REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-25

Subject: Payment for Biosimilars

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Referred to: Reference Committee J

At the 2025 Annual Meeting, the House of Delegates referred Resolution 103, "Inadequate Reimbursement for Biosimilars," which was sponsored by the American Society for Gastrointestinal Endoscopy, the American College of Rheumatology, and the American Gastroenterological Association and asked the American Medical Association (AMA) to:

> Work with stakeholders to advocate for legislation that amends section 1847A(c)(3) of the Social Security Act to remove manufacturer rebates from the average sales price (ASP) payment structure for biologics.

The following report discusses the history and adoption of biosimilars in the United States (U.S.) as well as existing and potential alternative payment structures and their impacts. Additionally, this report reviews AMA policy and advocacy on the topic and offers recommendations in line with Resolution 103-A-25.

BACKGROUND

A biosimilar drug is a type of biologic that is similar to a Food and Drug Administration (FDA) approved branded biologic, or reference medication. Biosimilars are produced by living organisms and are required to have no meaningful clinical differences in safety, potency, or purity from a reference medication.[1] While similar to the idea of generic versus branded medications, biosimilars differ in that they are not an exact copy of the branded reference drug but rather have slight differences in the chemical makeup from the reference medication.[1,2] Biosimilar adoption in the U.S. was initiated later than the European market, with the first U.S. biosimilar gaining FDA approval in 2015, nine years after introduction in European markets.[3] Biosimilar adoption in the U.S. was relatively slow for the first five years with only nine drugs on the market by 2020. However, the last five years have shown relatively significant growth in this market with 72 biosimilars FDA approved as of July 2025.[3,4] While recent years have shown growth in the U.S. biosimilar market and adoption, estimates still only place usage around a quarter of the overall market share.[5] This is particularly important, as biosimilars provide a potential opportunity for significant savings for patients, providers, and payers. Biologics are exceptionally expensive, often the most expensive drugs available, and cost the U.S. health care system over $250 billion in 2024.[5,6,7] More specifically, recent reports have found that biologics make up about 46 percent of all pharmaceutical spending in the U.S. but only represent two percent of US prescriptions.[5,7] Biosimilars are a much cheaper alternative that can produce similar clinical outcomes at a fraction of the cost. For example, in 2023 biosimilar usage saved over $12 billion with only 57 approved medications. Additionally, research has demonstrated that the adoption of biosimilars has increased patient access to treatment.[6,7]

While there is no single direct cause for the initially slow uptake of biosimilars in the U.S., it seems that patient and physician hesitancy, oversight/regulation, and a lack of insurance coverage have contributed significantly. Specifically, both patients and physicians have voiced concerns regarding the safety, efficacy, and immunogenicity of biosimilars. However, research suggests that educational campaigns may be successfully dissuading these concerns.[8,9] Additionally, regulations and legislation around biosimilars and their adoption/approval process may have initially slowed the uptake.[10] However, through the Patient Protection and Affordable Care Act (ACA) Biologics Price Competition and Innovation Act, Congress passed an abbreviated licensure pathway in order to encourage increases in biosimilar approval in the U.S. through a more efficient approval process.[11] In addition to federal regulation, the majority of states have passed legislation allowing for the automatic substitution of biosimilars for a prescribed reference medication by a pharmacist. Importantly, in these states, physicians are able to prevent automatic substitution by indicating that the prescription be "dispensed as written."[10] Council on Medical Service Report 4-I-24, Biosimilar Coverage Structures, presents a detailed review of patient and physician attitudes towards biosimilars and the related legislative and regulatory history.

BIOSIMILAR COVERAGE

In addition to the aforementioned barriers to adoption, biosimilar coverage has proved to be a significant roadblock to increasing use. Payers have historically not incentivized patients or physicians to utilize biosimilars and in many cases actually incentivized the use of the more expensive reference medications.[8] It seems that this incentivization is primarily done through rebates offered by manufacturers, typically via negotiations done by pharmacy benefit managers (PBMs).[11] It is hypothesized that due to the higher list price of biologics, payers are able to negotiate greater rebates, making that medication, rather than the biosimilar, more financially lucrative for the payer.[5,11] As a result, payers may not include biosimilar medications on preferred formulary tiers or may deny coverage altogether. However, these rebates are rarely, if ever, passed along to the patient, resulting in higher patient out-of-pocket (OOP) costs and, in many cases, physicians being influenced to prescribe based on the financial incentive to the payer and/or PBM.[5,6,11] More detailed information about PBMs practices and formularies can be found in Council on Medical Service Report 5-A-19, The Impact of Pharmacy Benefit Managers on Patients and Physicians and Council on Medical Service Report 9-A-25, Minimum Requirements for Medication Formularies.

