Government-Mandated Pharmacy Benefits

The Academy of Managed Care Pharmacy (AMCP) believes managed care organizations (MCOs) and their clients, (e.g., individuals, employers, government), must be able to independently make decisions regarding health benefits in order to meet the medical needs of their patient populations. Mandates imposed by government restrict an MCO's ability to deliver a quality product and decrease the affordability and financial sustainability of the benefit. This statement discusses three types of government mandates that can affect a managed care pharmacist's ability to design an appropriate pharmacy benefit: mandated formulary content, mandated coverage parity terms, and mandated coverage of medications for specific indications.

Mandated Formulary Content

Health care professionals within MCOs use a variety of tools and strategies to design pharmacy and medical benefits that deliver comprehensive quality care to specific patient populations in an organized, cost efficient manner. Formularies are one example of a tool health plans use when designing a prescription drug benefit. Formularies outline which drugs are covered under a particular benefit and the amount of cost-sharing, if any, that is the patient's responsibility. Decisions about which drugs to include on a formulary are made by a committee of health care professionals, often called a pharmacy & therapeutics committee. The committee uses scientific-based evidence and determinations of overall value to decide which prescription drugs most closely meet the patient population's needs.

In recent years, policy makers at both the state and federal level have favored legislation that would require certain plans to cover either specific treatments or all treatments for a given indication or disease state. Government-mandated formulary content is one example of a mandate that would prevent a health plan from having the flexibility to develop a high quality and affordable benefit to meet the needs of the patient population it serves. Specifically, government mandates that require certain medications to be included on formularies may have the following unintended consequences:

- *Encourage the use of less-effective medications, or medications with significant safety concern.* MCOs may use favorable formulary placement to encourage the use of treatments that offer the highest clinical value to patients. In order to protect patient safety, MCOs may also refuse to place a drug with a questionable safety profile on formulary, or otherwise limit coverage to certain patient populations. However, if coverage of a particular drug is mandated, an MCO would have little choice but to offer coverage to all patients, even if the effectiveness or safety of the drug is uncertain. These types of mandates could unnecessarily place patients at risk or otherwise jeopardize patient outcomes.

- *Discourage the development of safer, more effective medications*. The Food and Drug Administration (FDA) requires manufacturers seeking approval for new drugs to demonstrate only that the new drug is safe and effective when compared to a placebo. There is no requirement that the manufacturer show that the new drug is safer or more

effective than currently available treatments. In therapeutic classes with multiple acceptable treatment alternatives, MCOs may use favorable formulary placement as a negotiating tool with manufacturers to reduce costs. In other instances, an MCO might request evidence that the new drug appears to be safer or more effective than currently available drugs before offering coverage. This market dynamic, which is used by both public, (e.g., Veterans' Affairs Health System and Department of Defense) and private purchasers, is but one motive that encourages manufacturers to develop drugs that are demonstrably safer or more effective. Government mandates that require coverage of all FDA-approved treatments for a given indication or a specific therapeutic class remove this incentive. On the contrary, because medications must be covered regardless of their clinical value, comparative effectiveness, or cost, these mandates reduce market-driven incentives for developing clinically superior, high-value medication treatments.

- *Raise overall costs*. Mandates can raise overall costs for payers and patients in two ways. First, any mandate that expands coverage will generally increase the overall net costs of the plan simply because more health care resources will be utilized as more patients gain access to covered services. While the higher costs can, in certain instances, be justified by the positive patient outcomes that result from increased access to a necessary treatment, the likelihood of higher premiums and cost-sharing must be considered when evaluating any coverage mandate. Second, mandated coverage reduces, if not eliminates, a manufacturer's incentive to negotiate competitive prices with MCOs. As previously mentioned, MCOs often use their purchasing power to negotiate lower medication costs on behalf of their members. Mandates requiring coverage of all FDA-approved treatments for a given indication or those that belong to a specific therapeutic class, as well as specific drug products, severely limit an MCO's ability to negotiate affordable prices. Rising prescription drug costs can negatively impact premium rates and can also cause an increase in cost-sharing requirements for patients.

Mandated Coverage Parity Terms

As pharmaceutical manufacturers have developed new medications to treat certain disease states in innovative ways, mandates that would require MCOs to cover all treatment options for a particular disease state regardless of route of administration on a basis "no less favorable" to other treatments have gained in popularity. Generally, self-administered (i.e., oral) medications are covered under a patient's pharmacy benefit, and intravenously-administered medications, which usually require a visit to a provider's office or clinic, are covered under a patient's medical benefit. Due to the different structures of pharmacy and medical benefits, there can be significant patient cost-sharing differences between self-administered medications and intravenous medications. Mandates requiring coverage on a "no less favorable" basis would force MCOs to cover both self-administered and provider-administered medications at the same cost-sharing levels.

While these types of mandates can be appealing, they can also carry unintended consequences, which can jeopardize both patient outcomes and the financial sustainability of a benefit. Logistical challenges can also lead to patient dissatisfaction and unnecessary treatment delays. For example, government mandates regarding medication coverage parity may:

- *Cause benefit design to fall behind the rapidly evolving science of medication treatment.* New medications and treatment advances in oncology, autoimmune

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diseases, and neurological diseases are occurring at an unprecedented pace. As new biologic treatments, biosimilar therapies, and genetic tests are introduced, best practices regarding how these technologies should be incorporated into treatment and administered to patients are constantly evolving. The high costs of these new treatments are also threatening the affordability of benefits for patients and payers. Currently, if a new treatment is shown to be more effective than existing treatments, or to have a higher clinical value in comparison to existing treatments, an MCO may choose to offer more favorable cost-sharing requirements for that treatment relative to other treatments. This benefits patients by offering coverage of more effective treatments at the most affordable rate and also benefits payers by maximizing the value of dollars spent on treatment. Coverage parity mandates remove that tool. An unprecedented public and private investment in patient-centered outcomes research is being made with the expectation that it will help MCOs, providers and payers maximize positive patient outcomes and eliminate wasteful medical spending. It is more essential than ever that MCOs retain the flexibility to quickly respond to these developments and offer coverage solutions that best meet the needs of their members.

