



CALIFORNIA HEALTH ADVOCATES



Medicare Rights Center

The Knowledge Gap: Drug Plans Fail to Provide Critical Information to People with Medicare

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Medicare Rights Center (MRC) is the nation's largest independent source of Medicare information and assistance for people with Medicare. Founded in 1989, MRC helps older adults and people with disabilities get high-quality, affordable health care.

California Health Advocates (CHA) is a nonprofit organization dedicated to timely and responsive education and advocacy efforts on behalf of California Medicare beneficiaries and the pre-retirement population.

INTRODUCTION

People with Medicare are confronted with a complex and confusing landscape as they try to select a prescription drug plan that best meets their needs.¹ Plans differ widely in the drugs they cover and impose a range of restrictions on the drugs that are included on their formularies. Deluged with marketing materials, frustrated by inaccurate and conflicting information, people with Medicare and the friends, family members and professionals that counsel them, struggle to find consistent and accurate information for this important choice.²

Through regulation and guidance, the Centers for Medicare and Medicaid Services (CMS) has elaborated the types of consumer information plans must provide. Unfortunately, critical information remains unavailable. As this brief shows, a number of drug plans in California fail to meet both the spirit and letter of CMS' requirements, hampering the ability of state residents to select the most appropriate plan. Many of the plans at issue are also national plans and it is likely that the same failings apply nationwide and by extension to local and regional coordinated care plans that offer both drug and medical coverage to people with Medicare.

In particular, people with Medicare have a difficult time obtaining information on the "utilization management" practices plans impose on certain drugs that would make clear whether these restrictions will be used to deny coverage.

There are three broad types of utilization management. Plans may require **prior authorization** before they will cover a certain drug, demanding that physicians certify specific diagnoses that

are necessary for coverage. They may impose **step therapy**—the requirement that an alternative, cheaper, medicine is first tried and shown to be ineffective or cause adverse side effects before a more expensive drug will be covered. Finally, plans can impose **quantity limits** on certain drugs.

The impact of these techniques varies considerably. For example, quantity limits can specify the number of drugs a plan will cover per month or they can cap the total number of drugs it will cover at a set amount. Similarly, prior authorization can limit coverage of a drug by a wide or narrow set of conditions.

Although plan web sites and the web tool CMS has developed to allow for plan comparisons note which drugs are covered by utilization management techniques, they do not explain how these restrictions work in practice. People with Medicare need that information to decide if their drug regimens are compatible with the restrictions a plan imposes. For example, if they can determine whether they meet a plan's criteria for prior authorization, people with Medicare can decide if they will be eligible for coverage under the plan. Without this level of transparency, utilization management techniques could discourage enrollment in the new Medicare drug benefit and may steer people taking certain high-cost drugs away from the plans that impose them.

Conversely, a plan's failure to adequately explain its utilization management techniques leaves potential enrollees in the dark about how, and under what conditions a drug is covered. As a result, many potential enrollees may believe, incorrectly, that they will obtain coverage of their drug under the plan.

In addition, drug plans are generally not providing information on their transition policies, which may provide temporary first fills for new plan members of drugs not covered by a plan's formulary or subject to utilization management restrictions. Although CMS anticipated that transition policies would provide a basis of comparison among plans, consumers are forced to choose among plans without knowing what coverage they will receive during their first month of coverage.

Information on their plan's transition protections would enable new enrollees to assert their rights if plans fail to provide for automatic temporary fills at the pharmacy counter. With knowledge of the protections they are due, new members can take action if they are improperly denied temporary coverage.

The experience of Medicare beneficiaries at the pharmacy counter during the first days of the new drug benefit underscores this point. The

PLANS FAIL TO EXPLAIN COVERAGE OF ESSENTIAL MEDICINES

When CMS laid out the ground rules for drug plan formularies, the agency recognized that the health of people with Medicare required plans to cover substantially all the drugs in six classes. This guidance spells out not only what drugs must be put on formulary but how, and for which patients, plans can restrict access through utilization management (Centers for Medicare and Medicaid Services, "*Medicare Modernization Act Final Guidelines*").

For patients taking drugs in the six classes—antidepressants, antipsychotics, anticonvulsants, antiretrovirals, antineoplastics (cancer medications), and immunosuppressants—these are vital protections. Unfortunately, for the vast majority of people with Medicare who have not read CMS' formulary guidance, the extent of these protections is not apparent.

Because of plans' failure to adequately explain their utilization management restrictions and their failure to publicize transitional processes, potential enrollees can receive a false impression that coverage for these essential medicines will not be forthcoming. This has the potential to cause unnecessary panic among vulnerable populations. It can also steer people taking these expensive drugs away from plans that paint a more restrictive picture of the coverage they offer. A few examples drawn from formulary searches of the 10 plans in California receiving auto-enrolled dual eligibles will illustrate the problem.

Cellcept (mycophenolate) is an immunosuppressant that is used to prevent patients from rejecting a transplanted organ. To be successful, immunosuppressant therapy needs to be continuous. Patients successfully taking Cellcept or other immunosuppressants should not be switched to other medications. In recognition of this, CMS required plans to cover all immunosuppressants and to maintain coverage, without restrictions imposed by prior authorization, of any immunosuppressant a new enrollee is taking.

However, immunosuppressants are sometimes covered by Part B, through which Medicare pays for physician services, and sometimes through a Part D plan. For example, if Medicare paid for the organ transplant, coverage is under Part B. In other circumstances, coverage may fall under Part D. As a result, following guidance from CMS, many plans require prior authorization for Cellcept and other immunosuppressants to determine whether Part D or Part B coverage applies. A survey of the 10 CA plans found that, with one exception, Unicare's MedicareRx Rewards, all plans list the drug as requiring prior authorization. None of the plans explain the criteria for prior authorization and only one plan explains that it is a process for the plan to determine whether Part D or Part B coverage applies. In addition, the plans fail to explain that for patients already stabilized on these drugs, the plans will maintain coverage, as CMS requires. As a result, only one plan appears to provide unrestricted access to the drug, even though it too will likely vet coverage to determine if it should be covered by Part B or Part D.

