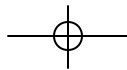


RESPONSE TO COMMENTS

Regarding AMCP's Format for Formulary Submissions



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RESPONSE TO COMMENTS

Since publication of The Academy of Managed Care Pharmacy's (AMCP) *Format for Formulary Submissions* in October 2000, AMCP and the Foundation for Managed Care Pharmacy (FMCP) have received hundreds of questions and comments regarding its use. To fully comprehend the significance of the *Format* it is important to understand AMCP's mission and place within the community of managed care pharmacy practitioners and organizations. The Academy is a professional membership association that represents pharmacists who have chosen to practice pharmacy in a variety of managed care settings. Therefore, AMCP does not act in the role of a trade association, representing businesses. The Academy strives to improve the practice of managed care pharmacy through outstanding educational programs, initiatives and tools, such as the *Format*, that assist its members in promoting wellness, providing rational drug therapy for individuals and enrolled patient populations and raising the bar of professional conduct for pharmacists.

Regarding the AMCP *Format*, the Academy has created a set of guidelines designed to improve the evaluation of medications for formulary consideration. The *Format* is intended to help pharmacists and their health systems achieve two principal goals; (1) decisions regarding a medication's inclusion on a formulary will be based on the overall value that medication brings to a specific population, and (2) the value argument will be based on good scientific evidence.

It is not the Academy's role, responsibility or desire to dictate to health care systems how they should implement the AMCP *Format*. However, this does not preclude AMCP from strongly recommending that its members follow certain procedures to improve the process. As AMCP and FMCP staff and a committee of select experts sifted through the hundreds of comments received by health system and pharmaceutical industry personnel, they identified several common themes. This document is devoted to addressing many of those common themes. By addressing these comments and concerns, the Academy and the Foundation hope to foster greater understanding and widespread adoption of the *Format* process. The Revision Committee did not intend to address every comment or concern, but rather those that have been repeatedly and consistently communicated to them since the *Format's* publication.

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COMMENT ONE

The AMCP *Format* requires a significant effort to evaluate medications. P&T Committees could simply put new or expensive drugs on the third tier of their benefit structure and avoid the cost and effort of the AMCP *Format* process.

One of the key purposes of a formulary is to make medications that produce the best positive outcomes at reasonable costs (those drugs that show value) available to a plan's membership. The AMCP *Format* guidelines are specifically designed for that purpose. They allow a P&T Committee to determine the clinical benefits of a drug, verify any cost savings the drug may generate, and determine the overall cost consequences to their health system.

If a health system simply puts a new or expensive medication on the third tier, two negative consequences could arise. First, despite its high cost, the medication may have significant clinical value. Providing appropriate incentives for its use could ultimately improve health and possibly lower overall health care costs. By simply choosing to place it on the third tier, a plan would in effect be disincentivizing their members from using it, resulting in missed opportunities to improve the health outcomes for individuals and groups of patients. Second, automatically putting the medication on the third tier denies the Pharmacy & Therapeutics (P&T) Committee or other decision making body the opportunity to fully assess the clinical and economic impact of the product on the health system's patient population. Paying for a drug that has little or no value could result in unforeseen dire consequences for patients and health systems.

COMMENT TWO

The AMCP *Format* is actually just a pharmacoeconomic tool and many P&T Committees have little expertise in evaluating outcome models.

A careful examination of the *Format* document will clearly show that these guidelines, first and foremost, require the health system staff to perform a thorough clinical evaluation of the medication based on all possible available information obtained from the manufacturer and other sources. If the desired outcome of the medication is not significant or the side effects too onerous, an economic review would be unnecessary. It is imperative to determine the potential clinical impact of a drug on its target patient population before considering the economic consequences.

The field of pharmacoeconomics is relatively new. Therefore, the current number of individuals in this country with a great deal of knowledge and experience in analyzing the type of information required by the *Format* is limited. While pharmacoeconomic models and outcomes research have become increasingly accepted as tools for helping health care systems make formulary decisions, many health systems do not have a pharmacist on staff with sufficient experience to analyze this information. There are at least two solutions to this problem. One would be to acquire the training on pharmacoeconomics for one or two staff pharmacists. Numerous organizations around the country provide this type of training, including the Foundation for Managed Care Pharmacy. Another solution is to hire an outside consultant to perform the reviews on the pharmacoeconomic models. Private consultants and faculty at colleges of pharmacy can help meet the needs of our health systems.

