REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-24

Subject: Biosimilar Coverage Structures
(Resolution 207-A-24, Referred Resolve)

Presented by: Stephen Epstein, MD, MPP, Chair

Referred to: Reference Committee J

At the June 2024 Annual Meeting, the House of Delegates (HOD) adopted amended Resolution 207-A-24 which encourages the Federal Trade Commission (FTC) and Department of Justice (DOJ) Antitrust Division to closely scrutinize long-term exclusive contracts signed between biologics originators and pharmacy benefit manages (PBMs) to ensure they do not impede biosimilar development and uptake (Policy H-125.973). The HOD also referred a proposed new resolved clause to Resolution 207-A-24, which was introduced by the Medical Student Section and asked the American Medical Association (AMA) to "support coverage structures that increase use of lower cost biosimilars when clinically appropriate, share savings between patients and payers, and reduce patient costs."

This report provides an overview of biosimilars, the current state of coverage, and related incentives to increase their use. Additionally, this report presents policy recommendations consistent with intent of the referred new resolved clause to Resolution 207-A-24.

BACKGROUND

A biosimilar drug is a type of biologic, or drug that is produced by living organisms, which is very similar in both structure and function to a Food and Drug Administration (FDA) approved branded biologic, or reference medication. Biosimilars may not have the same chemical compound as the reference medication but must have the same efficacy and chemical structure to act on the body (detailed definitions can be found in Appendix A).[1] They are often compared to generic medications; however, they are slightly different. While generic medications are identical to the name brand medication, biosimilars have the same performance as the reference biologic, but there are slight chemical differences in the makeup of the medications.[1] For a more in-depth discussion as to the chemical and molecular makeup of biologic medications, how they differ from the reference medication, and interchangeability please see Council on Science & Public Health Report 5-A-24, *Biosimilar/Interchangeable Terminology*.

While biosimilars have been on the European market since 2006, the first biosimilar was approved by the FDA for use in the United States (U.S.) in 2015.[2] Since then, the U.S. market has seen steady, if rather slow, growth of biosimilars.[3,4,5] Between 2015 and 2020, only nine biosimilar medications entered the U.S. market. However, in recent years there has been significant growth in this market; as of August 2024, there are 59 FDA approved biosimilars in the U.S. market.[6] In 2010, via a portion of the Affordable Care Act (ACA), the Biologics Price Competition and Innovation Act, Congress passed an abbreviated pathway to licensure in order to encourage

increases in biosimilar approval in the U.S..[4,5,7] This abbreviated pathway from the ACA made it possible for biosimilars to be approved in a more efficient manner. Congressional support for biosimilars was primarily based on the potential for financial savings that these medications have for both payers and patients.[3,4,8]

Biosimilars are often thought of as preferable to their equivalent reference medication due to the fact that they are typically less expensive. Cost savings have been seen in both the European Union and the United Kingdom National Health System, which have each saved millions annually by switching to biosimilar medications.[5] Estimates indicate that the use of biosimilar medications could result in a 15-35 percent overall savings in the U.S. market.[5,7,8,9] This is especially important as biologic medications account for just over 40 percent, or about $211 billion, of all annual drug spending in the U.S..[9,10] Some research has indicated that an increase in the use of biosimilars could save the U.S. health care system nearly $54 billion over 10 years.[4,5] While there have been actual savings in the U.S. due to the use of biosimilars, they have only amounted to $12.6 billion, or five percent of a projected $54 billion savings. Additionally, research indicates that savings to patient out-of-pocket cost is, if present at all, only marginal and very dependent on medication type.[7,8]

While it is possible that savings have not been realized due to slow introduction of biosimilars to the U.S. market, it is also possible that payment structures often do not incentivize the switch to biosimilar medications.[7] Recent research finds that there may be several factors affecting the likelihood of biosimilar initiation, including type of insurance coverage and patient age.[11] Medicare Advantage beneficiaries were the most likely to initiate, accounting for 74 percent of all biosimilar initiation. Pediatric patients were the least likely to initiate, likely due to complications of approvals for use in children. Overall, the study found that biosimilar initiation is growing, with 27 percent of patients initiating biosimilars in 2022, up from one percent in 2013.[11]