Patients stabilized on the antipsychotic drug Seroquel (quetiapine) need to maintain their drug regimen or risk a psychotic episode. SierraRx and WellCare both list the drugs as requiring step therapy on its formulary but offer no further explanation. Potential enrollees are not informed that a transition plan would provide a temporary fill or that patients already stabilized on this drug will be able to maintain coverage. Lacking this information and fearing the loss of coverage, potential enrollees may well turn to an alternative plan that does not impose such restrictions.

More serious repercussions are also possible. Fearing an immediate termination of coverage, a patient stabilized on this medicine may decide to ration his or her existing supply, with potentially destabilizing effects. The scenario is not fantastic, given the difficulty people with Medicare are experiencing disenrolling from their assigned plans or enrolling in alternatives, according to accounts provided by nursing home pharmacists, people with Medicare and PDP representatives.

authors of this brief, beneficiary advocates nationwide and CMS itself have received numerous accounts of plan enrollees failing to receive transitional supplies of non-formulary drugs upon their initial visits to the pharmacy. Although at the end of December CMS released a summary of the transition policies of all stand alone prescription drug plans (PDPs) and this information was sent to state officials and leaders in the pharmacy community,³ it was not made readily available to people with Medicare.

The lack of information about plan transition policies and utilization management techniques most severely impacts the more than six million impoverished citizens who switched from Medicaid to Medicare drug coverage on January 1. In California, there are approximately one million of these so-called dual eligibles—people covered by both Medicare and Medicaid.⁴ These people were either auto-enrolled into one of 10 PDPs with premiums low enough to qualify for full subsidies or, if they were already enrolled in Medicare Advantage (MA) managed care plans, were retained in those plans for 2006. Both the stand-alone PDPs and the drug plans offered by MA plans (MA-PDs) were required to develop transition policies, since the formularies would impose different restrictions than state Medicaid programs.⁵ Assignment to PDPs was random and without regard to whether the plan covered all the drugs on its new enrollee's drug regimen.⁶ Retention into an MA-PD was similarly done without regard to a person's drug needs.

Dual eligibles take more prescriptions than the average person with Medicare.⁷ They are more likely to have diabetes or other chronic

conditions. About 40 percent are cognitively or mentally impaired.⁸ Their low income does not provide them with the resources to pay out of pocket for drugs not covered by their Medicare plan.

As a result, it is essential that dual eligibles, their caregivers and counselors have access to information about their plans' transition policies. Such information will allow dual eligibles to take advantage of the protections they are afforded or so they can switch to an alternative plan that offers greater protections. Similarly, full transparency on the plan's utilization management restrictions will allow dual eligibles to determine if they were assigned to the most appropriate plan.

In this paper, the second in a series by California Health Advocates and the Medicare Rights Center, we will explore regulatory guidance CMS has provided to drug plans regarding the information they must provide on their transition and utilization management policies. We will then detail the information that is and is not available to people with Medicare, using the 10 PDPs that received auto-enrollments of California's dual eligibles as a test case.⁹ Finally, we will argue that both the spirit and letter of CMS' regulatory guidance requires plans to provide a greater level of transparency and will recommend that CMS clarify the standards that plans must meet and penalize plans that violate these standards.

WHAT PLANS MUST DO

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)¹⁰ envisions a system of private prescription drug plans competing to enroll customers into their

benefit packages. Under this market based system, supporters of the MMA theorized, plans that could combine the lowest premiums and cost sharing with the broadest coverage would be rewarded with the highest number of members.

This system generates incentives for plans to limit coverage of high cost drugs and to discourage enrollment by beneficiaries with high-cost drug regimens. Through regulation and guidance designed to set minimum coverage standards and bar discriminatory plan designs, CMS has attempted to protect beneficiaries.

Similarly, marketing guidelines¹¹ issued by CMS are intended to prevent plans from misinforming potential enrollees about the coverage provided or to dissuade high-cost beneficiaries from enrolling. Without transparency in plan practices and policies, however, the market will be skewed against consumers. Plans with inferior benefit packages and higher costs will be allowed to gain market share and certain plans will be allowed to discourage enrollment of high cost-consumers.

Within guidelines developed by CMS to ensure coverage of all “medically necessary” drugs, plans have broad discretion in their design of formularies.¹² This means that for most types of drugs, such as cholesterol-lowering medicines, plans can choose which of the competing brand or generic drugs they will cover. If a drug is not covered beneficiaries are required to pay the full price, file an “exception request” to try to get a non-formulary drug covered, or have their physician switch them to a covered drug. If none of these options are viable, beneficiaries will go without their medications.

Plans can also use tiered cost-sharing to steer enrollees towards generics or lower cost brands. Additionally, they can use step therapy to require beneficiaries to first try a lower cost alternative or require prior authorization to ensure that drugs are prescribed only for certain indications.

Because people with Medicare generally have drug regimens that were developed by physicians without regard to the formularies imposed by the new drug plans, it may be difficult to find a plan that provides unrestricted access to all a beneficiaries’ medicines. Although all plans are required to provide an exceptions and appeals procedures, the process will likely be daunting to new enrollees, especially dual eligibles. Historically, very few persons with Medicare have exercised their appeal rights.¹³ Dual eligibles, in particular, have difficulties navigating plan processes and procedures.¹⁴

In addition, the Medicare Part D appeals and exceptions procedures are a new and untested process for consumers, pharmacists, providers and plans alike. Unless primary care physicians have the time, resources and willingness to help their patients with exceptions processes for multiple plans, the system may well prove unworkable. Another potential barrier to the use of the exceptions and appeals process is the difficulty in obtaining individual plan’s procedures and documentation requirements. Reports received by consumer advocates during the first month of Part D coverage indicate that both these barriers are impeding beneficiaries’ ability to secure coverage through the exceptions and appeals process.