**COMMENT
THREE**

The FDA closely regulates the information a pharmaceutical company can provide regarding their medications. There is concern that complying with the *Format* information requirements may raise concerns at the FDA.

Beginning long before the *Format*'s publication, the Academy has maintained an ongoing dialogue with the FDA to keep them apprised of the project's progress and to seek their guidance. FDA officials have stated on several occasions that they are comfortable with the Academy's position that the *Format* represents an unsolicited request from a health system to a pharmaceutical company for all possible published and unpublished studies and information regarding both FDA-approved indications and anticipated off-label uses of the product. However, the FDA has three areas of concern relative to this process. First, the information provided cannot be false or misleading. Second, the request must truly be unsolicited. Third, the response must be specific to the requestor.

Regarding the first concern, FDA regulations require pharmaceutical companies to provide accurate information that will benefit the requestor. The pharmaceutical industry takes this responsibility seriously and the AMCP *Format* recognizes the importance of these requirements. Health systems and manufacturers can virtually eliminate the second and third concerns if they follow some simple procedures. Health systems must initiate the request and make clear what information they desire. The AMCP *Format* is a template designed specifically for this purpose. AMCP recommends that health systems also submit a signed request letter to accompany the *Format*. Pharmaceutical companies must refrain from taking any proactive steps that could be construed as marketing or promotion such as preparing identical formulary submission documents (dossiers) for a product with the intent of soliciting health system pharmacists by asking them to request a dossier. In this scenario, the request would not be truly unsolicited nor would the contents of the response (the dossier) be specific to the requestor.

COMMENT FOUR

Pharmaceutical companies have repeatedly expressed concern about the confidentiality of dossier contents.

AMCP has always supported the desire by the pharmaceutical industry to maintain the confidentiality of certain information contained in product dossiers. The most recent version of the *Format* contains the following statement, "By submitting this request (the health system) recognizes that confidential information may be provided. (The health system) recognizes the need to respect and honor commercial-in-confidence information and may be willing to sign necessary confidentiality agreements under agreed circumstances." As public agencies such as state Medicaid agencies and the Department of Defense have begun to adopt the *Format*, some pharmaceutical companies have expressed an increasing level of concern about the need for confidentiality. The Academy has counseled public agencies that are considering the use of the AMCP *Format*, to develop procedures that will allow them to keep the dossiers confidential. The Academy strongly recommends that any organization that is using AMCP's *Format* should work diligently to find ways to keep the dossiers confidential and examine all opportunities to work within state statutes in meeting this goal. If issues of confidentiality cannot be overcome due to state public disclosure statutes, the information provided by a pharmaceutical manufacturer may not contain sufficient evidence for a public agency to make a rational evidence-based decision regarding the value of the product under consideration. In addition, AMCP encourages any organization that begins using AMCP's *Format* hold the presubmission meeting with pharmaceutical companies called for in the *Format* to disclose the level of confidentiality that will be possible and to ascertain what level of data can be expected to be furnished.

COMMENT FOUR

continued

In supporting this concern, it is important to point out that this stipulation is unique to the United States, since dossiers submitted in Canada, the United Kingdom and Australia are available to the public. The concerns in this country seem to revolve around the pharmacoeconomic model, the submission of unpublished studies and off-label use information and the creation of the dossier itself. While some pharmaceutical companies have spent a great deal of time and money on outcomes research, pharmacoeconomic modeling, and creation of dossiers, others are not as scientifically sophisticated. Because of this broad variation, some pharmaceutical companies would like to keep their work confidential to prevent their competitors from capitalizing on their efforts.

COMMENT FIVE

There should be substantial on-going communication between the health system and the pharmaceutical company throughout this process to manage expectations and maximize the quality of the deliverables.

