMs, like health plans, should be subject to federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.

The Council recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders – but not patients. The Council is concerned that the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor manufacturers currently have an incentive to lower list prices. As such, the Council questions whether rebates that are being negotiated by PBMs are resulting in any true savings. Moreover, the Council notes there is insufficient evidence regarding what percent of the savings associated with rebates are being passed through to patients or to payers.

To improve transparency in this space, the disclosure of rebate and discount information, financial incentive information, and P&T committee information would constitute critical steps forward. The Council also believes that manufacturer rebates and pharmacy price concessions should be applied to drug prices at the point-of-sale. This policy, which also applies directly to DIR fees, would add much needed transparency and ensure that beneficiaries benefit from discounts, and dispensing physicians and practice-based pharmacies have more clarity regarding their true reimbursement rates. As these policy changes are implemented, the Council believes that it will be essential to monitor their impact on premiums, medication list prices, and the discount/rebate structure.

In order to maintain cost transparency for patients and keep patients stable on their medications, the Council urges improved transparency in formularies, prescription drug cost-sharing, and utilization management requirements. Requirements and restrictions should be easily accessible by patients and prescribers and unless a change is made for safety reasons, PBMs and health plans should be prohibited from making changes during the duration of the patient's plan year. As such, the Council recommends the reaffirmation of Policy H-125.979.

Utilization management practices employed by PBMs can undermine the ability of patients to have timely access to the medically necessary treatment that they need. The Council notes that reaffirming existing AMA policies helps to highlight the need for new and additional efforts to track and quantify the impact of PBMs' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. Existing AMA policies also aim to protect patients in managed care cost containment practices involving prescription drugs, and state that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the CMS and other appropriate organizations to resolve them.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) support the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance. (New HOD Policy)

2. That our AMA develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight. (Directive to Take Action)

3. That our AMA support 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. (New HOD Policy)

4. That our AMA support 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. (New HOD Policy)

5. That our AMA support 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. (New HOD Policy)

6. That our AMA encourage increased transparency in how DIR fees are determined and calculated. (New HOD Policy)

7. That our AMA reaffirm Policy H-125.979, which aims to prohibit drugs from being removed from the formulary or moved to a higher cost tier during the duration of the patient's plan year. (Reaffirm HOD Policy)

8. That our AMA reaffirm Policy H-320.939, which supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. (Reaffirm HOD Policy)

9. That our AMA reaffirm Policy H-285.965, which outlines AMA policy objectives addressing managed care cost containment involving prescription drugs. (Reaffirm HOD Policy)

10. That our AMA reaffirm Policy D-330.910, which states that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare & Medicaid Services and other appropriate organizations to resolve them. (Reaffirm HOD Policy)

11. That our AMA reaffirm Policy H-320.958, which states that our AMA will advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession. (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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