Because of the variety of limits plans can impose on drug coverage, it is critical that consumers receive accurate

and complete information. Recognizing this, CMS has required plans to provide potential enrollees with information the agency believes is essential to their decision making.

In its final rule on the drug benefit and in subsequent guidance, CMS addressed plans' responsibilities to provide information on their transition policies and their utilization management.¹⁵ The agency has expressly told plans they must publicize their transition policies, arguing that such policies will serve as a useful measure in comparing plans. CMS also told plans they must inform potential enrollees about which drugs are subject to utilization management. However they stopped short of explicitly calling for detailed explanations of how these procedures operate, leaving most beneficiaries without adequate knowledge of this process.

TRANSITION PROCESSES

In March 16, 2005 guidance to plans, CMS outlines the need for all plans (PDPs and MA-PDs) to provide a transition process for their new enrollees, recognizing that such protections provide a counterbalance to the flexibility in coverage plans are allowed in order to make their coverage affordable.¹⁶

These processes are designed to transition new enrollees "whose drug therapies may not be included in their Part D Plan's formulary."¹⁷ For drugs that are covered, but subject to step-therapy or prior authorization restrictions, plans "should ensure that procedures limiting access are appropriate in situations in which a new enrollee is already stabilized on a drug or has already tried lower step agents."¹⁸

For patients stabilized before enrollment on drugs in six classes—antidepressants, antipsychotics, anticonvulsants, antineoplastics (cancer medications), immunosuppressants and antiretrovirals, CMS expects that "plans would not use management techniques like prior authorization or step therapy, unless a plan can demonstrate extraordinary circumstances."¹⁹

In a January 6 memorandum to Part D plans and again in a January 13 policy clarification, CMS explicitly states that the provision of transitional fills also applies to drugs that are subject to prior authorization or step therapy restrictions. CMS told plans that "as a general matter, prior authorization and step edits should be suppressed so as to not prevent an enrollee from receiving their medications under a transition period."

"[W]e must stress that delaying or denying the filling of initial prescriptions for new enrollees at point-of-sale because of prior authorization/step edit requirements is not consistent with the intent of CMS' transition policy."²⁰

Plan transition processes should include medical review of non-formulary drugs and a process, when appropriate, to switch enrollees to therapeutic alternatives. In its March 16, 2005 transition guidance, CMS encourages, but does not mandate, that plans provide temporary "first fills" lasting 30 days of non-covered drugs. However, CMS also notes in this guidance that plans with large numbers of dual eligible enrollees may not be able to rely on education and outreach as an alternative to providing temporary first fills. Temporary one-time transition supplies "may represent the most efficient method of triaging requests for filling initial prescriptions of

non-formulary drugs for large numbers of new enrollees,” according to CMS.²¹

Although some plans initially proposed transitional fills of only 15 days, after problems surfaced with the transition of dual eligibles in January, CMS persuaded all plans to provide 30-day supplies, according to a January 18 memorandum from CMS Administrator Mark McClellan.²²

For residents of nursing homes and other long term care facilities, CMS mandated the provision of temporary fills, suggesting time frames between 90 and 180 days.²³

Finally, CMS outlines a

requirement that plans publicize their transition processes and provides a compelling public policy rationale.

“As a general matter, we believe plan sponsors must make transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug [plan] best meets their needs on a variety of factors. Having information about a plan’s transition may reassure beneficiaries that there will be plan procedures in place to assist them switching to therapeutic

TRANSITION PLANS VARY AND ARE HARD TO FIND

In its effort to inform people about the transition from Medicaid to Medicare drug coverage, Medi-Cal, the state Medicaid agency, has been trying to disseminate the written transition policies of the seven sponsors of 10 plans receiving randomly enrolled dual eligibles.

Medi-Cal’s efforts have run into obstacles, however, with three plan sponsors initially balking at public release of their transition policies. By the start of the Medicare drug benefit on January 1, Medi-Cal has disseminated policies from all but one of the seven plan sponsors. Wellcare never granted the state permission to release its transition plan, although the company did make a one paragraph summary available to advocates upon request.

In communications to states and to pharmacy associations in the last week before the start of the Medicare drug benefit, CMS provided summaries of all PDPs’ transition plans (Centers for Medicare and Medicaid Services, “Summary of PDP Transition Plans”). These summaries provide the duration of temporary fills each plan will provide but omit detail, such as how the policies apply to utilization management restrictions, that is available in some of the more detailed summaries obtained by Medi-Cal. A summary document of MA-PD transition policies has also been distributed (Centers for Medicare and Medicaid Services, “Summary of MA-PD Transitions Plans”).

Neither the summaries compiled by CMS, nor the descriptions disseminated by Medi-Cal were made easily accessible to potential plan enrollees. They are not accessible either through plan web sites or through the web tool CMS provides to allow for plan comparison. Many pharmacists claimed ignorance of these transition plans during the first week of implementation of the new drug benefit leaving beneficiaries to pay the full cost of their drug or go without. In a January 4 letter to plans, CMS said it was receiving “numerous reports that plan CSRs are not aware of their plan’s transition policies and that plans are inappropriately denying some scripts.”

However, the transition policies that were obtained from seven plan sponsors illustrate the considerable variation in protections. That variation demonstrates the importance that these policies be publicized so they can serve as a comparison point for potential enrollees and those who are counseling them.

As required by CMS, all the plans include more robust transitional protections for long term care residents. The following summaries are of transition policies directed at enrollees in the community, although some of these policies may have changed after discussions between plans and CMS.

SierraRx outlines a transition policy that encompasses both medical review of requests for non-formulary drugs, coordination with providers for replacement medications and the provision of temporary fills. For new enrollees presenting at the formulary with a prescription for a non-formulary drug a temporary 30-day fill will be provided. The transition plan foresees no refill issues for any on-formulary drug; no special transitional protections are outlined for utilization management.