Research indicates that some payers are beginning to become less restrictive regarding biosimilar coverage. A 2020 study indicated that among major private insurance plans, only 12 percent of plans placed at least half of biosimilar medications on the "preferred" tier, and significant coverage restrictions were imposed in nearly 20 percent of cases.[8,13] Recent decisions from major payers indicate that coverage may be trending toward biosimilars, especially among higher cost biologics. For example, major payers and their associated PBMs recently announced movement away from coverage of the biologic Humira® (adalimumab) and toward coverage of its many biosimilars. Specifically, both CVS Caremark and Cigna Express Scripts, two of the three largest U.S. PBMs, recently announced that they would be removing Humira® from national template formularies and that coverage of Humira® biosimilars would be added.[14,15] While the third major PBM, Optum Rx, still includes Humira® in its formulary, its biosimilars are placed more favorably.[16] Even though Humira® and its biosimilars are subcutaneously injected drugs, and, therefore, not necessarily indicative of coverage trends among infused drugs, these examples illustrate how payers are not only increasing coverage of biosimilars but encouraging their use through diminished utilization management and/or cost sharing requirements.

Similar to private insurance coverage, Medicare and Medicare Advantage (MA) plans seem to be trending towards increased biosimilar coverage, if at a slightly slower pace than private plans.[17] Research suggests that when Medicare does cover biosimilars, they are placed on the same formulary tier as the reference biologic. While this is not necessarily harmful to the uptake of biosimilars, it also does not provide an incentive for patients to switch to the lower cost biosimilar.[17] Compared to traditional Medicare plans, MA plans seem to be incentivizing the switch to biosimilars via increased utilization management and/or higher cost-sharing for reference drugs.[18] As a direct comparison to the aforementioned Humira® coverage example, recent research demonstrated that 96 percent of Medicare Part D plans and 88 percent of MA plans include coverage for at least one Humira® biosimilar, with the vast majority requiring the same cost-sharing and utilization management for Humira® and its biosimilars. Importantly, under Medicare coverage, non-infused biologics, like Humira® and its biosimilars, are covered under Part D while infused drugs are covered under Part B. However, these findings indicate that while most Medicare/MA plans offer coverage for biosimilars, these plans are not incentivizing the use of biosimilars as many major private plans are.[17,19]

Importantly, federal legislation has been implemented in an effort to increase Medicare usage of biosimilars. For example, the Bipartisan Budget Act of 2018 offered extended manufacturer discounts and lowered plan contributions for biosimilars.[20] After the implementation of this legislation coverage of biosimilars by Medicare Part D plans increased 23 percentage points.[17] Additionally, the passage of the Inflation Reduction Act of 2022 (IRA) introduced significant changes to the coverage of prescription drugs, such as a change in OOP caps and federal subsidies and enhanced payment for biosimilar usage.[21] While the impact of the IRA has not been as dramatic as the 2018 budget, there has been a measurable impact on the biosimilar market. Research has indicated that 59 percent of practitioners reported their facilities had a slight or significant increase in biosimilar usage due to the increased add-on payment introduced in the IRA. However, this same study revealed that around 20 percent of practitioners reported a slight or significant decrease in usage and 20 percent of practitioners reported no change.[22] While the recently passed One Big Beautiful Bill Act does not directly address biosimilars, it is likely that due to an increase of uninsured individuals, there will be a decrease in overall federal drug spending.[23] Additionally, the Trump Administration has produced two executive orders aimed at decreasing drug prices, with one specifically calling for an increase in biosimilar availability as an avenue to decrease spending.[24,25]

BIOSIMILAR PAYMENT STRUCTURES

While biosimilar coverage has been slowly increasing by both public and private payers, the current payment structure is putting many physicians and their offices in significant financial distress. Per the Social Security Act, Medicare payment rates under Part B coverage for infused biologics/biosimilars are set at 106 percent of the ASP, often referred to as “ASP 6.” Although this rate was temporarily increased for lower cost biosimilars by the IRA to an eight percent add on rate, or ASP 8, this increase is only guaranteed through the end of 2027.[5,6,21] As outlined in legislation, ASP is calculated as the sales of a drug to all purchasers in the last quarter (“manufacturer price”) divided by the total number of units sold in the same quarter. While this seems like a relatively straightforward calculation, a number of concessions are included in the manufacturer price. Specifically, manufacturer-reported volume, prompt-pay, and cash discounts, chargebacks, and rebates are taken into account when calculating the ASP based payment rate.[6,26] These concessions, particularly rebates, can lead to rebate “walls” (sometimes referred to as rebate traps). While not specifically intended to lower payments rates to physicians/practices, these rebate walls often impact the ASP calculation by lowering the quarterly sales prices and, as a result, lowering the payments to practices.[27,28] These payment structures have become especially

problematic for physicians when prescribing infused biosimilars. Importantly, although private payers are not required to utilize an ASP payment system for biologics/biosimilars, many choose to follow the lead of the Centers for Medicare & Medicaid Services (CMS) and utilize this payment structure.