Despite the initial Congressional support and potential for cost savings, biosimilar use has been limited in the U.S. since their initial approval. A leading factor in the slow uptake of biosimilars is centered around patents. Specifically, manufacturers of the reference medication are able to use strategies, like a minor formula or name change, to ensure that patents last longer in order to delay the entry of biosimilars to the market.[7,8] Additionally, payment structures have historically not incentivized the use of biosimilars over reference medications. A full discussion of the impact of coverage structures can be found in a later section of this report. Furthermore, there has been a significant learning curve for patients and physicians as to the potential advantages of choosing a biosimilar medication over a reference medication.

While federal legislation related to biosimilars has been sluggish,[4] the vast majority of states have laws allowing, or in some cases requiring, the substitution of biosimilars.[12] All but four states, Alabama, Indiana, South Carolina, and Washington, have laws that allow for the automatic substitution of biosimilars for a prescribed reference medication by a pharmacist. In nine states, substitution is only permitted if the cost of the biosimilar is lower than the reference medication. Additionally, nearly all states with these laws require that both the patient and physician be notified regarding this change. Importantly, in every state, physicians and other prescribers are able to prevent automatic substitution by indicating that the prescription be “dispensed as written.”[12] Regardless of law, it is important to note that physicians are generally wary of pharmacist-led drug substitutions, and the AMA has advocated widely on this issue and a discussion of efforts can be found in the policy and advocacy section of this report.

BIOSIMILAR COVERAGE

Historically, public and private payers in the U.S. have not incentivized the use of biosimilar medications and, in some cases, actually incentivized the use of reference biologic medications.[4,7,8,9,13] While rebate information is not publicly disclosed, experts hypothesize that due to the higher list price of biologic reference medications, payers are able to negotiate greater rebates, making the reference medication more financially lucrative for the payer. As a result, payers may not include biosimilar medications on preferred formulary tiers or may deny coverage altogether.[12] Research has indicated that among 17 major private insurance plans, less than half had at least one biosimilar placed on a "preferred" formulary tier and only two plans placed at least half of biosimilar medications on the "preferred" tier.[7] Additionally, research indicates that private payers are either excluding or imposing serious restrictions on biosimilar medication coverage nearly 20 percent of the time. Coverage is most likely to be given in cases of cancer treatment and least likely in pediatric patients.[10] Recently, a few major plans have started to shift to cover biosimilars instead of the reference biologic. Interestingly, plans managed by the three largest PBMs were less likely to impose coverage restrictions on biosimilar medications. It is thought that this is a result of these PBMs leveraging their significant market power to negotiate for more advantageous rebates on biosimilars.[10,14]

In addition to the recent shift towards private payers covering biosimilars, federal legislation has encouraged the usage of biosimilars. The Bipartisan Budget Act of 2018 implemented Medicare formulary changes that provided discounts for biosimilars and led to 23 percent higher coverage of these medications.[5,9] The Inflation Reduction Act of 2022 (IRA) is likely to begin incentivizing biosimilar use in the Medicare program starting in 2025. The IRA has, among other things, a focus on lowering the cost of prescription medication for Medicare beneficiaries and to reduce the federal government's drug spending.[15,16] Historically, Medicare Part D, the portion of Medicare that covers prescription medications, has favored reference biologics over biosimilars. Biosimilars are covered at 80 percent, but only when the patient reaches the "catastrophic coverage" phase, meaning that the patient's out-pf-pocket spending has exceeded $8,000. Prior to patients reaching this phase, plans are formulated in a manner where the reference medication is covered more advantageously.[15]