By contrast, Humana’s transition plan encompasses both prior authorization and step therapy requirements. (Because Humana offers an open formulary, there are no off-formulary drugs that would require temporary fills.)

Under the transition, Humana will grant a one-time 30 day supply of a Part D drug, even though the claim would. (Continued on the next page.)

alternative medications where appropriate. It will also serve a dual purpose in educating advocates and other interested third parties about plan transition process; for example, state Medicaid agencies with regard to full-benefit dual eligibles auto-enrolled in prescription drug plans.”²⁴

CMS reiterates that information on the transition process should be provided in conjunction with plan formularies in an answer to a stakeholder query. “Plan sponsors should highlight their transition processes when providing information about their formularies. Thus, they should include this

information on the web site where their formularies are provided.”²⁵

However, CMS has not provided explicit written instructions to plans on how to publicize their transition processes. Marketing guidance²⁶ and detailed instructions on information to be included in both abridged and complete formularies²⁷ fail to require notice of transition processes. Instructions on the design of plan web sites also fail to mandate the inclusion of transition processes among the posted information.

Despite these omissions, we believe CMS’ guidance makes clear that

normally be rejected because of prior authorization or step therapy requirements. The temporary fill is designed to provide the new enrollee time to seek an exception, obtain authorization or find a therapeutic alternative that is not similarly restricted

“Humana will accept the pharmacy’s substantiation that the new enrollee has a history of taking the Part D drug and the one-time 30 day supply is to sustain existing therapy,” according to the company’s transition policy.

Humana also plans to make the transition processes available on its web site in the same area where the formulary is displayed, the company document says. No transition plan was readily available on the company web site on January 7.

A fact sheet provided by UnitedHealth describes a 30-day first fill policy that will apply to all non-covered drugs, including a brand-name drugs for which there is a generic equivalent. For drugs that are subject to prior authorization or step therapy, a transitional fill lasting only 5 days may be provided pending a coverage determination. United downplays the impact of its prior authorization requirements, saying they apply to less than 0.2 percent of claims for seniors. However, among the drugs that require prior authorization are an immunosuppressant used to prevent rejection of transplants and a brain tumor medicine as well as treatments for rheumatoid arthritis.

The temporary fill policy under Unicare’s transition process is the longest, providing for a 90 day fill for non-formulary prescriptions presented at the pharmacy counter by new members, including all auto-enrolled dual eligibles. Beneficiaries will also be informed of the availability of therapeutic alternatives and the exceptions process to obtain coverage for nonformulary drugs. No mention is made of transitional protections that apply to prior authorization or step therapy restrictions.

Health Net will generally provide temporary fills for drugs that require prior authorization, or that are non-preferred, presumably the plan’s term for off-formulary drugs, according to the policy obtained by Medi-Cal. New enrollees can receive up to a sixty day fill at a retail pharmacy or a 90 day fill through mail order if their pharmacist uses a “temporary supply override code.” The override code only works for maintenance drugs and also excludes drugs not recommended for older Americans or drugs covered by Part B. Quantity limits or length of therapy limits cannot be overridden.

The summary of HealthNet’s transition program posted on its web site provides less specifics, omitting, for example, the duration of the temporary fills it provides. It is also unclear from the web site whether the transition program applies to off formulary drugs.

PacifiCare’s transition policy specifically mentions that enrollees stabilized on medications in six classes – cancer medications, anti-depressants, anti-psychotics, anti-seizure medications, immunosuppressants and HIV/AIDS medicines-- will be able to continue on the drug regimen. However, the policy does not say it will override any prior authorization or step therapy requirements the plan imposes. Rather it refers to “non-formulary” drugs in these classes, even though, with the exception of one antidepressant, plans are required to cover all drugs in these classes.

For drugs in other classes, PacifiCare only provides a 15 day transitional fill, although Dr. Jeffrey Kelman, CMS’ chief medical officer for Part D plans, told a conference call January 3 that the plan had extended the duration of the initial fill to 30 days.

plans should post, at least, general summaries of their transition processes. Summaries should include the length of temporary fills both for community and long term care residents and, if the plan imposes these limits, classes of drugs for which the temporary fills are available and the process for obtaining them.²⁸ Information on transition processes should also be available through plans' toll-free customer services numbers, a request that CMS officials have made repeatedly to plan representatives.²⁹

CMS itself compiles summaries of the transition policies of most of PDPs and distributed them to pharmacy and state Medicaid contacts in late December.³⁰ While valuable, that information cannot substitute for plans themselves providing the information to consumers on their web sites, written materials and through their customer service help lines. CMS should take the additional step of posting on its plan finder web tool the summaries of the transition policies for both PDPs and MA plans.

UTILIZATION MANAGEMENT

CMS' guidance on how plans inform potential enrollees about their utilization management techniques is less explicit. However, the policy goals CMS enunciated in its rulemaking and subsequent guidance would best be served if the agency clarified that plans must provide a full explanation of how their utilization management techniques impact access to specific drugs.

In the preamble to its final rule, CMS agrees "that it will be critically important for Part D enrollees and prospective enrollees to have *complete formulary information* in order to make the best possible Part D plan selection

PLANS VARY IN THEIR EXPLANATION OF FORMULARY RESTRICTIONS

People with Medicare do not have to take exotic or high cost medicines to bump up against restrictions on their drug regimens under the formularies offered by the new Medicare plans.

Because it is private plans, and not the Medicare program itself, which negotiate with manufacturers and craft formularies, those restrictions can vary considerably. One plan may cover all seven drugs a beneficiary takes, but impose restrictions on four of them. Another may not cover one or two medicines on the drug regimen but is otherwise free of restrictions.

In order to make an informed choice in this situation, a potential enrollee needs to understand the impact of the utilization management restrictions on the ability to access coverage.

