CMS Issues Guidelines for the Review of Part D Formularies and Procedures; Additional Bidding Information Also Provided

The Centers for Medicare and Medicaid Services ("CMS") has issued several documents discussing the implementation of the Medicare Part D prescription drug benefit under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). These documents include draft guidance regarding CMS review of formularies and procedures proposed for Part D plans.\(^1\) This guidance document provides insight into some of CMS's likely responses to comments on the Part D proposed rule. The guidance is open for comment until December 30, 2004,\(^2\) and will not be finalized until publication of the Final Rule for Part D in January 2005. CMS also published several guidance documents for prospective Part D plan sponsors, including a timetable for submission and approval of bids. Comments on these documents also are due to CMS by December 30.

Guidance for Formulary and Procedure Review

The MMA allows CMS to approve Part D plans if, among other requirements, “the Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.”\(^3\) The new guidance document provides detail regarding the requirements that plan formulary lists, benefit management tools, and pharmacy and therapeutics ("P&T") committees must meet in order to be found to be non-discriminatory.

- **Plan Formulary Design and Drug Selection**
  - CMS may consider Part D plan formulary designs to be discriminatory even if the drug categories and classes are non-discriminatory. CMS will evaluate the specific drugs included within each formulary system, as well as the structure of the formulary system, in the plan's application for endorsement and on an ongoing basis thereafter. Strict adherence to the regulatory requirements and to the Model Guidelines developed by the U.S. Pharmacopeia (“USP”) may not provide adequate assurance that the plan is non-discriminatory: Plans also must take the additional steps detailed in the guidance. Formularies will be reviewed against a range of benchmarks derived from best practices from private sector, Medicaid, and Federal Employee Health Benefits (“FEHB”) programs. Outliers will be subject to additional review.

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2. CMS specifies that commenters need not restate points made in comments to the proposed Part D regulations. Id. at 2.
Formulary structures consistent with the USP Model Guidelines (possibly including structures that are similar but not identical to the Model Guidelines) will fall within a “safe harbor” with regard to the formulary structure only. The safe harbor does not provide plans with a significant advantage because CMS still will review the specific drugs covered by the plan. CMS “will not consider a classification system in isolation from the subsequent steps in [the agency’s] formulary review.”

CMS prefers formulary classification systems similar to those currently in “widespread use” in plans providing “high-quality drug coverage to millions of Medicare beneficiaries,” modified for specific features of the Part D program. Indeed, CMS will approve classification systems used in plans that currently provide drug benefits to a “significant number” of Medicare beneficiaries. Plan structures that differ from USP’s model and that are not currently in use will be reviewed for similarity to systems currently used in these types of plans. Formulary structures using fewer classes may be acceptable if they cover an adequate range of drugs, however.

In addition, CMS will review the drugs covered by each plan, as well as the drugs’ tier placement, to ensure that each formulary is non-discriminatory. Proposed Part D drug lists will be compared with each other and with benchmarks derived from existing widely-used formularies, taking into consideration widely accepted treatment guidelines. One possible benchmark is the “availability and tier position of the commonly prescribed drugs, particularly the top 25-50 drugs for the Medicare population in terms of cost and utilization.” Although the guidance does not state that orphan drugs will receive any special protection, CMS will assess each formulary for the availability and positioning of drugs commonly prescribed for uncommon conditions.

CMS thus may require fairly broad drug coverage. CMS “may require more than two drugs per class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy.” Indeed, “[i]n some cases, widespread industry practices and widely used treatment guidelines require all or substantially all drugs in a particular class to be covered.” CMS is considering whether to use the Model Guidelines’ third column (recommended subdivisions) as a

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4 CMS requests comment on whether “similar” formulary structures should fall within the safe harbor.
5 Formulary Guidance at 7-8.
6 Id. at 7.
7 CMS seeks comment on the existing classification systems that might provide appropriate standards. Id. at 8.
8 CMS seeks comment regarding the treatment guidelines that it should consider. Id. at 9.
9 Id.
10 Id. at 8.
11 Id. at 9.
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proxy for comprehensiveness, and seeks comment regarding the appropriateness of doing so.

➢ Where industry best practices generally require favorable tier placement for a particular drug, CMS will require plans to justify any less favorable placement. CMS also suggests that drugs may be placed on a less preferable tier only if therapeutically equivalent drugs are available in a preferred tier.12

• Benefit Management Tools

➢ CMS will review plans' proposed policies and procedures for prior authorization, step therapy, and generic substitution against current industry standards, current practices of plans providing drug coverage for the elderly and disabled, and guidelines from organizations such as the National Committee for Quality Assurance (“NCQA”), Academy of Managed Care Pharmacy (“AMCP”), and National Association of Insurance Commissioners (“NAIC”). Similarly, CMS will review proposed drug utilization review procedures for consistency with the plan sponsor’s practices in its commercial coverage, as well as with industry best practices.