- *Create administrative challenges for determining parity, leading to treatment decisions based on cost, not on safety or efficacy.* Coverage parity mandates can create administrative challenges for MCOs when attempting to determine parity between two or more medications that are dissimilar to one another. Medications may be administered with variations in frequency, dosing, and routes of administration for different conditions. Therefore, one treatment might require more frequent dosing than another treatment, which may lead to higher out-of-pocket costs for the patient if a copayment is taken at each administration within an office as opposed to each monthly refill at a pharmacy. In turn, more vulnerable patients may be forced to choose less-advantageous treatments because they are less costly than safer, more effective treatments.

- *Create confusion and disruption for members.* Coverage parity mandates present a logistical challenge for MCOs to implement. One challenge is the potential for confusion for patients at the point-of-sale, whether that is at a pharmacy or provider's office. Treatment could be unnecessarily delayed, leading to frustration.

Mandated Coverage of Medications for Specific Indications

AMCP is opposed to any mandate that would require coverage of a medication for certain indications, regardless of whether the medication has received FDA-approval to treat the indication or not. MCOs use a variety of management tools to ensure that patients receive the appropriate medication for their condition. AMCP believes that MCOs must retain the flexibility to use all tools available to them to encourage the use of the safest treatments for their members that offer the best value to payers, while fulfilling the contractual agreements they have with health care purchasers.

Medications may be approved by the FDA for the treatment of just one condition, or multiple conditions. For one of those conditions, it may be the optimal, or only, treatment, while for another condition it may be one of several acceptable treatments. Similarly, medications may also be prescribed for conditions for which they have not been FDA-approved. This practice is commonly termed "off-label" use. Through efforts to expand medication coverage and limit administrative burden to physicians, legislators and policy makers have considered requiring MCOs to offer coverage of a medication for all FDA-approved indications and for any off-label indications found in recognized medication compendia.

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The FDA approval process is complex. Most drugs are approved by the FDA on the basis of clinical trials proving only that the drug is safe and efficacious, meaning that the drug performed successfully in controlled clinical trials with a carefully selected patient population that is not representative of the population as a whole (e.g., gender, age, ethnicity, lack of comorbidities, patient adherence rates, and concomitant medications). There are still many unknowns about a drug when it enters the marketplace; while most drugs cause few, if any problems, some drugs can cause serious side effects that were unknown at the time of approval. In order to protect patient safety, an MCO must retain the flexibility to determine when and how to introduce coverage of new medications to their members. Similarly, these mandates can fail to consider potentially less costly, but equally safe and effective, therapeutic and generic equivalents that have established safety records and which MCOs may wish to cover at a more favorable level.

AMCP is also opposed to mandates that would require coverage of a medication for an off-label use, even if it is recognized in medication compendia. While many medications are safely used to effectively treat many medical conditions for which they are not FDA-approved, medication compendia are but some of many sources of medication information. While they can be one potential source of identifying effective treatments, information obtained from compendia is just one consideration when determining which medications are the best treatment values for a certain patient population or an individual patient.[1] Specifically, there is often wide variability among indications listed in different compendia; compendia are not always the most up-to-date references available; and the quality of scientific evidence used to drive a medication's listing in compendia may vary. [2,3,4]

Government mandates can appear to offer an easy solution to challenges that face patients, MCOs and payers, but in reality, they often threaten to disrupt the stability of the very benefits they are intended to strengthen. MCOs offer benefit plans today that are designed to be affordable and to improve the value and quality of health care. Government mandates can hinder a health care delivery system's ability to customize needs for specific patient populations and develop innovative solutions to meet the growing demand for high-cost pharmaceuticals. They can also preclude efficient and effective use of health care resources and result in increased medical costs, reduced patient access to care, and reduced quality of care. Therefore, AMCP does not support government mandates for the specific design and content of pharmacy benefit programs.

See also AMCP's Position Statements on Formularies, Generic Drugs, Off-Label Use of Pharmaceuticals, Prescription Drug Coverage, and Therapeutic Interchange: www.amcp.org/positionstatements.

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[1] Radley DR. Off-label prescribing among office-based physicians. *Arch Intern Med*. 2006; 166; 1021-1026.

[2] Abernathy AP et al. Compendia for coverage of off –label uses of drugs and biologics in an anticancer chemotherapeutic regimen. Tech Assessment. Agency for Healthcare Research and Quality. Rockville, MD, May 2007. Available at http://www.cms.hhs.gov/determinationprocess/downloads/id46TA.pdf.

[3] Abernathy AP et al. Systematic review: Reliability of compendia methods for off-label oncology indications. *Ann Intern Med*. 2009; 150; 336-343.

[4] McKinney et al. White Paper: Potential Conflict of Interest in the Production of Drug Compendia. (Prepared by the Duke Evidence Based Practice Center under Contract with HHSA 290 2007 10066 I.) Rockville, MD. Agency for Healthcare Research and Quality. April 2009. Available at http://www.ahrq.gov/clinic/techix.htm.

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