It is possible to provide that information in understandable form and some plans in fact are doing so.

For example, a search of PacifiCare's web site explains that Benicar (olmesartan), a brand name angiotensin II inhibitor used to treat hypertension may be covered for patients that have tried ACE inhibitors, another type of blood pressure medication, and the plan receives that information from the enrollee's physician. Similarly, the Humana web site includes forms to obtain authorization for a range of drugs, including gastrointestinal medications like Prevacid (naproxen), that list specific conditions for which the plan will permit coverage.

This type of information can assure a beneficiary knowledgeable about his medication history that the drug will be covered. It also provides supplemental information that the beneficiary can use to consult with his pharmacist or physician before selecting a plan.

By contrast, WellCare provides only generic descriptions of step therapy for both Benicar and Prevacid.

Plans also vary considerably in the information they provide on quantity limits. Some plans detail the amount per month they will cover. Others simply list QL next to the drug and leave potential enrollees guessing.

For all plans, however, the absence of information on transition policies paints an unduly dire picture of the coverage limitations. New enrollees looking at a dwindling pill supply after the holidays should have known they had time to navigate the restrictions on coverage in January.

for their particular medical and prescription drug needs.” Plans are required to provide “information about *the manner in which the formulary functions* (including tiering structures and any utilization management procedures used).”³¹ Emphasis added.

In the rule, and in subsequent guidance on marketing materials, CMS only specifies that plans must note which drugs are subject to specific utilization management restrictions. However, the language of the preamble, which articulates the importance to prospective enrollees of “complete formulary information,” and the requirement that plans provide information “about the manner in which the formulary functions,” can only be adequately satisfied if the utilization management techniques are fully explained in reference to specific drugs. Just as the plans translate the tiering structures into specific copayments and coinsurance for specific drugs, utilization management should be elaborated in a way that adequately explains how the restrictions will operate.

CMS received full explanations of the utilization management imposed by plans in their formulary review.³² These explanations included criteria for prior authorization, the specific quantity limits imposed and the algorithms for step therapy (what drugs must be tried first). These explanations should be accessible to beneficiaries on CMS’ plan finder web site and with the formularies posted online by individual Part D plans.

WHAT PLANS ARE DOING

Generally, drug plans are failing to meet CMS requirements to provide public notice of their transition plans and are inconsistent in their ability to explain

utilization management restrictions. These shortcomings contribute to the feelings of confusion and trepidation among people with Medicare when faced with a bewildering array of plan choices and the prospect that they may lose coverage for some of their drugs. That atmosphere has been fueled by misleading and aggressive marketing techniques by some plans as well as erroneous information on the CMS plan finder web tool and inconsistent service from the contractors running 1-800-MEDICARE.

The failure of plans to meet their public notice requirements only exacerbates the problem. A December survey of the web sites maintained by the seven sponsors of plans that were assigned dual eligible enrollees in California revealed that only one plan had posted information about its transition policies on its web site, although another plan has since promised to do so. The release of some plans’ transition policies by Medi-Cal, California’s Medicaid agency, reveals that the extent of beneficiary protections varies considerably. Plans provide initial fills of nonformulary drugs ranging from 30 to 90 days and also differ on whether transitional policies apply to utilization management techniques.

Follow-up calls to plans’ toll-free numbers made on December 9, 2005 also failed to yield an explanation of the transition policies, with most customer service representatives instead discussing procedures to appeal for coverage of off-formulary drugs. Supplemental information received by mail also fails to mention transition processes.

Plans’ failure to publicize their transition processes presents dual eligibles with an incomplete and

inaccurate picture of their transition from Medicaid to Medicare drug coverage. For those who find one or more of their drugs is not covered or is subject to restrictions in their assigned plan, the switch to Medicare coverage in January may be perceived as immediately terminating coverage of some vital medicines. As prescriptions filled by Medicaid dwindle in the initial month of Medicare coverage, this may engender unnecessary panic and cause members of this vulnerable population to start rationing their intake, potentially with life-threatening consequences.

To the extent plans differ in their transition processes, the lack of information inhibits dual eligibles from making the best choice among competing plans. Although the information would have proved most valuable in the months preceding the January 1 transition, it remains relevant. Dual eligibles retain the ability to switch plans if they find coverage unsatisfactory in the plan they were assigned. Similarly other people with Medicare will want to know about transition policies as they sign up during the initial enrollment period, which lasts until May 15. Transition protections will also be crucial for people with Medicaid drug coverage who become newly eligible for Medicare.

The lack of detailed information on utilization management restrictions also prevents informed consumer choice. Here, the responsiveness of the plans surveyed during December 2005 was more mixed. Some plans provided detailed explanations of step therapy requirements. Others posted prior authorization forms that list specific conditions for physicians to certify, indicating the diagnoses that will trigger coverage. Some plans also explained

quantity limits, citing specific limits for individual drugs and differentiating between monthly limits and limits that capped the duration of therapy.

But such transparency was not uniform. A number of plans simply highlight the drugs that are subject to quantity limits, prior authorization or step therapy with no further explanation. Even for plans that provided more information about their utilization management tools, such transparency applied to selected drugs, not all the drugs subject to these restrictions. None of the plans adequately explained that for patients stabilized on drugs in six classes, prior authorization or step therapy may be waived, or the process for obtaining such a waiver. The failure of plans to provide this information could discourage enrollment by patients taking these medicines and will likely cause them unnecessary distress.

The response of plan hotline operators to queries about prior authorization restrictions was much less helpful. The operators simply gave general assurances that the drug would be covered if it was on formulary. The inadequate responses from plan customer service representatives (CSRs) also points to the importance of web based information. These plan web tools can be used by CSRs as a resource to provide potential enrollees with more detailed information. Web based information also helps with counseling provided by state health insurance assistance programs. Finally, web based information would facilitate CMS' oversight of the type of information plans are providing prospective enrollees.