These infused biologic medications are covered by Medicare Part B, and many private payers, under a "buy-and-bill" model, meaning that physicians/practices purchase the drug and then bill the payer after the drug is administered with payments coming quarterly via a set fee schedule.[6,28] This means that physicians are not only responsible for prescribing the drug but also ensuring that these treatment decisions do not have negative financial implications for their practice.[6] When assessing the financial implications of a biosimilar, physicians/practices must also take into account the acquisition, day-to-day, and administrative costs associated with the drug. For example, many biosimilars have specific storage requirements that can require costly investments on the part of the physician/practice.[5,6] This can be particularly harmful for small practices that may have less negotiating power than larger practices or hospitals. Additionally, these small practices must find funding for the fixed costs associated with biosimilar/biologic administration with lower patient volume than larger practices/hospitals. In conjunction, while these payment models are harmful for most practices, they are particularly challenging for small practices to overcome. This payment model, as previously mentioned, can cause significant financial distress for physician practices due to impacts of net cost recovery. A quarterly payment structure is not as responsive to changes in ASP and may lead to a "lag" in payment, resulting in the purchase of a reference biologic over a biosimilar.[28] As previously mentioned, ASP calculations include provider discounts and rebates, resulting in actual provider acquisition costs being, in some cases, higher than the ASP. Additionally, while the add-on percentage to the ASP is intended to cover the additional costs associated with biosimilars, particularly infused drugs, many physician practices find themselves "underwater" as the actual associated costs are significantly more than the payment.[6,27,28] In these cases, physicians/practices are faced with the decision as to whether to refer patients to hospital outpatient departments, often leading to higher patient OOP costs and more spending for the health system overall.[28]

In order to address the issues that are often caused by the ASP and buy-and-bill payment structures, experts have offered alternatives. While some have suggested raising the ASP add-on rate, the IRA did not seem to solve the problem of physician/practices being "underwater" even though it raised the ASP add-on rate from ASP 6 to ASP 8.[5,6,28] It is possible that raising the ASP add-on rate further could help mitigate the problem. However, because the ASP model may operate at too slow a pace to provide immediate full financial relief to physician practices, alternatives may need to be explored.[28] One potential alternative to ASP based payment is to move towards shared savings programs. In these programs, the shared saving of switching to a lower cost biosimilar is shared with the physician. While these programs have shown some promise in European markets, there is speculation that they may not be as effective in the U.S. unless they are implemented in conjunction with the changes to the buy-and-bill system.

Alternatively, experts, including the Office of Inspector General, have offered the use of least costly alternative (LCA) payment structures instead of ASP.[5,6,29] Within LCA payment structures, CMS would pay 80 percent of the defined rate, set at 106 percent of the least costly biosimilar, and the patient would pay the remaining amount. Should a drug have a cost equal to or less than the LCA, the patient would pay the standard 20 percent cost sharing. However, in the case that the drug costs more than the LCA, the patient would pay the difference in addition to the traditional 20 percent cost share, with CMS payment remaining steady at 80 percent of the LCA.[28] While this would result in cost savings for CMS, it would likely have a harmful impact on patients that require higher cost drugs and would increase financial risk for physicians if/when patients are unable to

fulfill their cost sharing.[28] Additionally, due to Medicare prohibition of balanced billing, it is unlikely that LCA would be implemented successfully.[30] A more promising alternative may be a "blended" payment rate system. In this system, all interchangeable biosimilar and biologic products would be grouped together and paid at a weighted-average ASP 6 for all of a group's drugs.[28] This would likely result not only in an increase in competitive pressure on manufacturers but also an increase in the payment rate for physicians, as the higher cost biosimilars would be incorporated into the ASP for all related biologics.[28]

In addition to this blended payment rate system, changes and/or alternatives to the buy-and-bill system could be considered. For example, the Medicare Payment Advisory Commission has recommended the Drug Vendor Program which would allow CMS to contract with competitive third-party intermediaries to negotiate lower prices and fewer utilization management requirements. Experts posit that this type of system would not only allow for lower patient cost-sharing but also be financially and administratively advantageous for physicians.[28,31] While there is not a clear single alternative to either ASP payment models or buy-and-bill systems, it is important that payment structures ensure both patient access to prescribed drugs and physician/practice sustainability.

