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# Improving Access to Medications

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With thousands of pages of legislation, regulations, guidance documents, and white papers, no one would argue that the Medicare Modernization Act (MMA) is not a complex law. Although it rivals a tome with terse and sometimes cryptic language, it is much more than a forest of documents. It stands among the more seminal legislation of our time. By now, everyone should be aware that the MMA authorized the establishment of a Medicare prescription drug benefit under a new national program known as Medicare Part D. Within all of the parlance and vernacular, the MMA prescribes an outline of how this outpatient pharmacy benefit will be implemented by private drug plans. Navigated correctly, Medicare Part D can provide increased access to prescription drugs for Medicare patients. However, if one takes the wrong tack, Medicare Part D can raise obstacles to accessing these very same medications. Because compensation by Medicare and other health plans relies increasingly on a pay for performance system, providers will be forced to focus not only on making the correct diagnosis and writing the correct prescription, but on ensuring that patients actually have access to these medications.

The Centers for Medicare and Medicaid Services (CMS) has stated that Medicare Part D will aim to be “cost effective” relative to prescription drug costs, but never at the expense of appropriate medical care.<sup>1</sup> To accomplish this, CMS has committed to review private drug plans periodically in order to ensure that beneficiaries are receiving clinically appropriate medications at an affordable cost. The ongoing CMS review process will focus on three areas: Pharmacy & Therapeutics (P&T) Committees, formulary management, and benefit management tools.

With well over 300 plans established to administer the Medicare Part D benefit, there are a large number of new P&T Committee members. As a result, education about these complex rules and a significant responsibility will be required of those not currently accustomed to these roles. In addition, pharmaceutical manufacturers will need to reevaluate the information that they provide to plans and providers.

It has been estimated that 29 million of the 42.6 million Medicare beneficiaries will enroll in a Part D plan.<sup>2</sup> Unfortunately, this

will leave many Medicare beneficiaries who would benefit from enrolling in a Medicare D plan without prescription drug coverage, in part because the demands of the Medicare population are more complex and diverse than most other patient populations. The higher prevalence of comorbid conditions is associated with greater drug usage and, in some cases, the need for more costly medication therapies to address this population’s growing needs. Through the new legislation, CMS now mandates that P&T Committees have the authority and responsibility to make binding decisions when placing drugs on formulary and that they develop and implement policies that will ensure that formularies provide access to the most appropriate and up-to-date medications for Medicare beneficiaries.<sup>1,3</sup> Plans need to ensure that a process is in place that gives beneficiaries the option to appeal a refusal to cover a particular drug or include it in a preferred tier. This medical review of nonformulary requests should be established and reviewed by the plan’s P&T Committee. CMS also mandates that an actively practicing physician and pharmacist with experience in caring for the elderly and who are independent with no conflict of interest with respect to the health

plan or any pharmaceutical manufacturer be represented on the plan's P&T Committee. For P&T Committees to face these challenges and meet the government's expectations, prescription drug plans (PDPs) and Medicare Advantage Prescription Drug Plans (MAPDs) will need to update the composition of their P&T Committees to include physicians and pharmacists with expertise in the care of seniors and/or those with disabilities. Such experts are more familiar with and better understand the needs of the Medicare population. In addition, they will play a critical role not only in formulary development, but also in meeting the ongoing challenges of formulary management.

### The Environment for MMA

In the year 2000, there were >35 million people >65 years of age, comprising 12.3% of the total population. By the year 2020, this number is estimated to rise to just over 54 million, accounting for 15.8% of the total population.<sup>4</sup> In the year 2003, about 97 % of persons  $\geq 65$  years of age had some form of health insurance through Medicare or Medicaid, most with supplementary coverage, although 27% of seniors were still without any prescription drug coverage.<sup>5</sup> In addition, Americans are living longer now than ever before, as evidenced by a life expectancy of 13.9 years at 65 years of age in 1950 versus a life expectancy of 17.9 years at 65 years of age in the year 2000. Increased longevity has increased the number of people >65 years of age with chronic conditions that require medical and long-term care services. More than two-thirds of

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those aged 65 to 74 years have hypertension, and the proportion of overweight seniors has risen from about 55% between 1971 and 1974 to >70% for females and 77% for males between 1999 and 2000. These factors coupled with the high reported prevalence of chronic conditions and disabilities, such as arthritis (36.8%), heart disease (32%), cancer (17.8%), hearing difficulties (41.3%), and vision deterioration (18%), among the elderly are placing a large burden on the healthcare system.<sup>5</sup>

### Formulary Development Process

The initial formularies for Medicare Part D plans were submitted to CMS in April 2005, were approved in May 2005, and applicants were notified of their acceptance as PDPs in September 2005.<sup>3</sup> In evaluating these plans, CMS utilized 6

principles to determine the adequacy of a plan's formulary<sup>6</sup>:

- *Key drug types*—reviewed for inclusion of  $\geq 1$  drug for each of the 146 key types of drugs
- *Risk adjustment data*—assessed for inclusion of drugs commonly used in the Medicare population
- *Treatment guidelines*—evaluated on the basis of inclusion of guideline-recommended therapies
- *Tier placement*—examined the cost-sharing tier position of the 40 drug classes most commonly prescribed for the Medicare population to determine the effects on medication access
- *Cherry picking*—reviewed tier placement to ensure no discouragement of specific beneficiaries
- *Choice of medications*—checked for inclusion of “a majority” of drugs in the antidepressant, antipsychotic, anticonvulsant, anti-retroviral, immunosuppressant, and antineoplastic therapeutic classes

All formulary designs used in commercial plans—typically described as open, closed, or partially closed; restricted or incentivized; and positive, negative, or preferred<sup>7</sup>—were likely considered, and some were used in the development of Part D plans. Since the formulary management strategies typically used in commercial plans also can be used in plans designed for this population, it is expected that most attempted to adapt their current formularies and formulary process to include the Medicare population so as to avoid undue administrative burden. These approved formularies, however, must continually be reevaluated, updated, and maintained.

## Formulary Management Process

The overall costs of providing prescription drug benefits continue to increase. Driving the increases are rising drug costs and increased physician prescribing. The greater use of drugs is reflective of current clinical guidelines, which call for more proactive control of chronic conditions with medications.<sup>8</sup> While the vast majority of drugs are appropriately prescribed, some drugs are overused or used inappropriately by large segments of the American population.<sup>9</sup> A recent survey of Medicare beneficiaries found that over a 2-year period, many did not adhere to drug treatment regimens due to cost.<sup>10</sup> This was associated with poorer health and higher rates of hospitalization.<sup>10</sup> When properly designed and implemented, the formulary system can promote rational, clinically appropriate, safe, and cost-effective drug therapy.<sup>11</sup> Because of today's competitive and quality-driven environment, it is imperative that Part D plans maintain a formulary process that manages escalating costs while providing the best possible clinical care.

There are a number of regulations that apply specifically to Part D plans that affect the formulary process. As mandated by the MMA legislation, the US Pharmacopeia (USP) established model categories and classes that managed care organizations (MCOs) and pharmacy benefit managers (PBMs) could use in administering drug benefits for Medicare enrollees. Plans had the option to adapt this format or use their own format, but had to include at  $\geq 2$  drugs from each approved category and class (unless only 1 drug was available) and  $\geq 1$

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drug in each of the *Formulary Key Drug Types* identified by USP.<sup>1</sup> In the ongoing maintenance of these formularies, plans may generally change drug categories and classes only once a year, whereas formulary drugs and their tiers can change at any time as long as plans provide a 60-day prior written notice to affected enrollees, pharmacists, prescribers, and other affected parties. Since November 2005, formulary changes have been accepted by CMS on a regular basis within 30 days after a P&T Committee decision has occurred.

### Formulary Review Process

Although formularies list approved products, a formulary system should include processes that drive the formulary, such as procedures for the use of specific medications, organizational policies on prescribing, and an educational compo-

nent.<sup>7</sup> Regular review of agents currently on formulary is a must as new clinical information is constantly being developed. It has been estimated that there is a 20% probability that a new drug will acquire a new black box warning or be withdrawn from the market in a 25-year period.<sup>12</sup> For these reasons, it is recommended that plans review all agents in a class on a regular basis to incorporate new data.

A traditional review of drugs for formulary inclusion relies heavily on efficacy and safety data provided in the results of FDA-mandated, randomized, placebo-controlled trials or meta-analyses of such trials.<sup>9,13</sup> Economic factors, such as average wholesale price (AWP), the impact on the plan's pharmacy budget, and manufacturer rebates, are factored in after the clinical review is complete. In the worst scenarios, formulary decisions are made on the basis of drug acquisition cost and manufacturer rebates instead of clinical outcomes, with some of even the most progressive formulary decisions still being based on aggregate measures that are not tailored to individual patient circumstances.<sup>9</sup> For many commercial plans, the long-term effects of preventive medicine are not realized while a patient is covered by their plan due to frequent job changes (and subsequent plan changes) or employers shopping around for different plans. The same problem exists with Medicare Part D because members are not tied to a single plan for a long period of time. Most beneficiaries have the ability to change plans on a yearly basis. Others, such as the dually eligible and those residing in long-term care facilities, have the

ability to change plans at anytime. Unlike employer-sponsored plans, beneficiaries will have the opportunity to select the plans in which they participate, possibly leading to a long-term commitment to a plan and making the long-term management of patients that much more likely. However unlike MA-PDs, PDPs are not at risk for medical costs and, therefore, may not recognize a benefit in promoting preventive medicine even if beneficiaries select PDPs for long periods of time.

Basing formulary decisions on patient outcomes will require plans to look at a drug's overall impact on determining its effectiveness in clinical, social, and economic terms, rather than in terms of just efficacy and cost. To achieve this goal, there has been an increase in demand by the plans for trials that evaluate overall effectiveness as opposed to only efficacy and safety. These studies include head-to-head drug comparisons and trials that produce health, quality of life, and economic outcomes data in environments that mimic real-world conditions.<sup>8</sup> The demand by US plans for health outcomes data and pharmaco-economic models that provide estimates of the potential cost and benefits of a new drug relative to existing therapies has increased.<sup>8</sup> International agencies, such as the National Institute for Clinical Excellence (NICE) in England and Wales, the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), and the Australian Pharmaceutical Benefits Advisory Council (PBAC), have made a practice of basing national coverage decisions on these type of data. Similarly, the US government has given the Agency for Healthcare

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Research and Quality (AHRQ) the responsibility of evaluating health outcomes. However, unlike the aforementioned international organizations, the AHRQ does not make national coverage decisions. Instead, it is charged with the development of scientific knowledge without mandating guidelines or standards for measuring quality.

During economic analyses, factors such as costs for laboratory tests, staff, hospitalizations, and recovery times should be considered in addition to the price of the drug. One concern is whether plans give weight to information on medical cost offsets that can result from drug formulary choices. In many cases, plans operate in a "silo," where the effect on the pharmacy budget is the only consideration, and decisions are not made on the basis of how pharmaceutical expenditures affect overall healthcare utilization within the organization. Although the structure of PDPs dif-

fers across regions, they are subject to the same problems because they are not responsible for medical costs. The question then becomes how can the process be improved for health plans so that the program more efficiently provides improved patient outcomes?<sup>8</sup>

Medicare patients and their physicians can evaluate formularies utilizing the [www.Medicare.gov](http://www.Medicare.gov) comparison tool finder. Through this site, a Medicare patient can evaluate plans based on their medication needs and preferred pharmacy. Physician practices can similarly evaluate different plans on the basis of the medications they most often prescribe. Since patients often rely on their physicians for plan recommendations, this information will prove to be very valuable.

### **Formulary Management Strategies and Tools: Moving Forward**

There are a number of management tools available to plans for use in managing the formulary process. Management tools such as prior authorization (PA), step therapy, quantity limitations, generic substitution, and therapeutic interchange protocols have long been staples of the managed care industry. These tools are expected to be used in Part D plans in the same way that they are in existing commercial formulary systems, both in terms of the situations in which they are used and the timeliness of the process.<sup>7</sup> Many of these tools have been used to prevent moral hazard, yet patients in this population already may be sensitive to the real costs of treatment due to cost sharing built into the Part D plan design.