THE IMPACT SO FAR OF INADEQUATE INFORMATION ON TRANSITION

POLICIES, UTILIZATION MANAGEMENT AND APPEALS PROCESSES

One month into the drug benefit, it is evident that, without clear mandates from CMS, plans have failed to provide adequate information in these three areas, resulting in real impacts on beneficiaries' access to vital medicines. These failings, together with systems problems that impeded the ability of dual eligibles to obtain coverage under the new Part D plans prompted California and at least 20 other states to provide stop-gap coverage through their Medicaid programs.

Plans refusal to publicize transition policies has been coupled with

a widespread failure to operationalize them through claims processing systems with network pharmacies.

CMS acknowledged the problem in a January 6 memorandum to pharmacists saying it was continuing to "receive numerous reports that plan CSRs are not aware of their plan's transition policies and that plans are inappropriately denying scripts."³³ Two days later, a memorandum to drug plans reiterated the point, and cautions plans that their CSRs "should not be informing beneficiaries that the plan does not have a transition policy or indicating that access to non-formulary drugs can only be provided via the exceptions policy."³⁴

In the same letter, CMS also

ACCESS TO INFORMATION ABOUT EXCEPTIONS AND APPEALS

Along with the flexibility given to private plans in designing individual formularies, Part D plans will have considerable flexibility in designing their own exceptions and appeals processes—the mechanisms through which enrollees try to obtain coverage of non-formulary drugs or obtain covered drugs at a more favorable cost-sharing level.

For example, Part D plans can decide whether to require prescribing physicians to submit evidentiary support for exceptions requests orally or verbally to Part D plans, as well as the level of medical evidence required for such requests (e.g., whether medical records or supporting medical journal articles are required). Thus, simply knowing that a Part D plan has an exceptions and appeals process—which each plan is required to have—is not enough information to submit a successful exceptions request. Enrollees and their physicians must know how each plan's particular exceptions and appeals process works.

Access to information about each plan's exceptions and appeals processes—along with utilization management tools and transition plans—will be vital for beneficiaries as they transition into Medicare prescription drug coverage. For example, if a new enrollee of a Part D plan is given a transitional "first fill" for a drug that she is currently taking but is not on her new Part D plan's formulary, she will need to file an exception with her plan to obtain coverage beyond this first fill. Her doctor will need to know—very quickly—exactly what information is needed to submit to her plan, and how to submit such information.

In addition to difficulties trying to obtain information about utilization management and transition plans, beneficiaries and those that help them are having trouble accessing information about individual plans' exception and appeals processes. According to CMS, Part D plans do not need to provide Evidences of Coverage (documents that include information about exception and appeals processes) to enrollees until February 1, 2006. That may well be too late for some, as 30 day first fills provided in early January will be close to running out and fills of shorter duration will likely already have been consumed.

Beneficiaries that received transitional supplies in January often left the pharmacy without knowing that they must file an appeal in order to maintain coverage by their drug plan, according to reports from consumer advocates. Where they were alerted to this requirement, beneficiaries and pharmacists have had difficulty obtaining instructions from their plans on how to appeal because plan help lines have been swamped by calls and because customer service representatives have not been able to provide the information.

We urge CMS to require plans to make this information readily available to everyone. Plans should post their evidence of coverage documents, which provide the most detailed descriptions of their appeals policies, on their web pages. Plan customer service representatives should also be trained to answer detailed questions about the plan's exceptions procedures, including the documentation and evidence required as well as the appropriate plan contacts.

required transitional fills for drugs restricted by step therapy and prior authorization after it became clear that these policies were barring access to medicines. Rather than steering enrollees to alternative medicines through a transparent process that involves beneficiaries and their physicians, prior authorization and step therapy were simply functioning to deny claims at the pharmacy counter.

Even when they have been able to access transitional supplies, beneficiaries often remain uninformed about the next step they must take. Plans are reportedly inconsistent about following up with letters that outline appeals rights or indicate alternative medicines that beneficiaries could receive if they receive a prescription from their doctor. CMS instructed plans to send such letters, but has provided no written guidance on the required contents. Pharmacists have also failed to inform customers that the transitional fill merely serves as a temporary bridge until an appeal or an alternative prescription can secure coverage the following month.

According to reports received by consumer advocates when beneficiaries or their advocates do try to appeal for coverage they have consistently run into obstacles. Plan customer service lines have been swamped by calls and beneficiaries have been unable to obtain the information they need to pursue an appeal. Many doctors have also been unwilling to help with the appeals process or unable to schedule appointments within 30 days, leaving beneficiaries unable to document their need for coverage, according to reports received by beneficiary advocates.

If they have not taken steps to secure coverage since their last visit to

the pharmacy, beneficiaries will again be turned away from the pharmacy counter in February, this time because the 30-day transitional fills have expired.

CMS acknowledged this potential in a January 18 letter from CMS Administrator Mark McClellan to drug plan sponsors.

“[W]hile all of you have committed to provide an initial 30 day supply that will be adequate in most cases, we appreciate that you will use sound judgment to extend that coverage in the special situations where a longer transition may be required for sound medical reasons.”³⁵

The letter provides no evidence to support the contention that only “special situations” will require transitional supplies of longer than 30 days. It also provides no evidence that the “sound judgment” of plan sponsors will identify those situations.

In fact, the “sound judgment” exercised by drug plans resulted in transition plans that initially provided for fills of much less than 30 days. It was only after CMS persuaded plans to increase these protections that all plans provided this minimum. The initial transitional processes of some PDPs also provided no initial fills for drugs subject to prior authorization or step therapy. It was only after CMS issued a policy clarification that access was secured for these drugs.

In the judgment of some plans, transitional fills of 90 days are already necessary for enrollees to keep in compliance with their drug regimens.