The IRA has two portions that are expected to significantly alter this and lead to greater coverage of biosimilars before patients reach the "catastrophic coverage" phase. First, the IRA implements federally-mandated discounts for certain branded drugs. This is likely to lessen the power of high list prices yielding more lucrative rebates for payers, thereby removing a major incentive to choose reference biologics over biosimilars. Second, the IRA altered Medicare's catastrophic coverage by eliminating the beneficiary coinsurance requirement. Specifically, the IRA capped out-of-pocket costs at $3,250 and added a hard cap on out-of-pocket spending of $2,000. This is indexed in future years to the rate of increase in per capita Part D costs. It is anticipated that this removal of the catastrophic coverage gap will motivate coverage decisions to favor biosimilars over the reference biologic.[15,16] Additionally, the IRA implemented guidelines to ensure that physicians are not incentivized to prescribe higher cost medications due to greater reimbursement based on the higher sticker price. Specifically, starting in October 2022 the IRA implemented an add-on payment rate for biosimilars if the average sale price of that medication is lower than the reference biologic. This is intended to not only incentivize the use of lower-cost biosimilars but also mitigate issues around physician incentivization based in greater reimbursement for higher-cost biologics.[15]

BIOSIMILAR INCENTIVES

Trends in both public and private payers indicate that biosimilars will not only be covered at a greater rate, but plans may actually be transitioning to incentivizing their use.[14,17] Additionally, across all payer types, biosimilar medications are moving towards self-administration, eliminating the need for a medical professional to administer the medication. This is significant as the administration change may lead to more biologic, both reference and biosimilar, medications to be covered under plans' pharmacy benefits. Coverage under the pharmacy benefit could in turn allow for more efficient switches to biosimilar medications.[14]

In addition to medication administration changes, other incentives are being implemented to ensure greater use of biosimilar medications when clinically appropriate, such as the movement of financial incentives to biosimilars in lieu of reference biologics. Historically, the rebates tied to reference biologics have made them the more financially lucrative choice for payers. However, due in part to a 2022 Executive Order from the Biden Administration to the FDA, the FTC, and the Centers for Medicare & Medicaid Services, financial incentives for payers have started to shift towards biosimilar medications.[10] In turn, some plans are utilizing financial incentives for patients to encourage switching to biosimilars. Plans have provided patients with a monetary reward for switching from a reference biologic to a biosimilar.[14] Additionally, initial research indicates that payers are placing biosimilars on formularies or on more advantageous formulary tiers at a greater rate in recent years.[14]

It remains to be seen if payers' biosimilar financial savings will be passed on to patients in the long-term. However, it does seem that the financial incentives are initially leading to greater coverage of biosimilar medications. If the switch to biosimilar medications is to be successful, it is vital that physicians and patients are adequately educated and in control of the switch. With time, physicians have become increasingly well-educated on biosimilars and their potential advantages, allowing some to become more comfortable; however, others continue to express concern.[18,19] It is important to note that there are still significant legitimate concerns from physicians related to switching to biosimilars. For example, studies have found that as many as 65 percent of physicians indicated concerns with switching a patient from a reference biologic to a biosimilar medication. Physicians listed a wide range of reasons for concern related to the safety, efficacy, and immunogenicity of the biosimilar.[14]

It is also important that patients are adequately educated and supported in the use of biosimilars. Research has demonstrated that patients, like physicians, have a diverse set of opinions on the use of biosimilars.[19] While financial incentives or savings can be a powerful tool to increase interest in a biosimilar medication, some patients cite other advantages of a reference biologic, driving resistance to switching to a biosimilar. Specifically, services from reference biologic medication manufacturers like copay support, on-call support/transport services, and educational or administration materials/devices are often powerful in maintaining patient preference for the reference biologic over the biosimilar.[4,14] Additionally, patients often echo physician concerns related to the safety, efficacy, and immunogenicity of biosimilar medications.[18,19] While some of these concerns can be mitigated by physician/patient education as to the benefits of biosimilars, it is important to ensure that any switch to a biosimilar medication is done in agreement from both the physician and patient.

