REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 9-A-25

Subject: Minimum Requirements for Medication Formularies (Resolution 809-I-24)

Presented by: Stephen Epstein, MD, MPP, Chair

Referred to: Reference Committee A

At the 2024 Interim Meeting, the House of Delegates referred Resolution 809, which was introduced by the Mississippi Delegation, and asked that our American Medical Association (AMA) advocate for all payers to create, maintain, and enforce a minimum formulary for all beneficiaries that includes all "commonly prescribed, inexpensive, and generic" medications unless there are reasonable safety or economic concerns. The following report discusses the background and current state of formularies, impacts of their expansion, and AMA efforts on the topic. Additionally, the report recommends the adoption and reaffirmation of policies designed to balance formulary inclusion and economic concerns.

BACKGROUND

Formularies were initially simple lists of medications implemented by the military in the late 1700s during the American War of Independence.[1] In the mid-1900s, the concept of formularies became more widespread and took root in hospital pharmacies needing authorization to dispense interchangeable medications.[2] In 1965, with the inception of Medicare, formularies became well established as part of reimbursement eligibility requirements.[3] By the 1980s, formularies began to take a more contemporary shape, primarily due to the development of multi-brand categories of drugs with similar, but not identical, uses and prices. To encourage the use of their drugs, manufacturers began to offer rebates to purchasers. As a result, payers placed the more advantageous drugs, often due to higher rebates, in more favorable formulary positions.[4] Today's formularies continue to tout the goal of managing costs, ensuring patient access to therapies, and improving health outcomes.[4,5] While the actual outcomes delivered by formularies are diverse and occasionally questionable, they are highly influential in dictating what medications are accessible to patients.[4]

Contemporary formularies tend to follow similar rebate incentive structures as were developed in the 1980s, but with time have become increasingly complicated and, in many cases, opaque.[4,6] Formularies today are usually one of four types; open, closed, value-based, and tiered. Open structured formularies are those in which coverage for all prescription medications is granted.[6] While this may seem to be the most advantageous to patients, these types of formularies often see significantly higher cost to the patient and can actually block access due to high out-of-pocket (OOP) costs and/or high premiums.[4,6] Closed formularies are those that offer a narrower range of covered medications, but often at a lower cost to patients.[6] Within these formularies payers often select the medications that have higher rebates and, therefore, are financially advantageous to the payer.[4,6] Tiered formularies are more common and more complex in their execution. Within the tiers, payers incentivize the use of medications by placing them on lower tiers which, in turn, come

with a lower OOP expense for the patient. While there is no limit on the number of tiers, it is most common for plans to have a three-tiered structure. Typically, tier one includes the most preferred medications, tier two includes preferred name brand drugs, and tier three includes non-preferred name brand drugs. Drugs are typically considered to be "preferred" by the payer when more attractive rebates are offered by the manufacturer or if the list price of the medication is lower.[4,6] Finally, value-based formularies are based on an assessment of the impact of a treatment on overall health care spending and long-term health compared to other structures which are based solely on the upfront cost of the drug. While value-based formularies vary in the specific criteria used to determine high versus low value drugs, most take clinical parameters, quality of life, and utilization of health care resources into account. Similar to tiered formularies, the use of preferred drugs, in this case defined as the higher value drugs, is encouraged by lower OOP costs.[4,6]

While it may seem that generic medications would often be placed on lower formulary tiers, that is not always the case. In practice, many payers place name-brand drugs on lower tiers due to greater price concessions offered by manufacturers. Therefore, drugs with higher list prices can often yield payers higher rebates, although these cost savings are often not passed on to the patient.[6] In some cases, patient OOP costs are determined by the list price, and as a result patients end up paying more than a generic option.[7] While the data for private plans are limited, anecdotal evidence and research based on Medicare Part D plans seem to confirm the underuse of generic drugs to reduce cost. For example, one study found that 72 percent of Medicare Part D formularies had at least one branded product place on a lower tier than the comparable generic medication and 30 percent of branded multisource drugs had fewer utilization management requirements than the generic product.[8] Additionally, trends of generic drug usage in Medicare Part D seem to be declining as there was a 22 percent drop in generic medications placed on tiers between 2016 and 2025.[7,8]