➢ The guidance does not address in detail the requirements for plan grievance, appeals, and exceptions processes, stating that the Final Rule will address these issues. CMS does state that a non-formulary drug may be needed “when the formulary drug would cause adverse effects or would not be effective or both, based on scientific evidence or medical necessity.”13 CMS will review policies and procedures regarding non-formulary drugs.

• P&T Committees

➢ CMS will review the structure and use of each plan's P&T committee against established principles and best practices. The P&T committee must approve the plan’s formulary structure on an annual basis. If the committee does not review each new chemical entity within 90 days of its release onto the market, the committee must provide clinical justification for its failure to meet the timeframe.

➢ The guidance provides additional detail regarding the P&T committee’s role, although certain elements remain unclear. The P&T committee must have “a key role” in defining policies for utilization management activities and must review the policies for clinical appropriateness, ensuring that the tools are used to ensure medically appropriate and cost-effective access to Part D drugs. The guidance does not clarify the extent to which the committee’s decisions are binding on the plan. In addition, like the proposed rule, the guidance states that although the P&T committee’s decisions must be based on scientific criteria, the decisions also may be based on

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12 Id. CMS suggests that this constitutes the best practice in existing formularies, and states throughout the guidance that it will review formularies for consistency with best practices. CMS might allow other structures with justification.

13 Id. at 7.
pharmacoeconomic considerations. The extent to which pharmacoeconomic issues may influence committee decision making remains unclear.

- The guidelines reiterate many of the statutory and proposed regulatory requirements for P&T committee membership. In addition to the statutory requirement that one practicing pharmacist and one practicing physician be “independent and free of conflict with respect to the sponsor and plan,” each committee member must reveal “economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions,” such as relationships with manufacturers. Only the two specified members must be completely free from conflicts, however.

- **Implications of the Guidance for Drug Manufacturers**
  
  - Although this guidance, like the proposed rule, is only in draft form, this document provides additional insight into the likely structure and makeup of Part D plan formularies. It suggests that CMS will prefer—and may require—formularies that more closely resemble the expansive formularies proposed by patient groups and pharmaceutical manufacturers than the more limited formularies preferred by insurers. Moreover, USP’s Model Guidelines appear to play a less significant role than originally anticipated and than preferred by prospective plan sponsors. Among the several topics upon which CMS requested comment, manufacturers may wish to comment on this result in particular.

  - The use of industry best practices as a standard, although superficially helpful to patient groups and to manufacturers, is likely to result in uncertainty. The guidance and the proposed rule do not describe the method or the criteria by which CMS will determine the current “best” practices. Although treatment guidelines are well-established, formulary structures and drug lists vary significantly. CMS’s determinations may appear to be arbitrary unless the agency provides additional information. In addition, CMS has not described any system for general appeals or reviews of a plan’s formulary structure and drug list. Neither the guidance nor the proposed rule provide a means by which stakeholders such as health care providers, pharmaceutical manufacturers, and patient advocates can challenge a CMS determination that a particular aspect of formulary design or a particular drug tiering decision is non-discriminatory. It is unclear whether CMS has considered the necessity of such a procedure. Manufacturers may consider this point worthy of comment, as well.

**Additional Documents Issued by CMS**

In addition to the draft guidelines for CMS review of plan formularies, CMS released the following guidance and technical documents for organizations seeking to become sponsors of prescription drug

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14 Id. at 6.
plans ("PDPs"), Medicare Advantage plans offering prescription drug benefits ("MA-PDs"), or fallback plans: 15

- Draft Medicare PDP Solicitation.
- Draft Licensure Waiver Request and Draft Solvency Standards.
- Draft PDP Bid Instructions and Pricing Tool.

The White Paper on Application and Contracting Process provides a detailed draft timetable on the key milestones in the PDP application and review process. CMS has set the following key dates, establishing a timetable that will be challenging both to the organizations seeking Medicare Part D contracts and to CMS reviewers:

- Late January 2005 - CMS to release final solicitation for applications for entities seeking a contract to operate as a PDP sponsor
- Early February - Bidders Conference
- March - Applications due
- April 18 - Formularies due to CMS for review
- May 16 - CMS provides preliminary approval of formularies
- May/June - CMS notifies bidders of their eligibility for PDP contract
- June 6 - Bids due for each separate PDP and MA-PD plan for 2006
- July 24 - Preliminary CMS approval/disapproval of bids
- August 2 - CMS publishes national average Part D premium, to be used in determining the enrollee premium for each plan
- September 2 - CMS approves bids and enters into PDP contracts

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15 All documents are available via http://www.cms.hhs.gov/pdps. The documents released by CMS on December 3 did not include the anticipated guidance regarding waivers for employer-only Part D plans. That guidance is expected to be released in the near future, although CMS has not identified a specific date.
A similar schedule, with modifications to incorporate federal contracting processes under the Federal Acquisition Regulations ("FAR"), will apply to fallback plans. Successful fallback plan bids will not be announced until September 2005.

Covington & Burling continues to analyze the implications of this guidance and to identify issues upon which industry clients may wish to comment. We will be participating in the December 13 Open Door Forum discussing all of the topics addressed in this memorandum.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please call any of the following members of our health care practice:

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