AMA ADVOCACY AND POLICY

The AMA has a robust body of policy meant to ensure that prescription medications are affordable and that physicians are able to prescribe without financial penalty. Policy H-110.997 supports physician involvement in prescription medication pricing and ensuring that physicians are able to prescribe the medication that is best for the patient. Policy H-110.987 supports federal legislative and regulatory advocacy to reduce anticompetitive behaviors, like patent manipulation, in drug manufacturing and outlines the importance of physician support in lowering pharmaceutical costs. Policy H-110.990 outlines efforts to ensure that cost-sharing and out-of-pocket costs for prescription drugs are fair and patient-friendly. Finally, Policy H-110.959 outlines the importance of ensuring that drug payment methodologies do not result in physician practices being paid less than the cost of acquisition, inventory, storage, and administration of a drug.

In addition to policy designed to ensure that all prescription drugs are affordable and accessible, the AMA has policy supporting the use of biosimilar medications. Policy D-125.989 supports physician autonomy in determining if a biosimilar or biologic product is dispensed to a patient and ensuring that switches from biologics to biosimilars are not done without notification and authorization of the prescribing physician. Policy H-125.972 outlines AMA efforts to support physician education on biosimilars, their FDA approval process, and surveillance requirements. Policy H-125.973 encourages the FTC and DOJ Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologic originators and PBMs to ensure they do not impede biosimilar development and uptake. Policy H-100.940 outlines AMA support for incentivizing the use of lower cost biosimilars when it is safe, fiscally prudent, clinically appropriate, and agreed upon by the patient and physician. Additionally, this policy outlines support for eliminating acquisition costs and reimbursement disparities across in-office treatment locations and patient education on biosimilars.

In addition to the aforementioned policies, the AMA has engaged in extensive state level advocacy regarding substitution of interchangeable biosimilar biologic products since 2012. The AMA has worked with dozens of state medical associations to support state amendments to pharmacy practice acts to align with new federal definitions. For example, AMA advocated in support of new laws in Indiana, Washington and Mississippi. Additionally, the AMA has undertaken robust advocacy efforts to lower drug costs for patients, especially around regulation and increasing the

transparency of PBMs. Specifically, over the past two years the AMA has written a number of letters to payers, regulators, and legislators and testified before both the House and Senate regarding regulation of PBMs. The AMA also has an ongoing grassroots campaign, TruthinRx, designed to support patients and physicians in understanding and fighting the lack of transparency through education and advocacy.

DISCUSSION

Since their introduction into the U.S. market, biosimilars have faced slow adoption with incremental increases over recent years. While concerns have been expressed by patients and physicians around the safety, efficacy, and immunogenicity of biosimilars, current research and legislation suggests that support is trending towards even greater biosimilar adoption. As the biosimilar market is becoming more competitive, payers are recognizing the potential for cost-saving and adding more biosimilars to their formularies.

Greater adoption of biosimilars has the distinct ability to lower overall U.S. drug spending and, in turn, make expensive drug treatment more accessible to many Americans. However, the Council believes that it is essential that physician practices are not harmed in the process. With greater usage of biosimilars, payment structures for these drugs are becoming more important. Currently, Medicare Part B relies on an ASP 6 (temporarily ASP 8) payment structure for infused biologics and biosimilars. While this payment structure was not intended to be disadvantageous to physician practices, the speed at which the biosimilar market has been changing, coupled with the PBM system, has resulted in financial harm. Additionally, the inclusion of exceptions, such as manufacturer rebates, often cause the ASP to be even lower than the cost of acquisition. Due to the associated cost of acquiring, storing, and administering many biosimilars, especially infusible drugs, payment to physician practices may be less than the actual cost.