Those organizations that have been early adopters of the AMCP *Format* have expressed the importance of and concern for good communication. The basic element in most project failures whether it is from employee performance, the business plan, or vendor relationships, is communication. When a dossier is requested from a health system, it is important for that organization to explain to the pharmaceutical company some basic information, such as their time-line, the evaluation process, potential data sources, any special needs that might exist, etc. This also gives the pharmaceutical company an opportunity to discuss deliverables. If they cannot submit specific studies or provide a certain piece of the economic analysis, it is better to understand the limitations up front. Again, AMCP will not presume to dictate to its members that they should significantly alter or disrupt their normal lines of communication with pharmaceutical manufacturers. However, both parties should recognize that when there is a high level of collaboration, there is a relative increase in the chances that the process will be smoother and the quality of the dossiers submitted will be higher.

COMMENT SIX

While many acknowledge the benefits of the AMCP *Format*, there is the tendency on the part of many organizations to want to recreate their own similar process.

There is an important element in the AMCP *Format* that many people overlook. The element is consistency and standardization. As indicated previously, the AMCP *Format* is a template that any health system can readily adapt to their specific needs. This not only makes it easy for the health system, but also makes it dramatically easier for the pharmaceutical company. Although manufacturers must tailor their responses to the requesting health system, utilizing the AMCP *Format* allows a pharmaceutical company to have 80 to 90 percent of the information, especially the clinical information, completed and formatted. Individual health systems will severely diminish the element of standardization if they choose to create their own processes. While the Academy understands the need for some health systems to make small modifications in the AMCP *Format* template, the hope is that those health systems will refrain from making wholesale modifications.

**COMMENT
SEVEN**

Some health care systems are under the impression that only pharmacoeconomic models that strictly mirror a health system's targeted patient population are acceptable.

The AMCP *Format* describes in some detail the most important elements of the requested pharmacoeconomic model. The *Format* further stipulates that the economic data called for must be broadly applicable to a health system's population addressing the system-wide impact of formulary changes on both clinical outcomes and resource utilization and costs. The *Format*, however, does not specify methods for economic evaluation. It is the submitter's responsibility to utilize appropriate techniques and data sources. Ideally, a manufacturer would use a health system's own data to customize the model. Realistically, a highly individualized model may not be necessary, feasible, or scientifically plausible. Often, the information necessary to create a highly individualized model will not be available because health systems will be either unwilling or unable to supply it. A reasonable compromise would be for the health system to request a model based on national norms or a pre-existing model with the manufacturer justifying the relevance of the data to the health system's patient population. In addition, the model should be adaptable, allowing the health system to change multiple elements by inserting its own data. Once a manufacturer has received an unsolicited request letter, it could facilitate this process and avoid misunderstandings by asking the health system to answer a standard set of questions that would detail the information they would be willing to accept, such as national norm data or a pre-existing model. A manufacturer's dossier that met the health system's criteria would conform to the FDA's requirements for responses to Unsolicited Requests.

COMMENT EIGHT

There is an attitude among many health care professionals that all information coming from pharmaceutical companies is biased. Therefore, they assume that all pharmacoeconomic models created or sponsored by the pharmaceutical industry are of little value.

Certainly health care systems should expect that pharmaceutical manufacturers would exert considerable effort to put their products in the best light. Pharmacy & Therapeutics Committee members understand this principle and therefore examine all information with a degree of skepticism. It is healthy to be skeptical of information if it motivates an individual to carefully review studies to determine the accuracy of data and the conclusions drawn from them. If health care professionals assume that all pharmacoeconomic work or any other data is completely biased and of limited value simply because it is completed by industry, they ignore the fact that some of the best scientists and thought leaders trained in pharmacoeconomics have been hired by the pharmaceutical industry. Their work can be excellent. Successful implementation of the *Format* process requires a commitment on the part of the health system to devote resources to critically appraise the data supplied by manufacturers before its submission to the P&T Committee. In addition to a critical evaluation of the clinical information, the review should include an evaluation of the economic data by one trained in pharmacoeconomics.

