

AMA develops Rx for drug prices that are high and rising

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Arbitration in determining prescription drug prices is a viable mechanism to address the burden of high and escalating pharmaceutical prices in the U.S. market and builds upon existing policy in favor of drug-price negotiation—and opposed to price controls, says an AMA Council on Medical Services report whose recommendations were adopted at the 2019 AMA Interim Meeting in San Diego.

“Using arbitration will help rebalance the importance of prescription drug affordability with the need for innovation, as an alternative to the status quo, which allows unilateral price setting of drugs by manufacturers without regard to patient access and affordability,” says the report. “Importantly, arbitration provides an incentive for drug manufacturers and payers to arrive at a negotiated price.”

Legislative proposals have also been introduced that would use the average of a drug’s price internationally to serve as an upper limit in drug price negotiations, set a drug’s price or determine whether a drug’s price is “excessive” to trigger additional interventions. The report recommends safeguards to ensure that such international drug price averages are used in a way that uphold market-based principles and preserve patient access to necessary medications.

“As prescription drug prices have spiked, the AMA has strongly advocated for more competition and transparency in the pharmaceutical marketplace to protect patients,” said AMA President Patrice A. Harris, MD, MA.

“There are situations in which payers have weakened bargaining power to negotiate lower drug prices due to a drug’s lack of competition in the marketplace, which means patients are left with high out-of-pocket costs and questioning whether they will be able to afford the medications they need,” Dr. Harris said. “Physicians decided that additional AMA policy was needed to guide advocacy efforts on the use of arbitration and other innovative proposals to promote reasonable drug pricing.”

Delegates adopted policy supporting the use of arbitration in determining the price of prescription drugs that meet the following standards to lower the cost of prescription drugs without stifling innovation. Such arbitration processes should:

- Be overseen by objective, independent entities that have the authority to select neutral arbitrators or an arbitration panel.
- Require arbitrators to disclose of conflicts of interest and have safeguards to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process.
- Be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question.
- Include the submission of a value-based price for the drug in question to inform the arbitrator's decision.
- Require arbitrators to choose either the bid of the pharmaceutical manufacturer or the bid of the payer.
- Be used for pharmaceuticals that have insufficient competition, have high list prices or have experienced unjustifiable price increases.
- Include a mechanism for either party to appeal the arbitrator's decision.
- The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.

Delegates also adopted policy to guide the AMA's position on legislative and regulatory proposals that propose the use of international price averages in determining price and payment for drugs.

- Any international drug price index or average should exclude countries that have single-payer health systems and use price controls.
- Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation.
- The use of any international drug price index or average should preserve patient access to necessary medications.
- The use of any international drug price index or average should limit burdens on physician practices.
- Any data used to determine an international price index or average to guide prescription drug pricing should be updated regularly.

Delegates also adopted policy supporting "the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction."