Comments Submitted in Response to CMS Medicare Drug Benefit Proposed Rule

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”) provides for the addition of an outpatient prescription drug benefit to the Medicare program. This new optional Medicare Part D coverage will be available to Medicare beneficiaries beginning January 1, 2006.

The Centers for Medicare and Medicaid Services (CMS) has published a proposed rule to create regulations at 42 C.F.R. Parts 403, 411, 417, and 423, which will implement the new prescription drug benefit. In an August 2004 memorandum, http://www.cov.com/publications/download/oid6077/488.pdf, we outlined the provisions of the proposed rule that are of greatest interest to pharmaceutical industry clients.

CMS accepted comments on the proposed rule through October 4, 2004. This memorandum provides a sampling of some of the primary issues raised in the comments submitted by pharmaceutical and biotechnology manufacturers, physician and pharmacy provider groups, pharmacy benefit managers, insurers, employer trade associations, consumer groups, and state groups. This memorandum is not intended to be a comprehensive summary of the comments submitted to CMS.

The final rule is expected to be published in the Federal Register by mid-January 2005. Covington and Burling will issue a detailed summary/analysis of the rule following its publication.

Manufacturer Comments

Patient Access. Manufacturer comments focused heavily on ensuring that beneficiaries have appropriate access to necessary medications. Specifically, many manufacturers criticized the USP draft model guidelines, suggesting that overly broad categories and classes will jeopardize patient access. In addition to suggesting that the draft guidelines should be refined, manufacturers suggested a variety of other steps that CMS might take to ensure that an appropriate number of drugs are available to all beneficiaries. For example, some urged CMS to clarify that formulary drugs that are subject to certain utilization management tools (e.g., prior authorization, step therapy, and unusually high cost-sharing) may not count toward the two-drug per category/class minimum.

Manufacturers are also concerned that dual-eligible beneficiaries, who will not be covered by Medicaid after January 1, 2006, may experience a gap in coverage if they are not automatically enrolled in a Part D plan until May 15, 2006. Many manufacturers recommended that CMS automatically enroll full-benefit dual-eligibles by January 1, 2006.

Most manufacturers objected in some manner to CMS's definition of “appropriate notice” for formulary changes as 30 days prior to implementation. Many objected to the allowance of any mid-year formulary changes because such changes could subject enrollees to “bait and switch” tactics – i.e., providing an attractive drug formulary to encourage enrollment and then eliminating drugs from that formulary after the open enrollment period has expired and enrollees are locked into the plan. Many comments suggested that if mid-year changes are allowed, enrollees should be granted continued
access to their current drug regimen at the same cost-sharing level for the duration of the plan year.

Manufacturers applauded CMS’s position that assistance from bona fide charitable organizations and state pharmacy assistance programs (SPAPs) should count toward a beneficiary’s true out-of-pocket expenses (TrOOP). Many also encouraged CMS to count contributions from manufacturers’ patient assistance programs (PAPs) toward the TrOOP. Along these lines, several comments requested assurance from the Office of Inspector General (OIG) that assistance provided by manufacturers through PAPs will be permitted under the federal fraud and abuse laws.

Manufacturers urged CMS to issue regulations that accommodate the needs of special populations. Special populations may include beneficiaries in long-term care facilities, dual-eligible beneficiaries, and beneficiaries with HIV/AIDS, mental health conditions, or cancer. Some manufacturers suggested that members of special populations should be guaranteed coverage through an open formulary so that they can obtain the medications needed to optimally manage their disease.

Coordination of Medicare Parts B and D. Manufacturers expressed widespread support for CMS’s position that claims submitted and denied under Part B should be automatically re-submitted to a Part D plan. Several, however, objected to CMS’s position that a drug denied under Part B for reasons related to “medical necessity” should also be denied under Part D. For example, one manufacturer pointed out that such a provision would effectively nullify Part D coverage for vaccines, which are generally not covered under Part B for reasons of medical necessity but which Congress intended to be covered under Part D.

Many manufacturers also indicated their concern over CMS’s statement in the preamble that “any drug covered under A or B could not be covered under D, whether it was covered for that individual or not.” Manufacturers urged CMS to clarify that this statement applies only to the extent that the individual is eligible for Part B but has declined to enroll in Part B.