In order to ensure that biosimilar payment is structured in a manner that allows physician practices to be financially sustainable, the Council recommends the adoption of three new policies and the reaffirmation of two existing policies. First, the Council recommends adoption of new policy encouraging the revision of the existing ASP payment model to fully cover costs to physicians/practices. This new policy encompasses the intent of the referred resolution and allows for greater ongoing advocacy to secure adequate payment. Second, the Council recommends the adoption of new policy to support the future implementation of payment structures that are fair and comprehensive to ensure support for payment structures that maintain patient access to biologic/biosimilar drug(s), address practice administrative and acquisition costs, and incentivize the use of biosimilars when safe, clinically appropriate, and agreed upon by the patient and physician. Third, the Council recommends the adoption of new policy to support the calculation of ASP to mimic the “blended payment” system outlined in this report. Finally, the Council recommends that Policies H-100.940, H-110.959, H-125.972, and D-110.987 be reaffirmed, as they support incentivizing biosimilar use when appropriate, oppose drug payment methodologies that are financially harmful to physician practices, support biosimilar education for physicians and patients, and encourage accountability and transparency for PBMs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 103-A-25, and the remainder of the report be filed:

1. That our American Medical Association (AMA) support the revision of the Average Sales Price (ASP) calculation of biologic/biosimilar drugs to more accurately represent the cost of drugs for the physician practice. (New HOD Policy)

2. That our AMA encourage public and private payers to implement comprehensive payment structures that allow for fair and timely payment for biologic/biosimilar drugs that:

a. Maintain patient access to biologic/biosimilar drugs prescribed by their physician consistent with AMA Policy H-100.940;
b. Account for physician/practice administrative and acquisition costs, including but not limited to, obtaining, storing, and administering the drug through a payment rate that covers these costs;
c. Incentivize the use of biosimilars when safe, clinically appropriate, and agreed upon by the patient and physician; and
d. Ensure that patient out-of-pocket costs are affordable. (New HOD Policy)

3. That Policies H-100.940, H-110.959, H-125.972, and D-110.987 be reaffirmed.

Fiscal Note: Minimal

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Council on Medical Service Report 4-I-25
Payment for Biosimilars
Policy Appendix

Prescription Medication Price Negotiation, H-110.959
1. Our American Medical Association (AMA) supports efforts to ensure that patients have affordable access to medications.
2. Our AMA encourages all payers, both public and private, in efforts to establish a reasonable and affordable cap on patient out-of-pocket prescription drug spending in a manner that does not increase patient premiums.
3. Our AMA opposes drug payment methodologies that result in physician practices being paid at less than the cost of acquisition, inventory, storage, and administration of relevant drugs and other necessary related clinical services.

Cuts in Medicare Outpatient Infusion Services, D-330.960
1. Our AMA will actively support efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services.
2. Our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents. (Res. 926, I-03; Reaffirmed and Modified: CMS Rep. 3, I-08; Reaffirmation A-15; Reaffirmed: CMS Rep. 10, A-16; Reaffirmation: I-18)

Biosimilar Coverage Structures, H-100.940
1. Our American Medical Association supports the development and implementation of strategies to incentivize the use of lower cost biosimilars when safe, fiscally prudent for the patient and not financially disadvantageous to the clinical practice, clinically appropriate, and agreed upon as the best course of treatment by the patient and physician.
2. Our AMA advocates to eliminate acquisition cost and reimbursement disparities for in-office biosimilar treatment across diverse treatment locations.
3. Our AMA supports patient education regarding biosimilars and their safety and efficacy. (CMS Rep. 04, I-24)

Biosimilar Use Rates and Prevention of Pharmacy Benefit Manager Abuse, H-125.973
Our American Medical Association will encourage the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologics originators and PBMs to ensure they do not impede biosimilar development and uptake. (Res. 207, A-24)

Cost Sharing Arrangements for Prescription Drugs, H-110.990
Our AMA:
1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;
2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes;
3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and patient-specific out-of-pocket costs of

individual prescription drugs, taking into account insurance status or payer type, prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition;
4. supports public and private prescription drug plans in offering patient-friendly tools and technology that allow patients to directly and securely access their individualized prescription benefit and prescription drug cost information; and
5. believes payers should not establish a higher cost-sharing requirement exclusively for prescription drugs approved for coverage under a medical exceptions process. (CMS Rep. 1, I-07; Reaffirmation A-08; Reaffirmed: CMS Rep. 1, I-12; Reaffirmed in lieu of Res. 105, A-13; Reaffirmed in lieu of: Res. 205, A-17; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS Rep. 07, A-18; Appended: CMS Rep. 2, I-21; Reaffirmed: Res. 113, A-23; Appended: CMS Rep. 01, A-23)

Pharmaceutical Costs H-110.987

1. Our American Medical Association encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports:
    a. drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase;
    b. legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and
    c. the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment.

11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation. (CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmed: Res. 801, I-23; Reaffirmed: Res. 801, I-23; Reaffirmed: CMS Rep. 04, I-24)