Finally, two strategies seem to be particularly salient to incentivize the use of biosimilars. First, ensuring that patient cost-sharing or out-of-pocket costs are reduced. In many European countries, patient cost-sharing strategies have been utilized to incentivize the use of biosimilars. Specifically, countries have adopted policies that dictate more expensive medications have a higher co-pay and

cheaper medications have a lower co-pay. In some cases, such as in Germany, the lower cost biosimilar has a copay as low as zero dollars, resulting in significant patient incentive to use that medication. Initial implementation of these plans seems to be resulting in higher uptake of the biosimilars with higher patient cost-sharing.[20] Second, allowing for cost-sharing to be shared between the physician and the patient. Shared savings-type programs have been successfully implemented in international settings and, more recently, in the Medicare program.[20,21] In France and Germany, shared savings programs have been implemented with the intent of increasing biosimilar use. These programs are based on agreements between payers and hospitals/physicians regarding the cost savings of specific biosimilars. Initial research has shown that these programs have been successful in increasing the rate of biosimilar uptake in both countries.[19]

AMA POLICY & ADVOCACY

The AMA has a strong body of policy meant to ensure that prescription medications are affordable and that physicians are educated about and able to prescribe biosimilars. 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 advocacy with federal legislators and regulators 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.

In addition to policy designed to ensure that prescription drugs are affordable and accessible to patients and that physicians can prescribe what is most clinically appropriate, 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 update.

In addition, 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 medical societies 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. Based on the concern many physicians express related to pharmacist-led substitution, these laws support the authority of physicians to limit substitution of biologic products. The AMA has rather extensive policy that both works to maintain the proper scope of pharmacist practice and allow physicians to limit or prevent substitution. Specifically, Policies H-125.995 and D-35.987 outline AMA opposition to pharmacist-led substitution without express permission from the physician. Additionally, Policies H-125.991, H-120.918, and D-120.922 all detail efforts to ensure that physicians have the ability to dictate that a prescription should be dispensed as written.

DISCUSSION

Since their approval in the U.S., the initial uptake of biosimilar medications has been slow, but recent years have demonstrated a quicker uptick in their market availability. Public and private payers are continuing to make changes that will likely incentivize and, in turn, increase the prevalence and use of biosimilar medications in the U.S. IRA-derived revisions to the Medicare Part D benefit will be implemented in 2025, and it is likely that these changes will further

encourage the coverage of biosimilars, initially by public payers and, with time, by private payers as well. Additionally, recent changes by large insurers and PBMs have signaled that these players are moving towards not only covering biosimilars at a greater rate but incentivizing their use via financial rewards. In order to ensure that these financial rewards are passed on to patients so that biosimilar medications are affordable and accessible, the Council recommends the reaffirmation of Policies H-110.987 and H-110.997, which both outline advocacy efforts to ensure that prescription medications are affordable and accessible to patients.

If biosimilars are to be successfully incentivized, it is important that it be done holistically and inclusively for all parties involved, and not just centered around financial incentives to payers, and that no physician is forced to prescribe a biosimilar. In some cases, patients and/or physicians may not be comfortable with prescribing a biosimilar over the reference medication. This could be for a number of reasons, including concerns about the safety, efficacy, and/or immunogenicity of the biosimilar. Therefore, the Council recommends the reaffirmation of Policy H-125.989 which ensures that physicians are able to switch patients to biosimilars if they wish, but no substitutions can be made without the notification and approval of the prescribing physician. To ensure that physicians are comfortable and confident in prescribing and discussing biosimilars, the Council recommends the reaffirmation of Policy H-125.972 which outlines support for physician education on the topic of biosimilars.

Finally, in order to further encourage the use of biosimilars, the Council recommends the adoption of two new policies. First, to lower patient out-of-pocket costs, when deemed appropriate by the physician and amenable to the patient, the Council recommends the adoption of new policy to support the development and implementation of incentivization strategies to increase the use of biosimilar medications, when agreed upon by the patient and physician. Second, to ensure that patients are knowledgeable and comfortable with switching from a reference medication to a biosimilar medication, the Council recommends the adoption of new policy to support patient education on the topic of biosimilars by appropriate organizations.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA):
    a. support 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, and
    b. advocate to eliminate acquisition cost and reimbursement disparities for in-office biosimilar treatment across diverse treatment locations. (New HOD Policy)

2. That our AMA support patient education regarding biosimilars and their safety and efficacy. (New HOD Policy)

3. That our AMA reaffirm Policy H-110.987, which works to ensure that prescription medications are affordable and accessible to patients. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-110.997 which supports the freedom of physicians in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices. (Reaffirm HOD Policy)

5. That our AMA reaffirm Policy D-125.989, which outlines efforts to ensure that physicians are able to transition patients to biosimilar medications with coverage from payers. (Reaffirm HOD Policy)

6. That our AMA reaffirm Policy H-125.972 which details efforts to encourage physician education related biosimilars. (Reaffirm HOD Policy)

Fiscal Note: Modest – between $1,000-$5,000.