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## **Drug Use Evaluation and Drug Utilization Review**

Processes such as drug use evaluation (DUE) and drug utilization review (DUR) are key for the maintenance of ongoing quality control. The Academy of Managed Care Pharmacy (AMCP) defines a DUR as the process used to assess the appropriateness of drug therapy by evaluating data on drug use in a given healthcare environment against data obtained using predetermined criteria and standards.<sup>11</sup> The CMS expects plans to develop a process that assures appropriate access to medically necessary therapies, while guarding against inappropriate or dangerous utilization of prescription medications.<sup>1</sup> It is also expected that P&T Committees will play an active role in the review of this process, as well as in the evaluation of its results. Standardized reports from Part D plans on denials, reconsiderations and appeals, and exception processes are required by CMS, which uses these data for management and oversight. As Part D plans already are collecting and organizing this material, it is suggested that the plans use such data to develop their internal quality initiatives.<sup>6</sup>

## **Medication Therapy Management Services**

Medication therapy management services (MTMS) have also been mandated by the MMA to “optimize therapeutic outcomes through improved medication use, and reduce the risk of adverse events, including adverse drug interactions for certain patients.”<sup>3</sup> This process is designed to target only patients taking multiple medications, with chronic conditions, or requiring

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high-cost therapies. While “high” cost has been defined by the Department of Health and Human Services (DHHS) at \$4000 per year, other definitions are made at the discretion of the individual plans. Part D plans also are responsible for establishing the payments related to this process, as well as determining who is a qualified provider of these services. Services suggested as part of MTMS involve assessing a patient’s health status; formulating a medication treatment plan; selecting, initiating, modifying, or administering medication therapy; performing a comprehensive medication review; documenting and communicating with other providers the care delivered through MTMS; verbally educating patients regarding their medication(s); providing information and support to encourage compliance;

and coordinating MTMS provided to the patient.

Being a new service, MTMS need to be developed, tested, and implemented—a process that involves the contracting and training of willing pharmacists. Implicitly linked to their design, MTMS, like other disease management programs, are likely to increase pharmacy spending in anticipation of expected medical savings. In time, PDPs will need to overcome certain challenges as they develop and implement MTMS. For example, with limited medical information available, they will need to establish outcome measurements along with the methods for collecting and tabulating the data. In addition, a plan for patient recruitment will need to be established since this is a voluntary program. Also, it is important to remember that MTMS are different from Drug Regimen Reviews (DRRs), a process mandated for long-term care residents. A DRR is required for all long-term care residents, not just those identified as targeted beneficiaries. In addition, unlike MTMS, which may be offered by any qualified provider, only a consultant pharmacist can complete a DRR. Many had thought that MTMS would replace DRRs. However, that is not the case, as these systems are very different.

## **Utilization of Outside Parties**

Another strategy that Part D plans may want to consider is enlisting outside parties to aid in the formulary process. Some commercial plans have implemented this strategy and have found it to be very successful. These independent bodies have taken on processes such as

gathering and presenting summarized clinical and health outcomes information to P&T Committees both for new pharmaceuticals, as well as formulary drug classes under annual review. Typically staffed with trained clinicians having no direct financial ties to commercial plans or pharmaceutical marketers of the products under review, these organizations are able to perform robust reviews without the perception of bias. This process can be used to engage the P&T Committee more fully in the formulary process by providing them with the scientific information needed for review of formulary agents.

### **Role of Pharmaceutical Manufacturers**

Pharmaceutical manufacturers can play a significant role in aiding the formulary process. The development of dossiers following the AMCP dossier submission guidelines<sup>14</sup> can aid plans in their review of new drugs, especially when the sections providing pharmacoeconomic data and models are complete. Although FDA-mandated studies for drug approval provide little data on comparative effectiveness with other drugs or on patient-oriented outcomes, this is the most relevant information for P&T Committee members when making formulary decisions. In order to have this information available, manufacturers must design phase III trials in a way that allows for continued outcomes data collection, such a prospective cohort study starting in phase III and continuing after product launch as open-label trials.<sup>8</sup>

It is common for manufacturers to counter these requests with the

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complaint that many managed care decision-makers lack the expertise required to interpret and effectively use health outcomes data and models.<sup>8</sup> An International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Task Force confirmed this opinion in a report on the use of pharmacoeconomic information in healthcare decision-making and concluded that training and assistance are needed at the local health plan level.<sup>15</sup> This report enforces the need for the continued education of managed care decision-makers in this area.