Regardless of the formulary structure or drug type, the placement of medications is determined by a pharmacy and therapeutics (P&T) committee.[5] These committees are typically made up of physicians, other practitioners, legal experts, and administrators. P&T Committees will generally assess the safety, clinical efficacy, patient adherence, patient satisfaction, and economic factors of a drug in order to determine if it is placed on a formulary and/or the appropriate tier.[4,6] While payers are able to develop their own formularies, most choose to rely on pharmacy benefit managers (PBMs) to create and maintain formularies due to the high associated costs.[6] Typically, PBMs will create a number of formulary choices for payers to select from and, if desired, customize. While there are no federal legislative or regulatory guidelines for non-Medicare plans, Part D plans must follow guidelines and participate in annual reviews coordinated by the Centers for Medicare & Medicaid Services (CMS). These requirements were put in place by CMS in 2006 and are designed to regulate how private Part D plans create and manage formularies.[4,5,6,9]

FORMULARY REQUIREMENTS

Since its founding, Medicare has required payers to provide formularies in order to be approved for reimbursement. In 2003, the Medicare Prescription Drug Improvement and Modernization Act (MMA) was signed into law and included specific details as to minimum formulary requirements. MMA's goal was to not only update Medicare's prescription benefits, but to ensure that all associated carriers and their plans provide beneficiaries with high-quality and cost-effective drug benefits.[9,10] Since 2006, Medicare has required that at least two medications from each class are included in the plan formulary. However, there is some flexibility in this requirement should a medication class not include two or more medications. Additionally, in cases when there are therapeutic advantages of a specific medication for patients with certain diseases, more than two medications may be required to be included in the formulary.[9,11]

The Patient Protection and Affordable Care Act (ACA), signed into law in 2010, also includes minimum formulary requirements for associated plans.[12] Due to the structure of the ACA, specific formulary requirements vary significantly across states. However, prescription medication is considered one of the Essential Health Benefits (EHBs) that plans are required to cover. Specifically, states must ensure that plans either cover one drug in each of the United States Pharmacopeia (USP) class or at least the same number of drugs in each category and class of the EHB Benchmark plan for the respective state.[13] The 2025 USP list includes 50 medication categories, 175 medication classes, 207 Pharmacotherapeutic informational groups, and over 2,055 example drugs and how each example fits into each category, class, and group.[14] States have the ability to, within reason, establish their own EHB Benchmark plan, or the floor plan, for their state. As a result, some states, like Washington, require that plans cover at least one drug in every USP class, while other states, like Illinois and South Dakota, have more nuanced basic requirements. Each state is required to submit a plan to the Center for Consumer Information and Insurance Oversight (CCIIO) for approval.[13] Part of the role of CCIIO is to ensure that EHB Benchmark plans allow consumers access to high quality insurance plans while minimizing payer ability to discriminate between types of beneficiaries and to encourage marketplace competition.[13]

Although private health insurance plans operating outside of Medicare do not have blanket minimum drug formulary requirements, some states require plans to meet the ACA minimum. Additionally, many organizations, including the AMA, have offered guidance around formulary best practices. Specifically, the AMA, along with other relevant organizations, endorsed the Principles of a Sound Drug Formulary System.[15] While these principles do not specifically outline a minimum formulary requirement, they do delineate the need to ensure that formularies provide patients with medications necessary to address their diagnosis in a manner that is clinically appropriate and economically responsible.[15] Other organizations, including the American Academy of Family Physicians and American Society of Health-System Pharmacists, have outlined the need for formularies to be balanced based on efficacy, safety, cost, and patient outcomes.[16,17]

FORMULARY EXCEPTION PROCESS

An important aspect of formularies is the exception process. Since the vast majority of plans do not cover every medication on the market, patients and physicians may need to engage with exceptions to seek coverage of a medication. These exceptions occur when the covered medication is not an option for a patient. Commonly, this is due to allergies, a history of unsuccessful use of covered medications, covered medications not meeting therapeutic need, and/or concern that a covered medication would exacerbate an existing condition(s).[18] There may also be the need to submit an exception if a patient needs a quantity, dosage, or delivery method that is not typically covered. Importantly, exceptions are not limited to medications that are not covered at all by a payer. In some cases, if a medication is placed on a formulary tier that makes it unaffordable to the patient, an exception can be requested. This type of exception is called a tiering exception while the traditional exception process is called a formulary exception.[18,19]

While there is not one standardized process for exceptions, typically the process includes a request from the patient/patient representative paired with a physician statement. In some cases, the physician may directly request the exception and provide the statement for the patient.[19] When requesting a formulary exception, the physician statement typically includes information regarding the medical necessity of the alternative medication and potential consequences should the covered drug be used. When requesting a tiering exception, the physician statement will discuss the medical necessity of the medication and why it is unaffordable. In some cases, payers may require a statement of patient financial hardship.[18] Payers will typically respond to exception requests within

72 hours from the submission of the physician statement, although in urgent or emergency situations the payer should respond within 24 hours.[18,19]

As previously mentioned, there is not a requirement for payers to utilize a standard exception process, and as a result there is variance in the criteria utilized to review exception requests. Most plans will compare applicable scientific evidence on the efficacy and safety of the covered and requested drugs. Should an exception request be denied by the payer, the patient and/or physician may file an appeal to reverse the decision.[19] Similar to the original exception request, there is not a standardized process for appeals, however plans should have a defined method in place. For example, Medicare Part D plans provide a multistep appeals process starting with redetermination by the drug plan and escalating to an appeal in a federal court.[10,19]

IMPACTS OF FORMULARY EXPANSION

While it may seem beneficial for all medications to be included in drug formularies, research has shown that this may have unintended consequences. Specifically, economists have shown that, at least among ACA plans, those that cover more EHB drugs have significantly more utilization management requirements in place.[20] This seems to hold true when new drugs are added to formularies, as plans are increasingly likely to add utilization management requirements, often in the form of prior authorization. As discussed in a number of previous Council reports (CMS 6-A-24; CMS 8-A-17; CMS 7-A-16) prior authorization and other forms of utilization management are extremely burdensome for physicians/physician offices and potentially dangerous to patients. However, utilization management is not the only way that physicians are impacted by formulary placement and expansion. Many physicians report challenges with securing payment for high cost, but necessary physician-administered medications placed on higher tiers. Others have reported difficulties in receiving the full payment rate for administering vaccines, especially in private practice settings, from public payers.[21] A fuller discussion of the challenges faced by physicians in adequate vaccine payment can be found in CMS Report 3-I-20.

In addition to the potential challenges faced by physicians if formularies are expanded, patients may face adverse consequences. A main concern is that if payers incur additional costs, in this case due to formulary expansion, those costs may be passed on to the beneficiary through premium increases or higher OOP costs. Specifically, payers could simply require higher levels of patient cost sharing if they are required to include more medications on a formulary. Additionally, payers may react to forced formulary expansion by placing more medications on less desirable formulary tiers, leading to higher patient OOP costs and/or more utilization management requirements.[22] In conjunction with the potential negative impacts on patients with expanded formularies, research has demonstrated that overall, stricter formularies may not negatively impact patients. In some cases, research has shown that stricter formularies are actually associated with reported positive impacts, such as better medication adherence and clinical outcomes.[22] At the same time, other research seems to show that these policies also reduce costs in the majority of cases.[23] Together these concerns and conclusions may suggest that more stringent formularies are not harmful to patients and may actually lower drug-related costs.

However, research has also demonstrated that when formularies are too restrictive, there can be negative outcomes like lower medication adherence and, in some cases, higher OOP costs for patients.[22,24] These two metrics go hand in hand as patients who face higher OOP costs are less likely to adhere to treatment plans, potentially incurring additional costs to treat the consequences from non-adherence down the line.[22,24] Additionally, the aforementioned utilization management does not just impact physicians but patients, as well. Patients who experience prior authorization have significantly increased wait times to access their medications and those who experience other

forms of utilization management, like step therapy, can face long, uphill battles to obtain the necessary medication(s).[22,25] Therefore, it is important that formularies are balanced enough to allow patients to access necessary medications while also ensuring that utilization management and patient cost-sharing are not egregious.

AMA POLICY AND ADVOCACY

The AMA has established a number of policies that address the development and maintenance of drug formularies. Policy H-125.979 outlines the need for formulary information to be available to physicians and prescribers in real-time at the point of prescribing. This policy outlines efforts to ensure that formulary lists are also accessible to patients and that medications are not removed during the policy term. Policy H-110.979 outlines the AMA's advocacy efforts to ensure that both PBMs and payers are not just transparent in the creation of formularies, but also that rebates and refunds received will be shared with patients. Policy H-125.991 details the AMA standards for the makeup of P&T committees, the approval of their decisions by medical staff within hospital or institutional settings, and suggested guidelines for the creation and maintenance of a formulary system. Finally, Policy H-125.985 encourages all entities who design formularies or benefit packages, including managed care organizations and PBMs, to follow the principles outlined in the aforementioned Principles of a Sound Drug Formulary System.

The AMA also has several policies outlining the ideal formulary exception process for payers. Policy H-285.965 outlines the steps that physicians should take to ensure that patients have awareness of the most advantageous course of treatment, even when engaging with a formulary exception process is necessary. Policy H-320.949 outlines efforts to ensure that payers are required to provide exception processes that have clear response times and appeal processes. This policy also dictates support for legislative and regulatory efforts to ensure that these standards are implemented. Policy H-185.942 details the basic criteria that should be followed by payers and physicians in relation to utilization management criteria and when it can be appropriately utilized. In addition to these policies, the second principle of the AMA Prior Authorization and Utilization Management Reform Principles outlines the flexibility that should be provided by payers to ensure that patients have the ability receive effective and individualized care. In addition to policies related to the formulary exception process, Policies H-320.939 and D-320.982 detail the AMA's fight to make sure physicians are not experiencing undue burdens related to prior authorization and to mitigate the number of prior authorizations required. Additionally, the AMA has a longstanding grassroots campaign (Fix Prior Auth) working to educate about how prior authorization impacts patients and physicians as well as working to fix the system.

Finally, the AMA has many policies outlining the need for prescription medications to be affordable and accessible to patients. Specifically, Policy H-110.997 outlines support for programs that work to lower the cost of prescription drugs while also maintain quality of care and physician autonomy. Policy H-100.964 builds on the previously mentioned policy and expands the support for efforts to ensure that medications are covered in a manner that allows patients to access medications affordably. Policy H-125.984 reiterates support for generic medications when deemed appropriate and cost effective for the patient. This policy also supports programs that are designed to bolster generic development and federal approvals. Among other strategies to improve the affordability of prescription medications, Policy H-110.987 outlines AMA support for legislation and regulation that works to reduce drug prices, anticompetitive behaviors, and price gouging in an effort to increase drug affordability. In addition to the AMA body of policy on drug pricing, there have been extensive advocacy efforts over the last few years to bring awareness and offer solutions to high drug prices through letters to regulators (CMS 2023, CMS 2024), legislators (Senate 2024), and payers (NAIC 2023), along with testimony provided to the House of

Representatives (House 2023, House 2023(a)). Additionally, the AMA grassroots campaign, TruthinRx, works to gather and disseminate physician and patient stories as well as to advocate for lower drug prices and increased process transparency.

DISCUSSION

While formularies have been around, in some form, for centuries, the current iteration is exceptionally complicated and, in many cases, opaque. As a result, the effectiveness of formularies increasingly has been called into question. Formularies are developed by P&T committees and, at least among private payers, are typically maintained by PBMs. Medication placement on these coverage lists is often heavily dictated by the rebates given to payers by drug manufacturers. Rebates, and other financial incentives are not required to be passed to the patient and, as a result, patients rarely see a share of the financial incentives that payers receive. Current formulary minimums vary greatly by payer type and state. While there is not a national minimum formulary requirement for private payers, public payers do have minimum standards that generally require a certain number of medications in each class to be included in each plan's formulary.

Patients must have access to medications deemed as most appropriate by their physicians and such access must be affordable in order to be effective. Formularies are one method designed to decrease medication costs. In some situations, more limited formularies have resulted in their intended outcomes: lower costs and greater patient access. Yet, when formularies are too restrictive, they may have the opposite effect: higher costs and lower access. In order to ensure that patients have access to affordable coverage and medications, the Council believes that formularies must find a middle ground between being too limited or too expansive, balancing the need for coverage with the potential for OOP or premium cost increases. It is essential to acknowledge that PBMs have significant negotiation power in formulary creation and drug placement and thus yield substantial power in the process. The complications of the negotiation process and the potential economic tradeoffs indicate the need for a nuanced approach to formulary minimum requirements. As such, support for a mandate to cover all medications could have serious adverse consequences on patients and physicians.

Therefore, the Council recommends the adoption of new AMA policy that supports a more nuanced approach, supporting all payers in setting a minimum formulary that covers all drugs in each of the protected classes and at least two medications in each of the non-protected classes. The Council believes that this minimum formulary requirement balances the intent of Resolution 809-I-24 while ensuring that patients and physicians will not face significant increases in OOP cost or utilization management requirements. Additionally, to ensure that patients have access to medications that are prescribed by their physician in an affordable manner, formularies exhibit transparency, and cost-savings are passed to the patient, the Council recommends that Policy H-110.979 be reaffirmed. While affordability and formulary composition are exceptionally important, it is also vital that patients and physicians have an avenue to request coverage when a medication is not included in a formulary. In order to protect and simplify this process the Council also recommends reaffirmation of Policy H-320.949, which details the AMA principles to ensure that utilization management, including formulary exception processes, are clear, not overly burdensome, and have a defined appeals process.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 809-I-24, and the remainder of the report be filed:

1. Our American Medical Association (AMA) support all public and private payers in maintaining a formulary that includes at least:
    a. Coverage for substantially all drugs in the six protected classes; immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics; and
    b. Coverage for at least two medications in each non-protected therapeutic category. (New HOD Policy)

2. That our AMA reaffirm Policy H-110.979, which outlines AMA efforts to advocate for transparency in formularies and that patients can access medications (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-320.949, which details AMA principles regarding requirements for the formulary exception process (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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Minimum Requirements for Medication Formularies
Policy Appendix

Private Health Insurance Formulary Transparency, H-125.979

1. Our American Medical Association (AMA) will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation:
    a. requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic.
    b. requiring insurance carriers to make this information available to consumers by October 1 of each year.
    c. forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA
    a. promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide.
    b. supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.
7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits. (Sub. Res. 724, A-14; Appended: Res. 701, A-16; Appended: Alt. Res. 806, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: BOT Rep. 20, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 2, A-21; Reaffirmed: CMS Rep. 06, A-24)

Value-Based Management of Drug Formularies, H-110.979

Our American Medical Association: (1) will advocate that pharmacy benefit managers (PBMs) and health plans use a transparent process in formulary development and administration, and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class; (2) will advocate that any refunds or rebates received by a health plan or PBM from a pharmaceutical manufacturer under an outcomes-based contract be shared with impacted patients; and (3) opposes indication-based formularies in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients. (CMS Rep. 6, I-20)

Drug Formularies and Therapeutic Interchanges, H-125.991

It is the policy of the American Medical Association (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)

Expanded Use of the AMA's Principles of a Sound Drug Formulary, H-125.985
Our American Medical Association (AMA) urges managed care organizations, pharmacy benefit managers, and others who design benefit packages and/or make pharmacy benefit decisions, to utilize the Principles of a Sound Drug Formulary System (as described in BOT Rep. 28, I-00) as they develop their pharmaceutical benefit plan(s) and that the Principles of a Sound Drug Formulary System be readily available on the AMA web site.(Res. 520, A-01; Amended: Res. 514, A-02; Reaffirmed: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmation A-06; Reaffirmed: CSAPH Rep. 01, A-16)

Prior Authorization and Utilization Management Reform, H-320.939

1. Our American Medical Association (AMA) will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
3. Our AMA 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.
4. Our AMA will advocate for health plans to minimize the burden on patients, physicians, and medical centers when updates must be made to previously approved and/or pending prior authorization requests. (CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: Res. 811, I-19; Reaffirmed: CMS Rep. 4, A-21; Appended: CMS Rep. 5, A-21; Reaffirmation: A-22)

Prior Authorization Reform, D-320.982

Our American Medical Association will explore emerging technologies to automate the prior authorization process for medical services and evaluate their efficiency and scalability, while advocating for reduction in the overall volume of prior authorization requirements to ensure timely access to medically necessary care for patients and reduce practice administrative burdens. (Res. 704, A-19; Reaffirmation: A-22)

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 American Medical Association (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 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)

Generic Drugs, H-125.984
Our American Medical Association (AMA) believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice.
(2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name products.
(3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.
(4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program.
(5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products.
(6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength).
(7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process. (CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmation A-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 525, A-10; Reaffirmed in lieu of Res. 224, I-14; Reaffirmed in lieu of: Res. 922, I-18)

Managed Care Cost Containment Involving Prescription Drugs H-285.965
(1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.
(2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