APPENDIX A
Definitions of key terms

Biologic drug (or large molecule drugs): a classification of drugs which are produced by living organisms (such as human or animal cells, yeast, or bacteria), rather than by chemical synthesis. As such, this class of drug tends to replicate or mimic common biologic entities. For example, antibody- or protein-based drugs are common examples of biologic drugs.

Small molecule drug: A classification of drugs based on the number of atoms (typically <100) in their structure. Small molecule drugs are generally prepared using chemical synthesis techniques. Small molecule drugs are estimated to represent over 90 percent of all pharmaceuticals used in the clinic today. Typically, small molecule drugs function by binding to a biological entity (protein, receptor, etc.) and altering its function.

Generic drug: A drug produced by a second manufacturer after the patent or other market protections have expired, allowing for manufacturers to be able to produce their own products with the same chemical substance as a branded drug. The term generic drug only applies to small molecule drugs, with few exceptions.

Biosimilar: A biologic drug that has a very similar structure and function to a branded biologic drug after its patent or market protections have expired. Unlike generic drugs, biosimilars are not required to be the same chemical compound, but they are required to have the same chemical structure to act on the body and efficacy.

Interchangeable: An additional designation provided for biosimilar drugs by the FDA. This designation is not required for market approval and indicates that a biosimilar has successfully demonstrated no changes in efficacy or immunogenicity when the biosimilar is substituted for the reference product after a patient has already initiated treatment with the reference product. This designation has implications for reimbursement, and state regulations around pharmacist practice.

Note: these definitions were originally outlined in the Council on Science & Public Health Report 5-A-24, Biosimilar/Interchangeable Terminology. A more in-depth discussion as to the scientific details of these definitions, and biosimilars in general, can be found in the aforementioned CSAPH report.

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Council on Medical Service Report 4-I-24
Biosimilar Coverage Structures
Policy Appendix

Cost of Prescription Drugs H-110.997
Our American Medical Association (AMA):
(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;
(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;
(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients. (BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18)

Pharmaceutical Costs H-110.987
1. Our AMA 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 drugv 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)

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-23Appended: CMS Rep. 01, A-23)

Substitution of Biosimilar Medicines and Related Medical Products D-125.989
Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of a product; (3) in the absence of express physician authorization to the contrary, allow substitution of the biologic or biosimilar product when (a) the biologic product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components; and (b) there are no data indicating clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product; and (c) the prescribing physician has been adequately notified by the pharmacist. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14; Modified; CSAPH Rep. 5, A-24)

Biosimilar/Interchangeable Terminology H-125.972
1. Our AMA encourages the FDA to continually collect data and critically evaluate biosimilar utilization including the appropriateness of the term "interchangeable" in regulatory activities.
2. Our AMA supports evidence-based physician education on the clinical equivalence of biosimilars, the FDA approval process, and post-market surveillance requirements. (CSAPH Rep. 5, A-24)

Therapeutic and Pharmaceutical Alternatives by Pharmacists H-125.995
The AMA opposes legislative attempts at any level of government that would permit pharmacists, when presented with a prescription for a drug product, to: (1) dispense instead a drug product that is administered by the same route and which contains the same pharmaceutical moiety and strength, but which differs in the salt or dosage form (pharmaceutical alternatives); and (2) dispense a drug product containing a different pharmaceutical moiety but which is of the same therapeutic and/or pharmacological class (therapeutic substitution). Our AMA will work with state medical associations to ensure that state pharmacy laws and medical practice acts are properly enforced so that treating physician's directions cannot be overruled or substituted without prior physician approval. (Res. 89, I-85; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CLRPD Rep. 2, I-95; Appended by Res. 501, A-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18)

Evaluation of the Expanding Scope of Pharmacists' Practice, D-35.987

1. Our AMA will re-evaluate the expanding scope of practice of pharmacists in America and develop additional policy to address the proposed new services provided by pharmacists that may constitute the practice of Medicine.
2. Our AMA will continue to collect and disseminate state specific information in collaboration with state medical societies regarding the current scope of practice for pharmacists in each state; studying if and how each state is addressing these expansions of practice.
3. Our AMA will develop model state legislation to address the expansion of pharmacist scope of practice that is found to be inappropriate or constitutes the practice of medicine, including but not limited to the issue of interpretations or usage of independent practice arrangements without appropriate physician supervision and work with interested states and specialties to advance such legislation.
4. Our AMA opposes federal and state legislation allowing pharmacists to independently prescribe or dispense prescription medication without a valid order by, or under the supervision of, a licensed doctor of medicine, osteopathy, dentistry or podiatry.
5. Our AMA opposes federal and state legislation allowing pharmacists to dispense medication beyond the expiration of the original prescription.
6. Our AMA opposes the inclusion of Doctors of Pharmacy (PharmD) among those health professionals designated as a "Physician" by the Centers for Medicare & Medicaid Services. (Res. 219, A-11; Appended: Res. 218, A-12; Reaffirmed: BOT Rep. 9, A-22)

Drug Formularies and Therapeutic Interchange H-125.991

It is the policy of the AMA:
(1) That the following terms be defined as indicated:
(a) Formulary: a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;
(b) Formulary system: a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;
(c) Pharmacy & Therapeutics (P&T) Committee: an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;
(d) Therapeutic alternates: drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;
(e) Therapeutic interchange: authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system; and
(f) Therapeutic substitution: the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.
(2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.
(3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:
(a) The formulary system must:

(i) have the concurrence of the organized medical staff;
(ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
(iii) have policies for the development, maintenance, approval and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;
(iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
(v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;
(vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;
(vii)provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;
(viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;
(ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and
(x) be in compliance with applicable state and federal statutes and/or state medical board requirements.
(b) The P&T Committee must:
(i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);
(ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;
(iii) conduct drug utilization review (DUR) activities;
(iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;
(v) analyze adverse results of drug therapy;
(vi) make recommendations to ensure safe drug use and storage; and
(vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.
(c) The P&T Committee's recommendations must be approved by the medical staff;
(d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and
(e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber; i.e., authorization for a new prescription.
(4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body, and must meet standards comparable to those listed above. In addition:
(a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their “medical staff” and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;
(b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this

process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and
(c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.
(5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies. (BOT Rep. 45, I-93; Reaffirmed by Sub. Res. 501, A-95; Appended: BOT Rep. 7, I-99; Modified: Sub. Res. 524 and Reaffirmed: Res. 123, A-00; Reaffirmed: Res. 515, I-00; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: Res. 533, A-03; Modified: CMS Rep. 6, A-03; Modified: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmed: CMS Rep. 2, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed: CMS Rep. 2, A-10; Reaffirmed: CMS Rep. 01, A-20)

Prescription Drug Dispensing Policies H-120.918

1. Our American Medical Association supports the development and implementation of clear guidelines and mechanisms to indicate that the quantity of a prescription should be dispensed only as written using such language as “dispense quantity as written” or “no change in quantity.”
2. Our AMA supports the development, implementation and/or use of electronic or other means of communication to provide cost and coverage information of various prescribing quantities at the point of care allowing physicians to make the best decisions with their patients regarding prescribed medication quantities. (CMS Rep. 05, A-23)

Transparency at the Pharmacy Counter D-120.922

Our American Medical Association advocates for legislation or regulation that mandates that pharmacies, whether physical or mail-order, must inform patients about their prescriptions, to include at a minimum:

1. The dosage and schedule of treatments as written by the prescriber.
2. Any restriction or alteration of the prescriber’s intent due to third party or pharmacy intervention, with the stated justification.
3. Details of other avenues to obtain the original prescription, including out of pocket options, with comparative costs. (Res. 718, A-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)