■ Correction Necessary Regarding CMS Guidance for Coverage of New Multiple-Source Brand Drugs

To the Editor:

In their article, "Medicare Part D: Selected Issues for Pharmacists and Beneficiaries in 2007," Kilian and Stubbings state that, if a plan replaces a brand medication with its generic equivalent, the plan must continue to cover the brand for affected enrollees at the original copay for the remainder of the year.¹ I do not believe this to be an accurate interpretation of the Centers for Medicare & Medicaid Services guidance.

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DISCLOSURE

The author discloses no potential bias or conflict of interest relating to this letter.

REFERENCE

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The Authors Respond:

DePue is correct. Part D plans may make maintenance changes to their formulary, such as replacing brand-name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness. Those changes must be made in accordance with the approval procedures described by Block and following 60 days notice to the Centers for Medicare & Medicaid Services (CMS), state pharmacy assistance programs, prescribers, network pharmacies, pharmacists, and "affected enrollees."¹ There are other types of formulary changes that are not considered maintenance changes, such as changing preferred or nonpreferred formulary drugs, adding utilization management, removing dosage forms, increasing cost sharing on preferred drugs (unrelated to the reasons stated above), or exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges). For these additional types of formulary changes approved by CMS, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year.

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DISCLOSURES

The authors disclose no potential bias or conflict of interest relating to this letter.

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■ Manufacturer Response to AMCP Format Dossier Requests

To the Editor:

We applaud Spooner et al.'s report on requests for an AMCP Format-based dossier and submissions by pharmaceutical manufacturers.¹ Case study reports by individual plans provide a context for understanding the diffusion of the *Format's* use. Although secondary to the study's main focus, their comments on a possible relationship between formulary placement and dossier submission raise a critical issue in a voluntary process such as this—will manufacturers see their interests better served by voluntarily submitting a dossier or is opting out without a downside risk?

A formulary placement decision is the result of numerous considerations, such as the clinical need for the product under review; the existence of viable alternatives; safety profiles; all else being equal, the relative costs for alternative products; and the evidence and analysis provided by a credible dossier. The number of variables for which data would be needed and the sample size for the number of organizations and product decisions that would provide adequate statistical power for stable estimates of effect for each of these factors require an effort that is unlikely to be logistically feasible for both methodological and business reasons.

Disentangling the effect of the dossier alone or attributing a decision about a product's placement to the existence of a dossier might be impossible quantitatively, but inferences can be generated qualitatively. Unfortunately the Spooner et al. study was not designed nor was it able to evaluate decisions qualitatively. It is interesting, however, that their observed preferred formulary placement (16.1%) is close to the reported percentage of innovative products approved in the National Institute for Health Care Management Foundation (15%).² This comparability does not prove that these decisions were based on an innovation scale, but it does reinforce the dossier's role—to identify evidence needed, to define how it should be presented, and to provide more complete data for a sound Pharmacy & Therapeutics (P&T) committee decision. Its role is not to be an evaluation process to lower prescription drug costs, a sales or marketing tool, a formulary kit, or a simple pharmacoeconomic evaluation tool.³

Colmenero observed a significant association between dossier quality and whether the drug is an innovative product.⁴ We intuitively expect this since manufacturers of products that represent a clinically significant advance in therapy would logically embrace the AMCP *Format* as a vehicle to showcase these products' therapeutic value. If the payer does not require a dossier as a precondition for formulary review, this factor could be an important confounder.

Unlike the experience in some other nations, the provision of a dossier using the suggested AMCP *Format* is voluntary, not part of a regulatory process. The *Format* was created to meet the information needs of P&T committees when they make decisions about product placement on a formulary. Success through a voluntary approach and arising from the marketplace may avoid a regulatory approach to obtaining the information contained in a dossier, and it is more consistent with an American preference. There is a long, slow learning curve for the development and integration of clinical and economic information into a meaningful dossier—Australia's experience suggests that regulation, explicit procedures for compilation, and fiscal consequences do not assure content or quality of the information and economic pharmacoeconomic models.⁵

The *Format* provides an opportunity for improved communications between manufacturers, health plans, and pharmacy benefit managers ("Communication—The Key To Success"). The *Format* recommends that this communication begin about 6 months prior to the launch of a product—enough time for discussions rather than demands regarding data needs and other aspects of the dossier request. Spooner et al.'s methodology used telephone and e-mail requests "about 8 weeks before the committee meeting." It is likely that this design decision had an impact on the observed results since only products for which a dossier was already available would have met this request.

From an industry point of view, not responding to an unsolicited request for a dossier is a lost opportunity. In the absence of the dossier process, the only information industry can legally provide is the information contained in the U.S. Food and Drug Administration-approved label. If the industry wants to communicate information that is not in the label (e.g., other supportive clinical studies, budget impact analyses, database studies, etc.), then the dossier process, in response to an unsolicited request, is the only mechanism that will allow them to do it.

We encourage more assessments of the use of the AMCP *Format* and study designs that make clear inferences about the relationship between the dossier and the subsequent formulary decision. Spooner et al. does not do this, but that was not their purpose. Our goal remains as stated in the introduction to the dossier: "The AMCP *Format* has the potential to serve as a national, unifying template for P&T committees to consider clinical and economic information in a systematic and rigorous

fashion. It is a welcome development for a U.S. health system that is in need of more rigorous evaluation of evidence."⁶

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DISCLOSURES

Alan Lyles and John D. Watkins are members of the AMCP *Format* Executive Committee. Lyles has consulted with pharmaceutical companies, PBMs, health plans, and governments.

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The Authors Respond:

We do not dispute Lyles and Watkins' suggestion that the results of the analysis may have been different with a longer lead time in making unsolicited requests for dossiers. As envisioned in the AMCP *Format*, health plans or pharmacy benefit managers who are able to set their Pharmacy & Therapeutics committee agenda 6 months or more in advance may have the opportunity to collaborate with manufacturers to build dossiers with customized content, particularly with regard to economic and disease state modeling. However, our experience in having only 2 months lead time to prepare materials for P&T committee evaluation may more closely approximate the real-world conditions that many health plans face. Further, no manufacturer has offered us the opportunity to collaborate with them to build a customized

dossier. In this instance, the short lead time and the inability to disclose the identity of the health plan we were working with were clear—and likely insurmountable—barriers to developing a customized dossier. However, dossier requests for other clients, with longer lead times and the ability to share plan-specific data, have met the same fate. Our experiences suggest that giving longer notice to manufacturers does not increase the likelihood of collaboration between the parties to build a customized dossier.

We thank Lyles and Watkins for their interest in our research. We share their goal, and the goal of the AMCP Format Executive Committee, to bring more and better evidence to members of P&T committees to better inform formulary decision making.

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Letters to the Editor

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January 2007 Supplement Correction

Solomon DH. The comparative safety and effectiveness of TNF- α antagonists in adult rheumatoid arthritis study by the AHRQ Effective Health Care Program. *J Manag Care Pharm.* 2007;13(1)(suppl):S7-S18.

The revised title is "The Comparative Safety and Effectiveness of TNF- α Antagonists."

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