CMS’ decision to again rely on a suggestion that plans extend transitional fills ignores the evidence accumulated over the last month that, absent clear mandates backed up with the threat of sanctions, plans will not on their own

provide enrollees with the necessary transitional protections.

CMS should issue written instructions requiring all PDPs and MA-PDs to provide transitional fills lasting at least 90 days for all drugs not covered by plan formularies or subject to utilization management restrictions.*

CMS should monitor plan compliance with these requirements and sanction plans that violate them.
CONCLUSION AND RECOMMENDATIONS

CMS has articulated clear goals and principals for the new Medicare drug benefit. Potential plan enrollees must be provided, both by CMS and by the competing plans, clear and complete information to enable them to choose the most appropriate plan. Plans cannot use formulary restrictions to discourage enrollment by populations who need coverage of high cost medications. CMS marketing guidelines have also been designed to ensure plans do not mislead potential enrollees about the coverage they will receive or to dissuade high cost beneficiaries from enrolling.

Achieving these goals is undermined by the failure of drug plans to provide public notice of their transition protections and by the inadequacy of their explanation of the restrictions they impose through utilization management.

As CMS noted, plans' transition processes may serve as a key

comparison point for beneficiary plan selection, particularly by dual eligibles who were randomly assigned to a plan. Transition processes also mitigate the immediate impact of formulary restrictions. Without knowledge of these protections, dual eligible enrollees and others may shy away from certain plans out of fear that restricted formularies will immediately terminate coverage of the drugs they depend on for their health.

Without adequate explanation, utilization management techniques may pose insurmountable barriers to access, similarly steering beneficiaries away from the plans that impose them. A full explanation of the criteria for prior authorization, for example, may assure a potential enrollee that, for their condition, a drug will be covered. Similarly, quantity limits, if properly explained, may well agree with a potential enrollee's drug regimen. This information is critical for informed plan selection. It also serves as a useful educational tool for new enrollees unfamiliar with navigating a formulary.

Through its guidance and rulemaking, CMS has already laid the groundwork to require this increased level of transparency from plans.

Guidance provided by CMS already requires plans to provide public notice of their transition processes on their web sites. CMS simply needs to follow through by issuing with specific instructions.

The importance of public dissemination of plan transition policies was made evident in the first weeks of the January, when there were numerous reports that dual eligibles were denied coverage at the pharmacy counter for drugs that were off-formulary or subject to prior authorization.

* As this brief was being released, Health and Human Services Secretary Michael Leavitt announced that all drug plans would be required to provide transitional fills for 90 days. (["Secretary's One Month Progress Report on the Medicare Prescription Drug Benefit,"](#) U.S. Department of Health and Human Services, February 2006)

If plans were implementing the public notice requirements, their customer service representatives would have been able to inform enrollees and pharmacists that temporary fills were available. Consumers and pharmacists would also have been armed with information that might have secured access to vital medicines.

Public notice of transition policies remains a crucial information element for consumers during the initial stages of the drug benefit. For many dual eligibles and other people with Medicare, their experience at the pharmacy counter in January provided the first indication that their drug regimens were not fully covered by the plan in which they were enrolled. Many may decide now to select a plan with more appropriate coverage but may still need to use transitional fills for some of the drugs on their regimen.

Additionally, the vast majority of Medicare beneficiaries and an untold number of dual eligibles are still not enrolled in a drug plan. As they enroll in the months ahead, they will need to access transitional protections.

CMS should immediately issue written instructions to plans making explicit their responsibility to post their transition processes on their web sites and to train their customer service representatives to inform prospective enrollees of these transitional protections. CMS must put plans on notice that their

compliance with these requirements is being monitored and that violations will be punished by sanctions.

Moreover, transitional protections, including temporary fills, will only be meaningful if the process for appealing for coverage is readily available.

CMS should immediately issue written instructions telling plans that they must, through their customer service representatives and on their web sites, provide information explaining the procedures and evidence required to seek an exception to coverage limitations.

CMS has through repeated iterations of both its formulary and marketing guidance clarified the coverage and information standards it is requiring of plans. New guidance on the information required on utilization management is needed.

CMS should clarify that plans must make full explanations of their utilization management techniques available on their web site, by mail and through their toll free numbers. These explanations should also describe how physicians, pharmacists and beneficiaries can obtain prior authorization and exemptions from step therapy and quantity limits.

CMS should monitor plan compliance with these information requirements and sanction plans that violate them.