Exceptions, Grievances, and Appeals. Manufacturers expressed concern about the complex nature of the exceptions and appeals process and advocated its simplification and clarification. Specifically, manufacturers urged CMS to clarify that the denial of a drug at the pharmacy counter is a “coverage determination” and that beneficiaries should, at the time of such denials, be provided the appropriate notice explaining their appeal rights. Many comments also asked CMS to require plans to provide coverage during the full course of an exceptions request for continued coverage. Currently, the proposed regulations provide for coverage only if the sponsor fails to make a timely decision on an exceptions request.

Pharmaceutical & Therapeutics (P&T) Committees. CMS has taken the position that P&T committee decisions regarding a plan’s formulary are binding on the plan. Many of the comments voiced their support for this interpretation, although some encouraged CMS to state this interpretation more explicitly. The comments did diverge with respect to the appropriate scope of this binding authority. One manufacturer, for example, urged that only P&T committee decisions relating to the list of drugs on the formulary should be binding and that the plan should be permitted greater flexibility in the process of assigning specific drugs to formulary tiers. Another manufacturer urged CMS to give P&T committees binding authority not only over the development of formulary lists, but also over all restrictive coverage policies.

The proposed regulations provide that P&T committee members must be free of conflict with respect to the sponsor, the PDP, and pharmaceutical manufacturers. Most of the comments urged CMS to reconsider the inclusion of pharmaceutical manufacturers in the independence requirement, noting that the statute does not mention manufacturers and that pharmaceutical clinical researchers are
precisely the type of physicians who should serve on P&T committees. Conflicts of interest, they suggested, can be avoided by requiring physicians to recuse themselves from all P&T committee decisions relating to drugs with which they have been associated.

Medication Therapy Management Programs (MTMPs). CMS proposed that MTMPs should be used to provide services that will optimize therapeutic outcomes for targeted enrollees, namely those with multiple chronic diseases who take multiple Part D covered drugs and who are likely to incur annual costs exceeding a fixed level. While the comments generally supported this use of these programs, many expressed concern that MTMPs would be used simply as another means of reducing pharmacy costs. These comments urged CMS to clarify that costs should not be the sole focus of these programs and that other issues such as compliance, persistency, optimization of multiple drug regimens, and patient education are an important focus.

Confidentiality. The proposed regulations require disclosure to CMS of aggregate information on negotiated price concessions, as well as information necessary to pay PDPs and MA-PDs for qualified prescription drug coverage, data regarding drug claims at an individual level, and other information CMS deems necessary. Several comments noted that the proposed regulations apply the confidentiality protections of the Medicaid rebate law to the aggregate price information, and they urged CMS to extend the Medicaid confidentiality provisions to the other information as well.

Physician and Pharmacy Provider Group Comments

Broadly speaking, physician and pharmacy provider groups are interested in ensuring patient access to necessary medications and to community retail pharmacies. Most importantly, provider groups urged CMS to require PDPs and MA-PDs to offer open or alternative formularies to special needs populations to ensure that they have access to a full range of medications. They also suggested that alternative formularies for vulnerable populations should be exempt from cost-containment measures that will prevent beneficiaries from receiving appropriate and effective treatment and that administrative burdens placed upon physicians with respect to cost-containment methods and the prescription of drugs for off-label uses should be minimized.

Provider groups recommended that, if CMS does not create an alternative or open formulary for vulnerable populations, it should create a special exceptions or appeals process for these populations. For example, provider groups urged CMS to require only a physician attestation or comparable certificate of medical necessity to accompany prescriptions for non-formulary drugs, rather than allowing individual PDPs to establish their own criteria for determining when an exceptions request should be granted.

Providers also expressed concern that plans may inappropriately steer beneficiaries away from community retail pharmacies and toward mail order pharmacies. To avoid this problem, providers suggested that cost-sharing requirements and formularies should be the same for retail pharmacies and for mail order pharmacies and that CMS should prevent PDPs from owning their own mail service pharmacies and steering beneficiaries to these facilities. Overall, provider groups suggested that the regulations should be modified to ensure greater access to and interaction with community retail pharmacies.

Pharmacy Benefit Manager (PBM) Comments

Formulary Structure. In general, PBMs noted that the proposed rule and the USP draft model guidelines strike an appropriate balance. One commenter supported CMS’s statement in the preamble allowing sponsors to populate categories with drugs used off-label. One PBM pushed for greater
flexibility, suggesting that if a class contains only two drugs, the plan should be allowed to cover only one and make the other available on an exceptions basis.