(3) Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a change to discuss the change with the patient.
(4) Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.
(5) Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.
(6) Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.
(7) Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.
(8) When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.
(9) Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.
(10) Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting
(11) In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed
(12) For physicians who do not have electronic access, hard copies must be available. (CEJA Rep. 2, A-95; Res. 734, A-97; Appended by Res. 524 and Sub. Res.714, A-98; Reaffirmed: Res. 511, A-99; Modified: Res. 501, Reaffirmed: Res. 123 and 524, A-00; Modified: Res. 509, I-00; Reaffirmed: CMS Rep. 6, A-03; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmation A-08; Reaffirmation A-10; Reaffirmed in lieu of Res. 822, I-11; Reaffirmation A-14; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-2)

Clinical Practice Guidelines and Clinical Quality Improvement Activities H-320.949
Our American Medical Association (AMA) adopts the following principles for the development and application of utilization management guidelines:

1. The criteria or guidelines used for utilization management shall be based upon sound clinical evidence and consider, among other factors, the safety and effectiveness of diagnosis or treatment, and must be age appropriate.
2. These utilization management guidelines and the criteria for their application shall be developed with the participation of practicing physicians.
3. Appropriate data, clinical evidence, and review criteria shall be available on request.
4. When used by health plans or health care organizations, such criteria must allow variation and take into account individual patient differences and the resources available in the particular health care system or setting to provide recommended care. The guidelines should also include a statement of their limitations and restrictions.
5. Patients and physicians shall be able to appeal decisions based on the application of utilization management guidelines.
6. The competence of non-physician reviewers and the availability of same-specialty peer review must be delineated and assured.
7. Maintaining the best interests of the patient uppermost, the final decision to discharge a patient, or any other patient management decision, remains the prerogative of the physician. (BOT Rep. 6, A-99; Reaffirmed: Res. 820, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: Res. 708, A-16; Reaffirmed: CMS Rep. 08, A-17; Reaffirmed: CMS Rep. 4, A-21)

Third Party Payer Quantity Limits H-185.942

1. Our American Medical Association (AMA) supports the protection of the patient-physician relationship from interference by payers and Pharmacy Benefit Managers (PBMs) via various utilization control mechanisms, including medication and testing and treatment supply quantity limits.
2. Our AMA will work with third party payers and PBMs to ensure that if they use quantity limits for prescription drugs or testing and treatment supplies, an exceptions process must be in place to ensure that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, and that any such process should place a minimum burden upon patients, physicians and their staff.
3. Our AMA supports interested states legislative efforts and federal action and will develop model state legislation to ensure that third party payers or PBMs that institute quantity limits for prescription drugs or testing and treatment supplies include an exceptions process so that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, including provisions such as the following:
    - physicians can specify limited supplies of medications during initial trials of a medication, or if a larger quantity of medication would expose an at-risk patient to potential harm (e.g., opioids, benzodiazepines, or psychostimulants)
    - physicians can appeal adverse determinations regarding quantity limitations;
    - payers must provide an easily accessible list of all medications and testing and treatment supplies with quantity limits and the requirements for the exception process on the payer's Web site;
    - payers must indicate, what, if any, clinical criteria (e.g., evidence-based guidelines, FDA label, scientific literature) support the plan's quantity limitations;
    - physicians with specialized qualifications may not be subject to quantity limits;
    - payers cannot charge patients for an additional co-pay if an exception request for a higher medication or testing and treatment supply quantity has been approved based on medical necessity;
    - payer decisions on exception, and subsequent appeal requests, of quantity limits must be made within two working days in non urgent situations and one working day in urgent cases; and

- physicians or patients can submit any denied appeals to an independent review body for a final, binding decision. (BOT Rep. 12, A-12; Reaffirmation: I-17; Modified: CMS Rep. 05, A-23)

Drug Issues in Health System Reform H-100.964

1. Our American Medical Association (AMA) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.
2. Our AMA supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
3. Our AMA reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
4. Our AMA supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
5. Our AMA supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
6. Our AMA encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
    a. Our AMA encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
7. Our AMA reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
8. Our AMA supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public disclosure of patient and reporter identities.
9. Our AMA opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.
10. Our AMA reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.
11. Our AMA reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs. (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97; Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11; Modified: CMS Rep. 1, A-21)