ENDNOTES

- ¹ Testimony of Jack Hoadley, Ph.D. Research Professor, Health Policy Institute, Georgetown University before the House Committee on Government Reform Briefing on Implementation of the New Medicare Drug Benefit, January 20, 2006 found at <http://www.democrats.reform.house.gov/story.asp?ID=992>.
- ² Appelby, Julie, “Glitch Inflates Medicare Drug Costs,” *USA TODAY*, November 30, 2005.
- ³ Centers for Medicare and Medicaid Services, “Summary of PDP Transition Plans,” found at <http://www.ascp.com/medicarerx/docs/PDPTransitionPolicy.pdf>.
- ⁴ California Department of Health Services, “*Medi-Cal Notifies One Million Senior and Disabled Beneficiaries Their Drug Coverage Will Switch Jan. 1*”, News Release Number: 05-85, December 14, 2005 found at <http://www.dhs.ca.gov>.
- ⁵ Centers for Medicare and Medicaid Services, “*Information for Part D Sponsors on Requirements for a Transition Process— March, 16 2005*,” found at http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/TransitionProcess_031605.pdf (hereinafter “*Requirements for Part D Sponsors*”) and Centers for Medicare and Medicaid Services, “*A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Prescription Drug Coverage – May 2, 2005*” found at <http://new.cms.hhs.gov/States/Downloads/strategyfortransitioningDE.pdf> (hereinafter “*CMS Dual Eligibles Transition Guidance*”).
- ⁶ Except in Maine where the state received permission from CMS to intelligently reassign dual eligibles to plans that covered 95 percent of their drugs. On January 1, like the rest of the country, Maine experienced significant problems ensuring dual eligibles access to the Federal Medicare Part D benefit. Testimony of Jude Walsh, Special Assistant, Governor’s Office of Health Policy and Finance, State of Maine, before the House Committee on Government Reform Briefing on Implementation of the New Medicare Drug Benefit, January 20, 2006, found at <http://www.democrats.reform.house.gov/story.asp?ID=992>.
- ⁷ Kaiser Commission on Medicaid and the Uninsured, *The New Medicare Prescription Drug Law: Issues for Enrolling Dual Eligibles into Drug Plans*, (Jensen, R.), January 2005 found at <http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=50409>.
- ⁸ Medicare Payment Advisory Commission (MedPAC), *A Data Book: Healthcare Spending and the Medicare Program*, June 2004, Section 2, found at http://www.medpac.gov/publications/congressional_reports/Jun04dataBookTofC.pdf.
- ⁹ In this brief, we confine our analysis to PDP plans (and not MA-PDs) since the majority of dual eligibles in California will be assigned to these plans.
- ¹⁰ Pub.L. No. 108-173 (2003).
- ¹¹ Centers for Medicare and Medicaid Services, “*Medicare Marketing Guidelines for Medicare Advantage (MA), Medicare Advantage Prescription Drug Plans (MA-PD), Prescription Drug Plans (PDP) and 1876 Cost Plans issued on August 15, 2005 – Updated November 1, 2005*” found at http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MarketingGuidelines_11.01.05.pdf (hereinafter “*Medicare Marketing Guidelines*”).
- ¹² Centers for Medicare and Medicaid Services, “*Medicare Modernization Act Final Guidelines – Formularies--CMS Strategy for Affordable Access to Comprehensive Drug Coverage Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures*” found at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf>
- ¹³ Testimony of Michael M. Hash, Deputy Administrator, Health Care Financing Administration, U.S. Department of Health and Human Services, Before the House Committee on Ways and Means on Medicare Appeals Processes, Subcommittee on Health, April 23, 1998 found at <http://www.hhs.gov/asl/testify/t980423a.html>.
- ¹⁴ Patricia B. Nemore, “*Medicare Part D: Issues for Dual Eligibles on the Eve of Implementation*,” Kaiser Family Foundation, November 2005 found at <http://www.kff.org/medicare/upload/Medicare-Part-D-Issues-for-Dual-Eligibles-on-the-Eve-of-Implementation-Issue-Brief.pdf>.
- ¹⁵ “*CMS Dual Eligibles Transition Guidance*.”
- ¹⁶ Centers for Medicare and Medicaid Services, “*Information for Part D Sponsors on Requirements for a Transition Process*,” March 16, 2005, found at: http://www.cms.hhs.gov/pdps/transition_process.pdf (Hereinafter “*Information for Part D Sponsors*”).



¹⁷ CMS notes that the transition policies should apply to a change in care setting as well (i.e., hospital to a skilled nursing home, hospital to home).

¹⁸ “*Information for Part D Sponsors.*”

¹⁹ Centers for Medicare and Medicaid Services, “*Why is CMS requiring “all or substantially all” of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?*” Found at <http://63.241.27.79/pdps/formularyqafinalmmrevised.pdf>.

²⁰ Centers for Medicare and Medicaid Services, “Pharmacy Transition Policies,” January 6, 2006, found at www.aahsa.org/advocacy/medicare_drug_benefit/resources/documents/transition_policy_reminder.pdf.

²¹ Centers for Medicare and Medicaid Services, “*Information for Part D Sponsors on Requirements for a Transition Process,*” March 16, 2005, found at http://www.cms.hhs.gov/pdps/transition_process.pdf.

²² Letter from CMS Administrator Mark McClellan to all Part D Sponsors, January 18, 2006, found at <http://www.ncsl.org/programs/health/cmsupdates.htm>.

²³ “*CMS Dual Eligibles Transition Guidance.*”

²⁴ Ibid.

²⁵ Centers for Medicare and Medicaid Services, “*Strengthening Implementation of Formulary Transition Policies,*” January 17, 2005 found at <http://www.ascp.com/medicarerx/docs/CMSGuidanceTransition.pdf> and “Pharmacy Transition Policies.”

²⁶ “*Medicare Marketing Guidelines.*”

²⁷ Centers for Medicare and Medicaid Services, “*Medicare Modernization Act Final Guidelines – Formularies*” found at

<http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf>

Also refer to Centers for Medicare and Medicaid Services, “*Model Comprehensive Formulary and Model Explanation of Benefits*”; found at

http://www.cms.hhs.gov/PrescriptionDrugCovContra/07_RxContracting_Marketing.asp.

²⁸ “*Requirements for Part D Sponsors.*”

²⁹ Centers for Medicare and Medicaid Services, “*Strengthening Implementation of Formulary Transition Policies,*” January 17, 2005 found at <http://www.ascp.com/medicarerx/docs/CMSGuidanceTransition.pdf> and “Pharmacy Transition Policies.”

³⁰ Centers for Medicare and Medicaid Services, “*Summary of MA-PD Transitions Plans,*” found at http://www.ascp.com/medicarerx/docs/CMS_MA-PD.pdf and “*Summary of PDP Transition Plans.*”

³¹ Preamble 70, *Federal Register*, January 28, 2005 found at

<http://www.ascp.com/medicarerx/docs/PartDFinalRegs.pdf>.

³² Centers for Medicare and Medicaid Services, “*Medicare Modernization Act Final Guidelines – Formularies*” found at

<http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf>.

³³ “Pharmacy Transition Policies.”

³⁴ Ibid.

³⁵ Letter from CMS Administrator Mark McClellan to all Part D Sponsors, January 18, 2006, found at <http://www.ncsl.org/programs/health/cmsupdates.htm>.