Coordination of Medicare Parts B and D. PBMs commented that much more structure is necessary in order for plans to determine whether a drug is appropriately covered and billed under Part B or Part D for a particular patient. They encouraged CMS to create clear rules for determining whether a claim is to be processed to Part B or Part D. Furthermore, they noted that Part B coverage varies by region and national sponsors cannot coordinate with local carrier review boards.

PBMs also suggested that plans will need additional information in order to determine the extent of a particular patient's coverage (e.g., whether a patient has Part B coverage) and whether a drug has been or should be covered under Part B (e.g., whether a transplant was covered by Medicare). They suggested that pharmacists could be enlisted to solicit information from patients, and they asked CMS to instruct beneficiaries to inform their plan sponsor if the covered drugs are “incident to” an office visit.

Pharmaceutical & Therapeutics (P&T) Committees. PBMs argued that the expanded role given to P&T committees in the proposed rule is inappropriate. In their view, the P&T committee’s binding authority should be limited to clinical decision making, including formulary categories and classes and drugs that are mandatory on formulary. PBMs argued that sponsors should not be required to involve P&T committees in tier design, drug placement on tiers, optional drugs, benefit design, cost-sharing, step therapy, prior authorization, generics programs, and other cost-containment measures. They also argued that P&T committees should not be involved in operational and policy issues that traditionally involve business decisions.

Drug Utilization Management. PBMs requested greater flexibility with regard to selection of drug utilization management tools. For example, they would like to be able to use step therapy at the class level as well as the subdivision level and would like to be permitted to require prior authorization for any drug in any category or class. One commenter also urged that PBMs should have flexibility to change the tier structure without being required to grandfather patients or guarantee a benefit to existing beneficiaries. PBMs also asked that CMS's review of the plan's tools be limited to an abuse of discretion or arbitrary and capricious standard of review.

Confidentiality. PBMs argued that the proposed confidentiality provisions are inadequate to protect proprietary data, including the details of contracts with pharmaceutical manufacturers. PBMs requested that CMS treat all information submitted by the sponsor as confidential unless regulations specifically require CMS to make the information available to eligible enrollees. Commenters argued that the sponsor also should have the right to receive notice of any intended disclosure (beyond the purpose for which the information was provided), the opportunity to object, and the right to obtain a court order if necessary.

Insurer Comments

Formulary Structure. Insurers urged CMS to modify the formulary provisions in several ways. For example, they asked CMS to allow generic-only choices in categories with many generic alternatives. They also asked CMS to allow coverage of a single drug if the plan demonstrates clinical efficacy on only one drug, suggesting that plans should not be required to include clinically inferior products simply to satisfy the two-drug per category/class requirement.

Insurers asked CMS to clarify that if a plan applies 100 percent cost-sharing to a drug, that drug is “non-formulary.” They also asked CMS to clarify that a formulary can give preference to some doses
over others but that a range of strengths and doses is preferable where feasible. Finally, insurers recommended that, for categories in which OTC drugs are available, CMS should either allow Rx-to-OTC switched drugs (e.g., Prilosec, Claritin) to count toward the two-drug per category/class requirement or should modify the two-drug requirement.

**Pharmaceutical & Therapeutics (P&T) Committees.** Insurers differed in their reactions to the proposal that P&T committee formulary decisions bind the sponsor. One commenter noted that this provision is consistent with the statute, but others disagreed that P&T committee formulary decisions should be binding. The same commenter urged CMS to change the language to allow MA plans to continue to meet accreditation requirements because MA plan accreditation requirements may require a plan to intervene in P&T committee action.

Insurers also differed with respect to the proper role of the P&T committee in utilization management activities. One insurer commented that P&T committees should be responsible only for reviewing utilization management activities to ensure that they promote the clinically appropriate use of drugs and optimum treatment outcomes. Another insurer, in contrast, supported the CMS proposal as written. Yet another insurer advocated a middle ground, agreeing that the P&T committee should be involved in formulary tiers and clinical programs but should not be involved in more specific benefit design issues such as co-payment level. One insurer requested that CMS allow plans the flexibility to determine their P&T committee's role.

**Requests for Clarification.** Insurers urged CMS to use language that clearly describes whether each provision applies to PDPs, MA-PDs, or both.