While plans must develop the resources to correctly judge the quality of information that is submitted, manufacturers must make efforts to provide plans with meaningful pharmacoeconomic data and models. Data presented should include real-world health and quality-of-life outcomes, not just cost-minimization studies based on drug acquisition costs. Outcomes or modeling of clinical compar-

isons should focus on the current standard of care and not just comparisons with placebo. When models are developed, they should be based on reasonable assumptions and current medical practice.<sup>8</sup> Managed care decision-makers can then process this information to assemble the best possible care for beneficiaries.

When preparing dossiers for submission, it is important to consider that Part D plans will especially benefit from the inclusion of pharmacoeconomic models showing positive health outcomes in the elderly population. Due to the assumptions that must be made while preparing these models, an important strategy in their preparation is the use of unbiased, independent third parties. These groups, operating at arm's length from the manufacturer and working frequently to develop similar models, are ideal for this type of work. Groups with expertise in the geriatric population can be especially useful in developing models for presentation to Part D plans.

### **The Importance of Ongoing Education**

Education of all the key stakeholders—CMS, health plans, clinicians, beneficiaries, and pharmaceutical manufacturers—will be a key component moving forward. Educational strategies must be developed to reinforce the rationale of this massive program. Without this, confused beneficiaries will stand on the sidelines and formularies will fail to be cost-effective or provide access to all medically necessary medications. This education can take the form of formal continuing education programs or

## Take-Away Message

- Medicare Part D is available to all Medicare beneficiaries to increase access to medications through lowered out-of-pocket expenditures.
- Formularies should be developed to encourage the appropriate use of medications.
- P&T Committees must take into account the entire scope of risks and benefits when recommending or restricting access to medications.

## ROI

- Point-of-service tools can assist in accurate prescribing, thereby reducing the number of call-backs for nonformulary medication and prior authorization requirements.
- Some of these tools include:
  - Medicare Web-based tools ([www.Medicare.gov](http://www.Medicare.gov))
  - ePrescribing systems (eg, Epocrates)

informal educational sound bites. Continuing education on topics such as formulary outcomes can be offered to PDP staff members, as well as P&T Committee members. Activities such as this can be supported independently or through educational grants from manufacturers. Informal education can take many forms. Feedback from regular DURs can be used to educate prescribers about prescribing patterns and provide a tool for benchmarking. The formulary itself can be used as an educational tool to help providers stay abreast of the growing number of therapeutic agents. Whatever the format, ongoing education of all stakeholders is essential to continuous quality improvement.

## Final Thoughts

The addition of a Medicare drug benefit is the most significant change to the Medicare program since its inception some 40 years ago. It affects all relevant stakeholder groups, including CMS, health plans, clinicians, beneficiaries, and pharmaceutical manufacturers. It is vital that all groups continue to work together for the successful implementation of this new Medicare component so that seniors are able to gain greater ac-

cess to medications, thereby realizing the improved health outcomes that are possible through greater adherence to prescribed medication regimens.

Historically, P&T Committees in managed care organizations were composed primarily of physicians and pharmacists. However, as the healthcare environment has evolved, so has the structure of P&T Committees. In addition to evaluating the efficacy and safety of drug therapies, P&T Committees today are required to weigh overall outcomes, both clinical and economic. Over the last few years, health plans have replaced primary care physicians with specialists, added requirements that physicians and pharmacists be in active practice, and have created specialty subcommittees. As we move into 2006 and the implementation of Part D plans, P&T Committees in managed care organizations will need to continue down the path of evolution, tailoring their efforts to the Medicare population. **MPM**

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