**Exceptions.** Insurers asked CMS to limit exceptions in several different ways. For example, they would like all plans to impose quantity limits based on FDA-approved dosing for drugs covered under an exception; they would require annual reevaluation of all exceptions that are the subject of continuing prescriptions; they would allow coverage of continuing prescriptions under an exception only if the drug is prescribed for a chronic condition; and they would allow plans to subject exceptions to additional coverage requirements (e.g., new step therapy requirements).

Insurers also asked CMS to clarify that exceptions are made case by case; that exceptions do not entitle beneficiaries to the lowest (generic) co-pay but only to the preferred co-pay applied to branded products; and that, where the sponsor delegates to the physician the question of medical necessity, the physician is not required to establish an elaborate exceptions process to reach this decision but that the beneficiary may request a redetermination from the sponsor if rejected.

**Confidentiality.** Insurers asked CMS to change the confidentiality provisions to ensure that proprietary and/or sensitive price data is protected from disclosure and to exclude all pricing information from FOIA disclosures. They also asked CMS to ensure that vendors cannot share prescription data and prescriber practice pattern data with manufacturers for marketing purposes. If the regulations do not prohibit this practice, insurers argued, they should allow insurers to limit pharmacy disclosures contractually.

**Employer Trade Association Comments**

**Requests for Clarification, Greater Flexibility, and Reduction of Administrative Burdens.** Employer trade associations asked CMS to clarify several aspects of the proposed regulations. For example, they requested clarification of the actuarial assumptions to be used in determining whether their prescription drug plans are actuarially equivalent to Part D, as well as guidance in determining the gross value amount for purposes of the actuarial equivalence test. They also requested a handbook or
similar guide to facilitate understanding of the steps and requirements for obtaining a waiver for providing employer-sponsored prescription drug plans, as well as model forms to streamline the application process.

Employer associations also urged CMS to afford employers greater flexibility with respect to the submission of annual subsidy applications. For example, employers would like to be able to file only a tentative subsidy application on September 30 and to have the opportunity to finalize their attestation regarding the actuarial equivalence for any changes in plan design or additional data received during open enrollment after September 30. Employers also would like greater flexibility in determining actuarial equivalence. Specifically, they would like to be able to choose from several commonly accepted actuarial methods and assumptions for determining actuarial equivalence.

Employer associations noted that some of the proposed procedures are administratively burdensome. For example, they believe that annual actuarial attestation of equivalency is unnecessary and that attestation need only be provided if the plan design has changed. They also urged CMS to allow employers to provide a standard notice of creditable coverage in disclosure materials that are routinely sent to retirees and to provide individual notices only if the employer is not providing creditable coverage. Employers also do not want to be required to provide specific information regarding drug benefits and costs in the notice and would like CMS to provide model notices for employers to use.

Actuarial Equivalence. Employers supported the two-prong test for determining actuarial equivalence and believe that it will adequately ensure that employers do not receive a windfall from direct subsidies.

Consumer Groups

Patient Access. Consumer groups are concerned about improving patient access to medications. For example, they urged CMS to delay the transfer date of dual-eligibles from Medicaid to Medicare to ensure that these beneficiaries do not experience a gap in coverage. They also asked CMS to require plans to permit a beneficiary taking a specific drug that was in the formulary during the enrollment period to automatically be considered exempt from any mid-year changes to the formulary status of that drug. In addition, consumer groups suggested that CMS count only in-network retail pharmacies toward the access requirements. They also asked CMS either not to apply the late enrollment penalty in the first two years or to reduce that penalty for the first two years.

Disenrollment. Consumer groups strongly argued that the disenrollment provisions are too harsh and should be revised. For example, they argued that beneficiaries should not be penalized by having to pay the late enrollment penalty if a beneficiary's enrollment or disenrollment is unintentional because of misrepresentations, errors, or inaction by a plan sponsor. Consumer groups also suggested that beneficiaries should be permitted a 30-day grace period for late premium payments before they can be disenrolled, and that the provision permitting disenrollment for “disruptive or threatening behavior” should be refined.

Communication Between Plan Sponsors and Participants. Consumer groups advocated provisions to facilitate communication between plan sponsors and participants. For example, they strongly urged CMS to prohibit plans from marketing additional services (e.g., financial services, long-term care insurance, or credit cards) in conjunction with prescription drug services. They also asked CMS to require plans to provide 24 hours-a-day, seven days-a-week access to a customer call center.

Exceptions, Grievances, and Appeals. Consumer groups strongly asserted that the current appeals process contains too many layers and delays, and they recommended a number of improvements. For
example, they recommended that a denial of a drug at a network pharmacy should be the first plan
determination and that pharmacies and plans should inform individuals of their options and appeal
ing the point-of-sale denial. They also suggested that plans should be required to provide a
temporary supply of the denied medication when requested until a suitable alternative treatment is
agreed upon, that there should be meaningful consequences for plans that fail to provide timely notice
or response for a redetermination, and that the time for implementing appeal rulings should be
expedited.

State Comments

Patient Access. State organizations echoed the concerns expressed by others with respect to the
potential gap in prescription drug coverage for full benefit dual-eligibles. One commenter
recommended that Medicaid coverage should not terminate for full-benefit dual-eligibles until they
have voluntarily enrolled in a Part D plan or until they have been automatically enrolled in a plan. That
commenter also recommended that the auto-enrollment process not be random, as contemplated by
CMS, but be determined by a detailed algorithm. Other comments recommended an open formulary
for dual-eligibles.

State comments encouraged expanded formularies for special needs populations, such as those with
HIV/AIDS or with significant behavioral health needs. Comments also encouraged CMS to allow
expenses paid on behalf of a beneficiary by AIDS Drug Assistance Programs (ADAPs) to count toward
the beneficiary’s TrOOP.

State groups also encouraged CMS to simplify the appeals and grievance procedures. One
commenter encouraged CMS to consider an appeals process that is similar to Medicaid, stating that
adequate notice and the opportunity for quick review of a plan action are essential to the dual-eligible
population.

Phased Down State Contribution (the “Clawback”). State groups commented on the phased down
state contribution to Part D benefit costs. The phased down amount is based on drug expenditures
covered during the calendar year 2003. The comments suggested that, because of lag times and
other factors, the figures for 2003 may not be indicative of actual expenditures. For example, the data
may not reflect manufacturer rebates. Comments urged the regulations to allow for the natural lag
time between purchase and collection of rebates so that the 2003 baseline data is as accurate as
possible. One association pointed out that failure to allow for this discrepancy may artificially increase
the baseline for the clawback, costing states hundreds of millions of dollars in the next ten years.

Price Concessions. State groups asked CMS to require plans to disclose negotiated price concession
data to SPAPs as well as to CMS; to disclose both the total concessions received and the portion
passed through to beneficiaries; and to pass through either 100 percent of price concessions or, at a
minimum, 75 percent.

Other. States asked CMS to allow SPAPs to collect the rebates that the plans have negotiated when
the beneficiary is in the donut hole or paying a deductible. SPAPs will be covering the entire cost
during these periods, but will otherwise be unable to obtain a rebate from the manufacturer and, as a
result, will be paying well above the normal amount during these periods.

One commenter recommended that the number of prescription drug plan service areas should be as
close to one per state as possible, as multi-state regions will present challenges to Medicaid programs
regarding access to data, population characteristics, and ensuring adequate access to needed health
care services.
Comments Reviewed

For purposes of this memorandum, comments from the following organizations were reviewed:

- **Pharmaceutical and Biotechnology Manufacturers:** Biotechnology Industry Organization (BIO), Pharmaceutical Research and Manufacturers of America (PhRMA), Amgen Inc., AstraZeneca, Biogen Idec, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., Pfizer Inc., and Schering-Plough Corporation.

- **Physician and Pharmacy Provider Groups:** American Medical Association (AMA), American Psychiatric Association (APA), American Society of Clinical Oncology (ASCO), and the National Association of Chain Drug Stores (NACDS).

- **Pharmacy Benefit Managers:** Pharmaceutical Care Management Association (PCMA), Caremark Rx, Inc., Express Scripts, Inc., First Health Services Corporation, Medco Health Solutions, Inc., and MedImpact Healthcare Systems, Inc.

- **Insurers:** America’s Health Insurance Plans (AHIP), Aetna Inc., Anthem Blue Cross and Blue Shield, Humana Inc., Kaiser Permanente, Ovations (a UnitedHealth Group company), United American Insurance Company, and WellPoint Health Networks Inc.

- **Employer Groups:** American Benefits Council (ABC) and the ERISA Industry Committee (ERIC).

- **Consumer Groups:** American Association of Retired Persons (AARP), American Federation of Labor - Congress of Industrial Organizations (AFL-CIO), and the Medicare Consumers Working Group.

- **State Groups:** National Association of State Medicaid Directors (NASMD), National Governors Association (NGA), California, and New Jersey.

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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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